

Changing practice in dementia care in the community: developing and testing evidence-based interventions, from timely diagnosis to end of life (EVIDEM)

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***National Institute for
Health Research***

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Abstract

Changing practice in dementia care in the community: developing and testing evidence-based interventions, from timely diagnosis to end of life (EVIDEM)

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Background: The needs of people with dementia and their carers are inadequately addressed at all key points in the illness trajectory, from diagnosis through to end-of-life care. The EVIDEM (Evidence-based Interventions in Dementia) research and development programme (2007–12) was designed to help change this situation within real-life settings.

Objectives: The EVIDEM projects were (1) evaluation of an educational package designed to enhance general practitioners' (GPs') diagnostic and management skills; (2) evaluation of exercise as therapy for behavioural and psychological symptoms of dementia (BPSD); (3) development of a toolkit for managing incontinence in people with dementia living at home; (4) development of a toolkit for palliative care for people with dementia; and (5) development of practice guidance on the use of the Mental Capacity Act (MCA) 2005.

Design: Mixed quantitative and qualitative methods from case studies to large database analyses, including longitudinal surveys, randomised controlled trials and research register development, with patient and public involvement built into all projects.

Setting: General practices, community services, third-sector organisations and care homes in the area of the North Thames Dementia and Neurodegenerative Diseases Research Network local research network.

Participants: People with dementia, their family and professional carers, GPs and community mental health team members, staff in local authority social services and third-sector bodies, and care home staff.

Main outcome measures: Dementia management reviews and case identification in general practice; changes in behavioural and psychological symptoms measured with the Neuropsychiatric Inventory (NPI); extent and impact of incontinence in community-dwelling people with dementia; mapping of pathways to death of people with dementia in care homes, and testing of a model of collaborative working between primary care and care homes; and understandings of the MCA 2005 among practitioners working with people with dementia.

Results: An educational intervention in general practice did not alter management or case identification. Exercise as a therapy for BPSD did not reduce NPI scores significantly, but had a significant positive effect on carer burden. Incontinence is twice as common in community-dwelling people with dementia than their peers, and is a hidden taboo within a stigma. Distinct trajectories of dying were identified (anticipated, unexpected and uncertain), and collaboration between NHS primary care and care homes was improved, with cost savings. The MCA 2005 legislation provided a useful working framework for practitioners working with people with dementia.

Conclusions: A tailored educational intervention for general practice does not change practice, even when incentives, policy pressure and consumer demand create a favourable environment for change; exercise has potential as a therapy for BPSD and deserves further investigation; incontinence is a common but unrecognised problem for people with dementia in the community; changes in relationships between care homes and general practice can be achieved, with benefits for people with dementia at the end of life and for the UK NHS; application of the MCA 2005 will continue to improve but educational reinforcements will help this. Increased research capacity in dementia in the community was achieved. This study suggests that further work is required to enhance clinical practice around dementia in general practice; investigate the apparent beneficial effect of physical activity on BPSD and carer well-being; develop case-finding methods for incontinence in people with dementia; optimise working relationships between NHS staff and care homes; and reinforce practitioner understanding of the MCA 2005.

Trial registration: EVIDEM: ED-NCT00866099; EVIDEM: E-ISRCTN01423159.

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Glossary

Read Code This is the standard clinical terminology system used in general practice in the UK. Read Codes are codes representing clinical terms, which are used by clinicians to record patient findings and procedures across primary and secondary care.

List of abbreviations

6CIT	Six Item Cognitive Impairment Test	DARE	Database of Abstracts of Reviews of Effects
A&E	accident and emergency		
ADL	activities of daily living	DCR-10	Diagnostic Criteria for Research
AE	adverse event	DEMQOL	Dementia Quality of Life tool
AI	Appreciative Inquiry	DemReg	Dementia Register study
AMTS	Abbreviated Mental Test Score	DeNDRoN	Dementia and Neurodegenerative Diseases Research Network
ANCOVA	analysis of covariance	DH	Department of Health
AQAA	Annual Quality Assurance Assessment	DNACPR	Do Not Attempt Cardiopulmonary Resuscitation
BNI	British Nursing Index	ENA	Educational Needs Assessment
BPSD	behavioural and psychological symptoms of dementia	EPOA	Enduring Power of Attorney
CareNap-D	Care Needs Assessment Pack for Dementia	EQ-5D	European Quality of Life-5 Dimensions
CEAC	cost-effectiveness acceptability curve	EVIDEM	Evidence-based Interventions in Dementia
CI	confidence interval	FI	faecal incontinence
CINAHL	Cumulative Index to Nursing and Allied Health Literature	FRAT	Falls Risk Assessment Tool
CMAI	Cohen–Mansfield Agitation Inventory	GCP	good clinical practice
CNWL	Central & North West London	GHQ	General Health Questionnaire
CONSORT	Consolidated Standards of Reporting Trials	GP	general practitioner
CPS	Cognitive Performance Score	GSF	Gold Standards Framework
CQC	Care Quality Commission	HSC	health and social care
CRF	Case Report Form	ICD-10	<i>International Classification of Diseases</i> , Tenth Edition
CRIPACC	Centre for Research in Primary and Community Care	ICER	incremental cost-effectiveness ratio
CSCI	Commission for Social Care and Inspection	ICIQ	International Consultation on Incontinence Questionnaire
CSRI	Client Service Receipt Inventory	IMCA	Independent Mental Capacity Advocate
CT	computed tomography	IMD	Index of Multiple Deprivation
DAA	Dementia Action Alliance	IRR	incident rate ratio
DAD	Disability Assessment for Dementia	LA	local authority
		LCP	Liverpool Care Pathway

LIST OF ABBREVIATIONS

LPA	Lasting Power of Attorney	PPI	Patient and Public Involvement
max.	maximum	PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
MCA	Mental Capacity Act		
min.	minimum	PSSRU	Personal Social Services Research Unit
MMSE	Mini Mental State Examination		
MRC	Medical Research Council	PV	prompted voiding
MRI	magnetic resonance imaging	PYAR	person-years at risk
NB	net benefit	QALY	quality-adjusted life-year
NDS	National Dementia Strategy	QOF	Quality and Outcomes Framework
NICE	National Institute for Health and Clinical Excellence	RCT	randomised controlled trial
NIHR	National Institute for Health Research	REC	Research Ethics Committee
NPI	Neuropsychiatric Inventory	RO	randomisation officer
NRES	NHS Research Ethics Service	RPE	Rate of Perceived Exertion
NTIS	National Technical Information Service	RW	research worker
NVQ	National Vocational Qualification	SAC	Safeguarding Adult Coordinator
OOH	out of hours	SAE	serious adverse event
OPCS	Office of Population Censuses and Surveys	SCIE	Social Care Institute for Excellence
OPWD	older people with dementia	SD	standard deviation
OR	odds ratio	SPSS	Statistical Package for the Social Sciences
OT	occupational therapist	SSCR	School for Social Care Research
PCRN	Primary Care Research Network	SSI	semi-structured interview
PCRN-GL	Primary Care Research Network-Greater London	STOPP	Screening Tool of Older Persons' potentially inappropriate Prescriptions
PCT	primary care trust	SUR	Seemingly Unrelated Regression
PEDro	Physiotherapy Evidence Database	TAU	treatment as usual
PhD	Doctor of Philosophy	TD	toileting difficulty
PIM	potentially inappropriate medication	THIN	The Health Improvement Network
PIP	potentially inappropriate prescribing	TSC	Trial Steering Committee
PIRG	Public Involvement in Research Group	TUSS	Timed Unsupported Steady Standing
POA	Power of Attorney	UI	urinary incontinence
		WHO	World Health Organization
		ZBI	Zarit Burden Interview

Plain English summary

The needs of people with dementia, and their carers, for information about symptom management and service access are too often inadequately addressed in the course of the disease, from diagnosis through to end-of-life care. With this in mind, we developed a research and development programme that was designed to help change this situation: the EVIDEM programme – Evidence-based Interventions in Dementia. A study of diagnosis and management in primary care (EVIDEM-ED) asked if workplace-based, tailored education would improve medical practitioners' recognition of, and responses to, dementia in general practice. It concluded that education would not change practice. An exercise therapy trial (EVIDEM-E) for behavioural and psychological symptoms in people with dementia did not reduce symptoms but had a positive impact on carer burden. An award-winning project on continence (EVIDEM-C) established the scale of continence problems in people with dementia living in the community, and developed new ways to reduce the impact of incontinence on people with dementia and their families. The End of Life Care study (EVIDEM-EoL) explored the experiences of people with dementia and their families at the end of life, and showed how they could be improved by promoting collaboration between care homes and general practice. How different types of practitioners working with people with dementia understood and applied the new Mental Capacity Act (MCA) (2005) was investigated in the EVIDEM-MCA study. Finally, the programme successfully piloted a research register for people with dementia, and their carers, who wanted to take part in research studies.

Scientific summary

Background

Dementia has an enormous impact on the lives of individuals and families, and on health and social care services, and this impact is increasing as the population ages. The needs of people with dementia and their carers for information and support are inadequately addressed at all key points in the illness trajectory. The consequences are poor quality of life, inappropriate and costly responses to the problems that emerge (such as avoidable admissions to hospital), prolonged inpatient stays and further disablement.

During the life of this programme there has been increasing public awareness of dementia, and growing policy support for developing services for people with dementia and their carers. The most visible evidence of this was the launch of the Dementia Strategy for England in 2009, and this policy momentum has continued with the Prime Minister's Challenge on Dementia in 2012.

Aims and objectives

The aim of this programme was to study interventions along the disease trajectory of dementia syndrome, involving a cohort of people with dementia and their families at different stages of the disease.

Its *objectives* were to develop and test interventions that improve patient/user, carer and service outcomes at different points on the disease trajectory, namely:

1. the recognition of the syndrome and the first responses to it, in primary care
2. the management of behavioural and psychological symptoms of dementia (BPSD) using exercise as a therapy
3. the management of incontinence in people with dementia living in the community (but not in care homes)
4. the care and support given to people with dementia at the end of life.

The programme also evaluated the impact of the Mental Capacity Act (MCA) 2005, and developed educational interventions to support its application, specifically in relation to safeguarding.

Research plans

We aimed to assemble a cohort of people with dementia and their families, recruiting through primary and secondary health care, social care services and voluntary organisations, and to nest five projects within it. These projects were:

1. an educational intervention for primary care management, psychosocial interventions and shared care of medication for people with dementia, developed and tested in an experimental study
2. a randomised trial of exercise as therapy for BPSD
3. studies of the experience of, and management strategies for, incontinence in community-dwelling people with dementia, followed by the development and testing of evidence-based resources to reduce the impact of incontinence on them and their carers

4. a study of the pathway to death of older people with dementia, and the development and testing of interventions that would enable the UK NHS, social care staff, and family members to work together to provide end-of-life care
5. an evaluation of the impact of the MCA 2005 and the creation of practice guidance to enhance professionals' concordance with the MCA and with safeguarding practices.

The research team

The EVIDEM (Evidence Based Interventions for Dementia) team was multidisciplinary, with members from the fields of medicine, nursing, social work, social science, psychology, statistics and health economics. It drew on experiences of different methodologies, and had a track record of fruitful collaboration and project completion and an international reputation. This programme built on successful earlier work on dementia diagnosis and management in primary care, among other studies. We had close working relationships with the Dementias and Neurodegenerative Diseases Research Network (DeNDRoN) and the Primary Care Research Network-Greater London (PCRN-GL). We drew on expertise from the National Institute for Health and Clinical Excellence/Social Care Institute for Excellence dementia clinical guidelines development group and the National Care Home Research and Development Forum.

The research environment

Central and North West London NHS Foundation Trust hosted the EVIDEM programme. The cultural and social diversity of London and surrounding areas provided opportunities for testing interventions in different population groups and contexts. The trust has an energetic user forum, which played a role in the design and management of some projects, and the research team contributed to an annual 'school' (continued professional development event) for trust staff on developments in dementia care, using different methods to reach staff – day conferences, study half-days and workplace-based seminars and workshops.

Outputs, outcomes and impact

The EVIDEM programme has produced the following:

1. *An educational intervention for general practice*, tested in a randomised controlled trial (RCT), combining timely diagnosis and psychosocial support around the period of diagnosis. This includes simple decision aids in electronic format, and shared care guidelines for medication use, to enhance the quality of primary care practice. The records of > 1000 people with dementia were audited for this RCT, and 161 patient–carer dyads agreed to participate in in-depth studies. The findings of the RCT, together with literature reviews of subjective memory impairment and methods for improving primary care's performance with people with dementia and their carers, are outlined in *Chapter 1*.
2. The experience of and findings from a RCT of exercise promotion for the *management of distressing or challenging symptoms* (BPSD), which involved 131 patient–carer dyads. Because of slow recruitment, this project was granted a no-cost extension. This time extension did allow sufficient recruitment and follow-up to conclude the study, which found that the exercise intervention did reduce carer burden significantly; however, it made no difference to behavioural and psychological symptoms (as measured by the Neuropsychiatric Inventory) of the patient. The intervention tested in the trial, methods used in the study and evidence underpinning the experiment are all reported in *Chapter 2*.

3. *Evidence-based practice resources for the management of incontinence* in people with dementia living at home. In addition, data from a feasibility study of effectiveness and acceptability of different designs of absorbent pads have been gathered to inform a future clinical trial. These developments, together with an epidemiological study of incontinence in almost 114,000 people with dementia using The Health Improvement Network (THIN) database, are reported in *Chapter 3*. A paper from this project won the Royal College of General Practitioners and Novartis Research Paper of the Year Award 2011.
4. *Methods for enhancing collaborative working* between primary and social care to provide end-of-life care in dementia, suitable for use in care homes without on-site nursing. The development of these methods is summarised in *Chapter 4*.
5. *Practice guidance on the use of the MCA 2005*, including its use in adult safeguarding work. Adopting a longitudinal approach, this study has charted changes in familiarity with, and confidence in, using the MCA among a broad range of practitioners. It has been the first to study the MCA as a whole and to research patient and carer decision-making experiences in this context. The development of this guidance is reported in *Chapter 5*.
6. *Increased research capacity in the community* in the study of care for people with dementia. The EVIDEM programme has helped create a register of people with dementia interested in research, alongside its cohort of study participants, both of which are described in *Chapter 6*. The working relationships developed across disciplines and boundaries in the programme have allowed new research studies to be designed and funded. Two Doctor of Philosophy (PhD) studies have been nested in the programme, which also provided a supportive environment for postdoctoral studies and academic general practitioners. The expertise acquired by individuals in dementia research is reported in each chapter.
7. *A broad range of publications*. The EVIDEM programme has, to date, published more than 30 papers in professional and academic journals and a dozen articles in the professional press. More than 70 presentations of the programme and its findings have been made in professional, academic and public conferences, internet seminars and meetings. This report contains further discussion of EVIDEM's impact in the description of each project in *Chapter 7*.
8. *Public involvement*. We have made wide use of patient and public involvement in these research and development projects, and user and carer perspectives have contributed to project design, implementation and analysis. The programme benefited from the interest and contribution of an expert and enthusiastic advisory group, comprising service users, carers, patients and public representatives, as well as professionals and academics. Each project also had its own advisory group with similar compositions.

Finally, *the implications of the main findings and some cross-cutting themes* from the programme's projects are discussed in *Chapter 7*, along with a summary of what we have found and suggestions for future research and development.

Trial registration

This trial is registered as EVIDEM: ED-NCT00866099; EVIDEM: E-ISRCTN01423159.

Funding

Funding for this study was provided by the Programme Grants for Applied Research programme of the National Institute for Health Research.

Chapter 1 EVIDEM-ED: a cluster-randomised controlled trial to improve early diagnosis and clinical management of dementia in primary care

Abstract

Aim To test a customised educational intervention developed for general practice, promoting both earlier diagnosis of dementia and concordance with management guidelines.

Design/method The intervention, based on practice-based workshops, was tested in an unblinded cluster randomised controlled trial (RCT) with a pre- and post-intervention design, with two arms: usual care compared with the educational intervention. Twenty-three general practices participated and the records of 1072 patients with dementia were audited. Our primary outcome was an increase in the proportion of patients with dementia who received at least two documented dementia-specific management reviews per year. Secondary outcomes were practitioner concordance with management guidelines in a subset of 167 patients with dementia; satisfaction and met need among 84 carers; and attitudes, knowledge and confidence with dementia diagnosis and management in general practitioners (GPs) and practice nurses.

Findings The estimated odds ratio (OR) of having two or more reviews in the intervention group compared with the usual care group was 0.83 [95% confidence interval (CI) 0.52 to 1.33; $p = 0.44$]. Case detection rates were unaffected by the intervention. The estimated incidence rate ratio (IRR) for the intervention group compared with the usual care group from multilevel Poisson regression modelling was 1.03 (95% CI 0.57 to 1.86, $p = 0.93$). Carers' recall of advice given suggested that a large minority had not received the information recommended by the National Institute for Health and Clinical Excellence (NICE) dementia guidelines. Carers of patients taking cholinesterase inhibitors reported more advice on some aspects of care.

Discussion An educational intervention customised to the needs of each practice did not appear to alter the documentation of clinical management of patients with dementia, nor did it increase case identification.

Background: why this study was necessary

Demography and impact

There is increasing interest in earlier diagnosis, because of:

- the ageing of the population and the rising prevalence of dementia
- the costs of care for people with dementia, and
- the perceived benefits for the person with dementia (PWD) and their carers of early intervention, with concerns about delays in diagnosis, especially in primary care.

Dementia is one of the main causes of disability in later life; in terms of the Global Burden of Disease, it contributes 11.2% of all years lived with disability, higher than stroke (9.5%), musculoskeletal disorders (8.9%), heart disease (5%) and cancer (2.4%).¹ The total costs of caring for people with dementia in the UK have been estimated at between £17B and £18B per year² – more than heart disease (£4B), stroke (£3B) and cancer (£2B).

Delayed recognition

Dementia syndromes are underdiagnosed and undertreated in primary care in all countries^{3,4} with an estimated 50% of primary care patients of more than 65 years not diagnosed by their primary care physicians.^{5,6} The complex reasons for this include patient, family, practitioner and service causes, and are discussed in detail elsewhere.⁷

The evidence suggests that there are tangible benefits to earlier recognition of dementia. Early disclosure of the diagnosis seems to be what people with dementia want to have⁸ and younger professionals want to give.⁹ The benefits of making a diagnosis include ending uncertainty about the cause of symptoms and behaviour change, with greater understanding of problems; giving access to appropriate support; promoting positive coping strategies; and facilitating the planning and fulfilment of short-term goals.^{10,11} There is also the potential for using cholinesterase inhibitor medication to modify symptoms and delay the need to seek care home moves among people with dementia.

Enhancing skills in primary care

The insidious nature of dementia means that it is most likely to present as a problem within primary care, but there are obstacles to earlier recognition in this setting. Therefore, considerable efforts have been made to provide educational programmes to enhance the diagnostic skills of primary care practitioners. Because of the apparent time constraints in primary care consultations, much research focus has been on the development of brief screening tests for assessing cognitive function. However, despite the availability of user-friendly cognitive function tests, there has been little evidence of improvement in primary care recognition of, and response to, dementia syndromes over the decade since the introduction of cholinesterase inhibitors. The UK evidence is particularly compelling on this point, especially from early educational interventions,¹² and recent analyses by members of the EVIDEM (Evidence-based Interventions in Dementia) programme of incidence and prevalence in a large GP data set.¹³

We find persuasive the argument that the problem of underdiagnosis is probably due to the interaction of case complexity, pressure on time and the negative effects of reimbursement systems that do not reward time commitment and systematic follow-up.^{14,15} However, in our view there is also considerable evidence that the main problem is not that primary care practitioners simply lack diagnostic skills, but that they lack the resources and management skills in both clinical management and in prioritisation of the needs of their patients with dementia. We have presented the evidence for this elsewhere.¹⁶

The response of primary care to the needs of people with dementia may be due, in large part, to the limited availability of support services but this does not mean that an educational intervention is unlikely to have an effect. Improved confidence in clinical knowledge and skills is still needed to allow practitioners to improve their performance with this patient group. It does mean that the effects of an educational intervention would probably be weak, unless other obstacles to earlier diagnosis and better management of dementia were reduced. Education alone does not usually change practice.

Fortuitously, three changes in UK NHS funding, in the law and in NHS priorities, created an environment conducive to changes in practice and thereby opening an opportunity to test an educational intervention in optimal circumstances. In 2006, the introduction of the Quality and Outcomes Framework (QOF), led to financial incentives for primary care to establish a dementia register and carry out annual reviews of patients. This was followed by the implementation of the Mental Capacity Act (MCA, 2005)¹⁷ in 2007, which clarified the law on the assessment of capacity to make decisions. The third was the launch of the National Dementia Strategy (NDS) in 2009,¹⁸ which prioritised improvements in the care of people with dementia, along the entire disease trajectory, and introduced new resources (such as 'dementia advisors' in some areas). GPs came under increasing pressure from primary care trusts (PCTs) to make diagnoses earlier, and to limit the prescription of antipsychotic drugs for behavioural and psychological symptoms of dementia (BPSD). They also began to experience rising demand for advice about memory loss symptoms, and to more frequently encounter situations in which they had to make difficult decisions about the best interests of people with dementia.

The timing for an educational intervention around dementia diagnosis and management in primary care could hardly have been better. Practitioners were under pressure to improve the quality of the care they gave, and were reimbursed for doing so, but knew that they lacked knowledge and skills and so were motivated to learn.¹⁹

Components of the trial

The EVIDEM-ED trial began with literature reviews that scoped the area, followed by co-design of an educational intervention. This was field tested for feasibility and acceptability before being tested in a definitive cluster randomised trial.

Literature reviews

In order to inform the planned trial of an educational intervention designed to change clinical practice, we carried out two literature reviews. The first was a rapid appraisal of the published, English language literature on barriers to earlier diagnosis of dementia. The second was a review of interventions in primary care designed to alter clinical practice with patients with dementia.

Review 1: Investigating Barriers to Good Practice

A full account of this review appears elsewhere.²⁰

Method

Publications in English, up to August 2009, relating to barriers to the recognition of dementia were identified by a broad search strategy, using electronic databases MEDLINE, EMBASE and PsycINFO. Exclusion criteria included non-English language, studies about pharmacological interventions or screening instruments, and settings without primary care. *Figure 1* shows the selection process for papers.

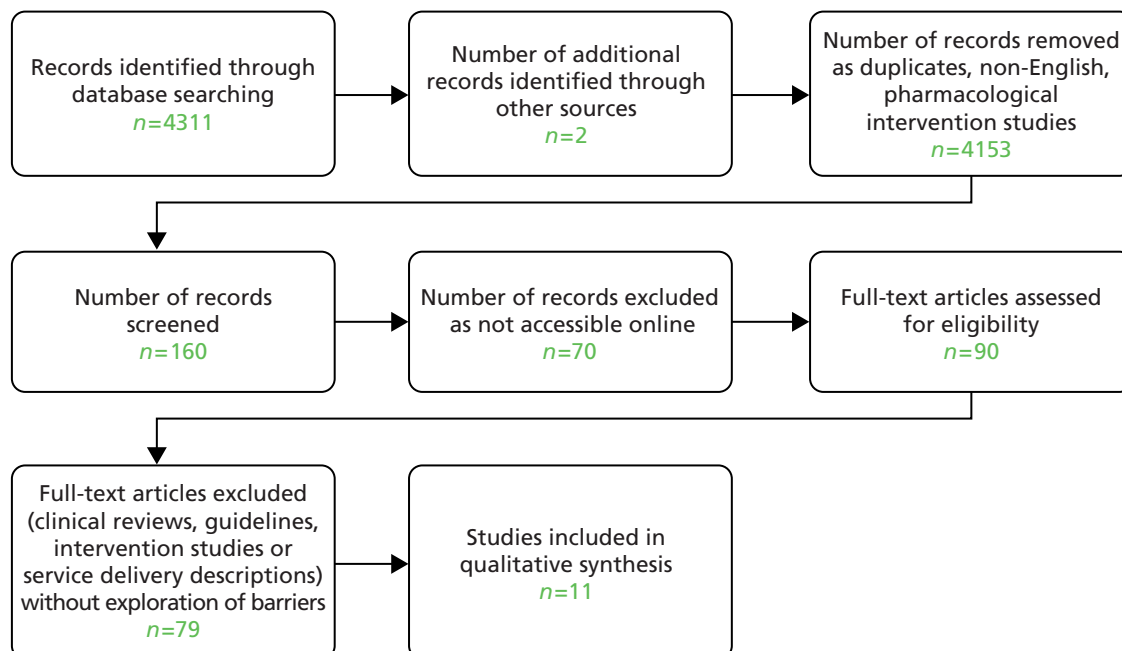


FIGURE 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart for EVIDEM-ED: Review 1, Investigating Barriers to Good Practice.

Results

Eleven empirical studies²¹⁻³¹ were found (see *Appendix 1*). The main themes from the qualitative studies were lack of support, time constraints, financial constraints, stigma, diagnostic uncertainty and disclosing the diagnosis. Quantitative studies yielded diverse results about knowledge, service support, time constraints and confidence. The factors identified in qualitative and quantitative studies were grouped into three categories: patient factors, GP factors and system characteristics. These are discussed in detail in the published review.²⁰

Conclusion

Much still needs to be done in service development and provision, GP training and education, and the eradication of stigma attached to dementia to improve the early detection and management of dementia. Implementation of dementia strategies should include attention to all three barriers, and further research should focus on their interaction.

Review 2: Changing Service Provision and Clinical Practice

We conducted a second review of potential solutions to the problem of underperformance in primary care. This second review aimed to identify and appraise empirical studies of interventions designed to improve the performance of primary care practitioners. A full account appears elsewhere.³²

Methods

Search strategy A rapid appraisal approach was adopted to inform the implementation of the NDS in England,¹⁸ introduced in 2009. To avoid delays in the analysis and completion of the review, papers that were not easily accessible were not included. Publications about the detection and management of dementia in the community were searched for using MEDLINE, EMBASE and PsycINFO, without restricting the date or language of publication. Searches were carried out up to February 2010. A broad search strategy was adopted and search terms are listed in *Box 1*. This was executed as a two-step process with *educat** added as the second step, after all of the other search terms. Bibliographies of articles discovered were also examined for additional relevant literature.

Search selection This search resulted in a total of 4579 articles. To prevent narrowing of the search scope and therefore potentially reducing the search sensitivity, the terms were not refined, but instead each title was reviewed with its abstract if available to ascertain its relevance. A number of exclusion criteria were then applied. All studies of pharmacological interventions were excluded, as were studies of the performance of cognitive function tests. Publications were excluded if they reported on the diagnosis or

BOX 1 Description of two-step electronic database search process

Dementia OR Cognitiv* Impair* OR Alzheimer's Disease

AND

Primary Care OR General Practi* OR Family Pract*

AND

Diagnos* OR Manag*

AND

Educat*

treatment of dementia in anywhere but a primary care setting (for example, the benefits of respite in long-term care facilities); if they related to a population outside the scope of this review (for example, interventions for caregiver health); or if they were clinical discussions about dementia diagnoses or care. Letters were also excluded, as were publications in languages other than English. Two other relevant articles were found, one directly from bibliographic searching, and a second was sourced following a recommendation from an expert in the field. *Figure 2* shows the search process, presented according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.³³

After applying these criteria, 162 articles remained, but 70 of these were not readily obtainable and these were also excluded for pragmatic reasons; 77 of the remaining 92 papers were excluded after analysis because they were clinical reviews, guidelines, studies of barriers or studies without interventions that were designed to change practice. References in the 92 papers were reviewed to identify other intervention studies.

Data extraction Data were extracted from each study report to allow comparison of interventions and to assess the quality of study designs. The characteristics chosen for comparison (including location and type of study, size, recruitment process, methodology, outcome measures, results and conclusions) and a detailed description of each intervention can be found in the published review.³² Randomised trials were assessed for quality using the Physiotherapy Evidence Database (PEDro) scale.³⁴ The PEDro scale was chosen because its assessment of blinding is very relevant to empirical studies in dementia. In quality-rating scales that consider double-blinding as the central methodological issue, studies would lose points for failing to be blinded. The PEDro rating scale divides blinding into participants, therapists and assessors, recognising that although not all of the components of trials can be blinded, it is preferable that some groups are blinded rather than none at all.³⁵

Results

Fifteen studies were identified of which one used qualitative methods only and three were unpublished. Of the 11 studies²⁹⁻³¹ included in the review, 10 were RCTs (see *Appendix 1*). Six^{21-24,27,30} reported educational interventions and five^{25,26,28,29,31} trialled service redesigns, either by changing the service

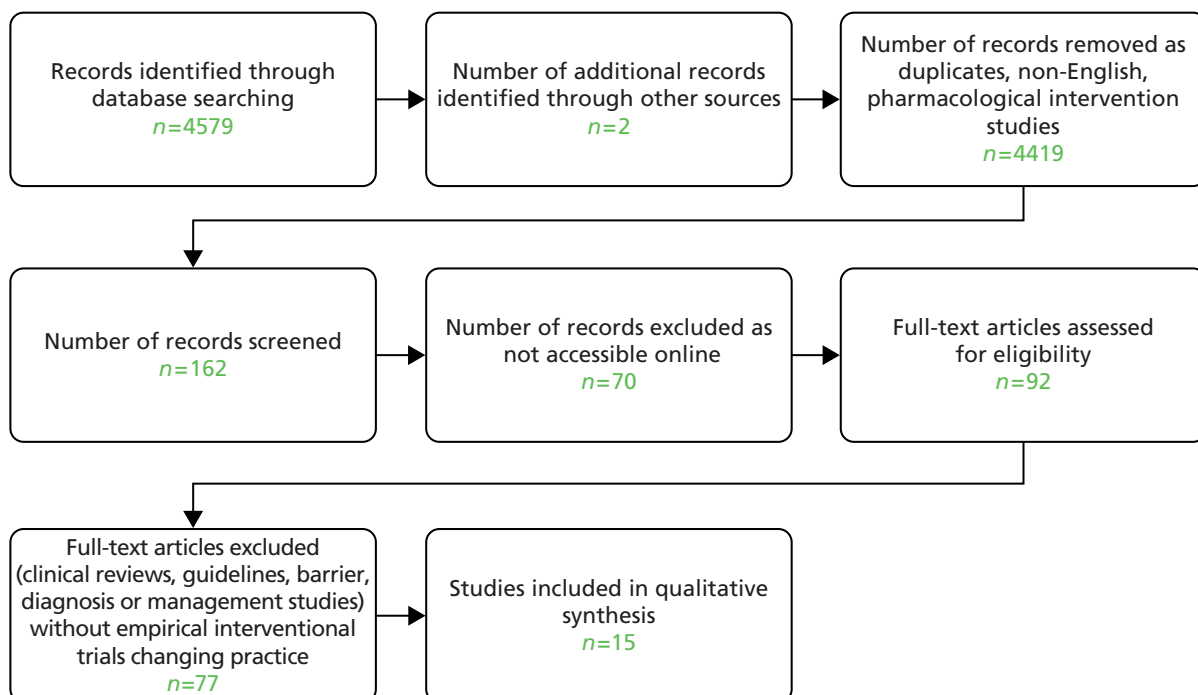


FIGURE 2 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart for EVIDEM-ED: Review 2, Changing Service Provision and General Practice.

pathway or by introducing case management. Educationally, only facilitated sessions and decision-support software improved GPs' diagnosis of dementia, as did trials of service pathway modification. Some of the case management trials showed improved stakeholder satisfaction, decreased symptoms, and care that was more concordant with clinical guidelines.

Conclusion

The quality of the studies varied considerably. Education interventions are effective when learners are able to set their own educational agenda. Although modifying the service pathway and using case management can assist in several aspects of dementia care, these would require the provision of extra resources, and their value is yet to be tested in different health systems.

Aims and objectives of the EVIDEM-ED study

Using the insights from the two reviews, we designed an educational intervention for general practice, combining timely diagnosis and psychosocial support around the period of diagnosis in concordance with management guidelines.³⁶

The objectives of the EVIDEM-ED project were to:

1. develop an educational intervention suitable for the workplace use that has the potential to change management practice in dementia care among GPs and practice nurses
2. include shared care guidelines for medication use by patients with dementia, as part of management in general practice
3. develop and test electronic resources that promote the above objectives.

Developing the educational intervention

The theoretical basis of the intervention is described in full elsewhere.¹⁶ In summary, the educational intervention was constructed using the following principles:

1. Diagnosis in primary care depends upon pattern recognition and the use of 'illness scripts' (more or less complex representations of diseases) in non-linear pathways to find the most probable explanations for presenting symptoms.
2. The first stage of diagnosing is not testing, but starting to suspect the possibility that a dementia syndrome may be emerging (*the trigger phase*). The doctor needs an *index* of suspicion to construct a diagnosis, which is often 'triggered' by a symptom within the patient's story.
3. A specific problem with dementia is that all involved – patients, families and GPs – are reluctant to diagnose dementia, a serious and largely unmodifiable disease, which carries a huge burden of stigma.
4. The diagnostic task is complex, therefore, because the accumulating cognitive impairments are occurring within complex personalities, themselves embedded in social relationships.
5. Any educational intervention needs to be flexible enough to correct context-specific deficits. In other words, there is no 'cook book' or 'one size fits all' grand intervention that will alter clinical behaviour in primary care.

A workplace approach

In primary care settings, the most effective educational methods hinge on adult learning approaches – problem-solving, small group work, solution focus, 'academic detailing' (on site rather than off site) – that permit flexibility in learning and allow adaptation of guidelines to local circumstances.

A co-design approach to the production of an Educational Needs Assessment (ENA) tool was adopted in order to gain the insights and experiences of a range of practitioners.³⁷ This involved an expert group of designers and an expert panel of 'critical friends' working in an iterative technology development process³⁸ to develop a prototype ENA tool for dementia diagnosis and management. The prototype was refined

and subsequently 'field tested' with volunteer practices. A full description of this process can be found elsewhere.³⁹

The expert group

The multidisciplinary expert group was made up of three GPs, an old age psychiatrist, a carer and a psychologist, and was attended by three members of the research team. Members of the expert group were chosen on the basis of their expertise or experience in dementia care, or in professional education, or both. The aim of the expert group was to decide which skills and attributes were essential for a primary care team to possess in order to deliver effective care for patients with dementia.

The expert group was given three objectives: to (1) design a care pathway that would assist practitioners in earlier diagnosis and enhance subsequent clinical management (the care pathway); (2) identify the attributes a practice would need to implement the care pathway (the task matrix); and (3) use the task matrix to derive a set of questions that would identify the practice's learning needs (the ENA).

The expert group was also asked to frame its work in terms of adult learning approaches, in other words, that learning would be problem-solving, case based and usable by practitioners at different points on the spectrum from novice to expert.^{40,41}

A modified nominal group technique was used with the expert group to develop the prototype ENA tool. Nominal groups are potentially powerful learning and development tools.⁴² They have a particularly useful role in analysing health-care problems⁴³ and can help bridge the gap between researchers and practitioners.⁴⁴

The expert group met initially to decide what the elements of a training programme designed to change practice in dementia should be. This meant identifying what tasks were needed to be performed in order to identify patients with dementia, and to care for them appropriately in the primary care setting. The expert group designed a flow chart and identified elements of the diagnostic process outlining the pathway that a clinician might follow once they suspect that a patient has dementia (see *Appendix 3, Figure 29*). In addition, the elements of a training programme for primary care teams were identified (see *Appendix 4*). From this, the expert group developed questions that would identify the practice's strengths and weaknesses in the care of people with dementia.

This cyclical process of adapting and refining ideas took place over one calendar year, and necessitated four meetings of the expert group. The prototype ENA was sent to the expert panel after the fourth meeting of the expert group.

The expert panel

The expert panel comprised a group of external, independent people who had registered their interest in the EVIDEM project by subscribing to a mailing list on the website. The expert panel had 13 members (one of whom dropped out in the course of the development process), with a mix of carers, patients, and professionals, including two GPs, a social worker, a practice nurse and an Admiral Nurse (a community nurse specialising in support of people with dementia and carers). Seven panel members were carers of people with dementia.

Expert panel members were blinded to each other as well as to the expert group members. They received and sent comments on all the documents by e-mail or post. The purpose of the panel was to review the proposals made by the expert group to ensure that no themes were omitted and to decide how comprehensive, valid and feasible the ENA was as a tool. They were also charged with assessing if the development of the prototype concurred with known factors favouring the adoption of an innovation, using literature that had been circulated to them in advance. When this had been completed the expert panel returned their comments and suggestions to the expert group for review.

Field-testing the Educational Needs Assessment tool

After incorporation of the feedback from the expert panel, a prototype version of the needs assessment tool suitable for field testing was prepared. This is shown in *Table 1*.

This ENA template was then field tested in volunteer general practices. The practices were based in north west and north east London, and were recruited directly by the EVIDEM programme as part of a RCT of an educational intervention. Practices were informed about the process and asked to choose either field-test status or RCT participation. The first five respondents wanting to join the field test were enrolled.

To carry out an ENA, two members of the research team held a group meeting at each practice. A team member experienced in group-based learning in general practice (the expert tutor), facilitated discussion of the needs assessment tool. The other acted as a participant observer, ensuring that all questions were asked and clarifying points where necessary, as well as taking notes about the assessment process. The practices were asked to invite whichever members of staff they thought should participate, including attached staff from community services. The times of meetings were left to the practice to choose. The research project paid for lunch when lunchtime meetings were preferred.

An educational prescription was agreed at the end of each needs assessment process, and up to three follow-up visits were arranged to work through the themes identified for the educational prescription. The educational prescriptions were used to collect and collate learning materials for each practice, and the subsequent workshops were also used to revisit and revise the questions in the ENA. The research team assembled material in written and electronic form for each of the items on the educational prescription workshops led by the expert tutor who had facilitated the ENA process, again with a participant observer from the research team.

Table 2 shows the characteristics of the practices in the field test, the participation of different disciplines, the number of workshops held with each practice, and the themes identified in their 'educational prescription'.

As a result of the field testing, the variety of learning materials used was broadened to include more reference material for use during sessions. The timing planned for topics was also amended and the expert tutors became more knowledgeable and aware of areas of need that were consistent across individuals and groups. The practices involved in the field test made it clear that they did not want decision-support software embedded in their electronic medical record systems but instead preferred simple, easily accessible guidance in an electronic format that functioned as 'look-up' documents.

The educational prescriptions developed through the ENA appeared acceptable and useful in volunteer practices. The time commitment (no more than 4 hours, spread out at the practice's discretion) appeared manageable. The pilot group of practices prioritised diagnosis, assessment of carers' needs, quality markers for dementia care in general practice, and the implications of the MCA 2005¹⁷ for clinical practice. The content of the ENA seemed to be comprehensive, in that no new topics were identified by practices in the field trial. On the basis of this pilot, the ENA tool was used in the full trial.

Developing a learner's manual

The themes identified by practitioners in the field test were researched by EVIDEM staff and a learner's manual was constructed (available via www.EVIDEM.org.uk). This manual was designed in a modular form with Microsoft Word version 97–2004 (Microsoft Corporation, Redmond, WA, USA) documents that could be accessed during consultations if necessary. The content of the learner's manual was developed using the expertise of all members of the EVIDEM team. The manual contains modules on the following:

- dementia diagnosis and cognitive assessment tools
- differential diagnosis of dementia by illness and types
- disclosure of dementia diagnosis and cultural diversity

TABLE 1 Educational needs assessment for dementia care in general practice

Question	What the answers tell us	What we do
1. How would you rate your current care for people with dementia and their carers (using a simple scale of good enough/satisfactory/needs substantial improvement)?	Answers will indicate whether focused educational input is needed or broader input (this is a very subjective assessment – the practice may be better or worse than it thinks)	Gives the research team some sense of scale of need and time commitment, and may permit preliminary selection of learning materials and resources
2. What grounds or criteria is your rating based on?	Identifies more clearly the areas of strength and weakness, from practice perspective. e.g. Is the major problem with diagnosis, or disclosure of the diagnosis, or judging impairment, or knowing what the appropriate responses and resources are?	Sense of priorities for learning will begin to emerge here
3. Does the number of people in your practice diagnosed with dementia correlate with the local prevalence figures?	Reflects (1) local demography and (2) under-recognition	GPs tend to overestimate prevalence and likely future workload, so some reframing possible (we need epidemiological data)
4. How do you arrive at your decision for diagnosis of dementia?	Tells us about the diagnostic procedure followed in the practice. It will also inform us on who makes the diagnosis	Helps identify roles within the practice team. Skill mix and experiences within the group can then be shared between colleagues with the opportunity for peer-to-peer learning
5. How many older people with suspected dementia did you refer last year?	Reveals the practice culture (transfer of responsibility to specialist services vs. GP care)	We will know if we need to increase their capacity to provide GP care or simply reinforce existing good practice
6. After diagnosis, what follow-up do you provide to people with dementia and their carers?	Opens up discussion about (1) systematisation of care within the practice and (2) resources available to the practice	(1) Case management methods (2) Local (and national) directory of resources
7. Are you using a shared care protocol for cholinesterase inhibitors? If 'yes' then (1) who was involved in producing the protocol, and (2) who is involved in its implementation (e.g. hospital consultants, community psychiatric nurses, Care of Older People team)?	Awareness of protocol (if it exists), and its appropriateness for general practice	Rehearse use of (GP developed) shared care protocol
8. How effective do you think cholinesterase inhibitors are and how effective have you found them in your practice?	Awareness of realistic likely impact of cholinesterase inhibitors	Discussion of trial data on cholinergic drug effects
9. What non-pharmacological alternatives do you have available to help your patients (and their carers)?	Will indicate extent of networking with local services and identify practice resources usable by people with dementia	Provision of information about cognitive reframing, other psychosocial support methods
10. Based on your experience, what do you think are the important quality markers in caring for people with dementia? (What would you want for yourself?)	Elicits both clinical and personal experience; may provide very useful case vignettes	Fit the practice's conception of quality markers to the NICE/SCIE guideline indicators ³⁶
11. Is there anything that you would like improve? If yes, what is it and why would you like it to change?	Prioritisation of learning needs	Highly focused educational input

SCIE, Social Care Institute for Excellence.

TABLE 2 Practice information, ENA attendance and themes identified for educational prescriptions

Practice	List size	Non-clinical staff present?	Community staff present?	Diagnostic methods	Shared care protocol	BPSD management	Carers needs and quality markers	MCA 2005 ¹⁷ and legal issues	Complex case discussion	Improved service awareness and collaboration	Care planning	No. of workshops
1. Inner city, GP led	6300	✓	-	✓	✓	✓	✓	✓	✓	-	-	3
2. Outer city, GP led	9100	-	-	✓	-	-	✓	✓	✓	✓	-	2
3. Outer city, nurse led	6000	✓	✓	✓	✓	✓	✓	✓	-	✓	✓	3
4. Outer city, GP-led training practice	5200	-	-	✓	-	✓	✓	✓	-	-	✓	2
5. Inner city, GP led	10,500	-	-	✓	✓	-	✓	-	-	✓	✓	3

- use of cholinesterase inhibitors, NICE/Social Care Institute for Excellence (SCIE) guidelines and shared care of medication
- management of BPSD and Department of Health (DH) guidelines for using antipsychotic drugs
- non-pharmacological interventions for dementia
- medication review and dementia
- needs of people with dementia and primary care
- case studies for management of people with dementia
- carer needs and support in general practice
- end-of-life care
- holistic care in dementia – personhood approach
- MCA, advance directives and Lasting Power of Attorney (LPA)
- Independent Mental Capacity Advocates (IMCAs) and Court of Protection
- financial and legal guidance: where to go for help
- dementia and driving.

Implementing the EVIDEM-ED trial

Trial design

The effectiveness of an educational intervention combining practice-based workshops and computer-based support was tested in a pragmatic, unblinded, cluster RCT, with a pre and post design, and with two arms: usual care compared with educational intervention [see CONSORT (Consolidated Standards of Reporting Trials) diagram in *Figure 3*]. The researchers were aware of group allocation but carers and people with dementia were not informed. A full description of the trial design – including management structure, participant involvement and patient and public involvement (PPI) – is available in the published protocol.⁴⁵

Standard significance tests assume that random sampling has taken place, and that the behaviour or knowledge of any one individual is not affected by others in the sample. However, this study, like many in the health service field, is based on clusters of individuals who may influence each other – in this case colleagues in a practice who share information or similar views, or patients who receive similar treatment.⁴⁶ This ‘clustering effect’ can mean that false conclusions are drawn about relationships in the data. This effect was controlled for by using cluster membership (i.e. respondents in each practice).

Study setting

The study took place within primary care practices in the geographical area covered by the North Thames (NT) Dementias and Neurodegenerative Diseases Research Network (DeNDRoN) – Metropolitan North London, Essex, Hertfordshire and Bedfordshire. Approval for the trial was received from Southampton & South West Hampshire Research Ethics Committee (REC) (A): reference 09/H0502/77.

The educational intervention

The educational intervention consisted of practice-based workshops with a tailored curriculum designed by a multidisciplinary expert group and supplemented by electronic resources. The educational interventions reflected different approaches to adult learning, namely workshops directly relevant to clinical practice, allowing learning to occur through peer reflection about real cases, and electronic resource materials suitable for ‘real-time’ use in consultations.

Recruitment

Primary care practices

Interested general practices in the North Thames DeNDRoN were identified in collaboration with the local Primary Care Research Networks (PCRNs): the Primary Care Research Network-Greater London (PCRn-GL) and the Primary Care Research Network-East of England (PCRn-EoE). Practices were contacted by the trial research team, by letter and awareness raising through general practice educational meetings, and regular newsletters.

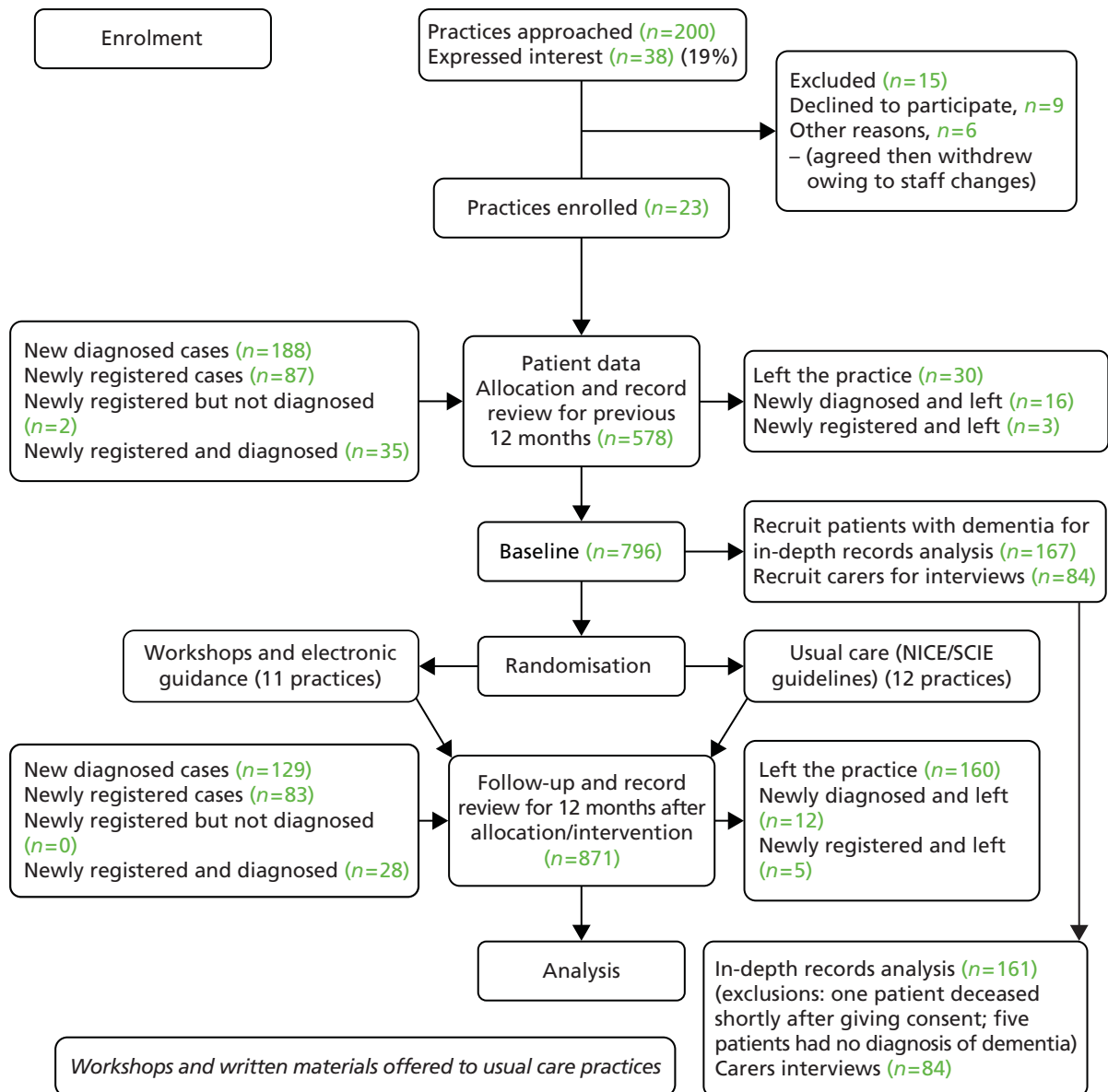


FIGURE 3 EVIDEM-ED: CONSORT flow diagram.

Inclusion criteria

The inclusion criteria for practices in this study were (1) routine data collection from clinical encounters on electronic medical records and (2) team commitment to participate in educational workshops held in the practice. (All staff working in the practice were eligible to participate in the study.)

Exclusion criteria

Practices that did not routinely capture clinical data in electronic records were excluded.

Patients with dementia and their carers

An in-depth study of medical care for patients with dementia was carried out in a subset of the practice populations. Patients identified by the practice were invited by their usual GP to permit analysis of their medical records, and their carers (where known) were invited to participate in face-to-face interviews, with telephone follow-up 12 months later.

Inclusion criteria

Being on the QOF register with a Read Code for dementia of any type documented in their medical records, with no lower age limit.

Exclusion criteria

Exclusion criteria were (1) participants who were unable to speak English, for whom there was no available interpreter; (2) either the patient or carer was involved in concurrent research; (3) the key clinical professional working with the patient felt that an approach to the person with dementia or their carer would be inappropriate or may increase distress; and (4) any other important reason that the lead clinical professional might have about why the person with dementia or their carer should not be contacted.

Every effort was made to include those who met the inclusion criteria and who might adequately understand verbal explanations or written information given in English.

Outcome measurements

Primary outcome, measured in the audit sample

We derived our primary outcome measure and the effect size from discussions with practitioners in the feasibility phase of the trial. The consensus was that the clinical tasks involved in providing good-quality care required at least two encounters per year, and that the educational intervention would promote this effectively in the majority of those in the intervention arm. Our hypothesis was, therefore, that the proportion of patients receiving two dementia-specific management reviews per year would increase between the intervention and control groups of patients by 50%, that is, 20% (usual care) compared with 70% (intervention), after the introduction of the educational intervention. Data relating to dementia-specific patient reviews and consultations relevant to dementia management were extracted from the practice records, first by electronic searches and then by hand-searching by research clinicians. Read-Coded dementia reviews were counted for each patient with dementia in the 12 months prior to intervention/randomisation and the 12 months following intervention/randomisation. Using the same time periods, all face-to-face consultations in which any aspect of dementia was documented as Read Code or free text were counted as 'opportunistic reviews', regardless of the problem triggering the consultation.

Sample size

Based on the study having 90% power to detect as significant, using a 5% two-tailed significance level, a 50% difference in the proportion of individuals with two or more dementia-related GP visits (usual care 20% vs. intervention 70%), the required sample size, based on individual randomisation, would be 23 per group – a total of 46 individuals. However, owing to the use of cluster randomisation, the total required sample size needed to be inflated in order to take account of this clustering. The number of patients recruited per practice was also inflated in order to maintain the sample sizes in the presence of attrition.^{47,48} With 20 practices (10 per arm), the power to detect the differences postulated would be maintained if the intraclass correlation coefficient were of the order ≤ 0.37 . Thus the effective sample size with 10 patients per cluster and 20 practices needed to be 200. If the expected attrition rate as 1/3 (33.3%) then 15 patients would need to be recruited per practice in order to maintain the sample size of 10 per practice.

Secondary outcomes, measured in the subset of patients with dementia who permitted review of their medical records

Concordance with guidelines

Documented concordance with the best practice recommendations from the intervention were assessed by the researchers examining the medical records of the subset of patients who had agreed to participate in the in-depth study. A medical records data extraction pro forma based on the intervention and best practice guidelines was developed (see *Appendix 7*).

Medical records at each practice were reviewed and analysed by independent clinical researchers, and diagnostic and management actions were coded using the pro forma, noting whether or not the action was taken in primary care.

Concordance with guidelines for diagnosis was operationalised by first identifying the *index* consultation. This was taken as the first consultation, communication or other entry in the patient record which indicated that dementia was being considered as a possible diagnosis – that is, by the use of the Read Code and/or the recording of symptoms of dementia. Examples of symptoms included were short-term memory loss, confusion, wandering, personality change and depression. The content of all consultations in the 6 months prior to the index consultation were reviewed. A count of specific actions recorded as part of the index consultation and/or in the period leading to formal diagnosis was then made. The actions were informed by the NICE/SCIE dementia guidelines³⁶ and agreed by the Project Management Group (see *Appendix 2*) as reflecting the working definition of good practice in the diagnosis of dementia. They were as follows:

Diagnosis in primary care

- Request for blood tests.
- Cognitive testing completed.
- Informant history taken.
- Referral to consultant, nursing or secondary care.
- Depression and/or psychosis considered.
- Carer concerns recorded.
- Behavioural and psychological symptoms related to dementia recorded (apart from depression, elsewhere classified).

Information was given by the practice to either the carer or patient or both, on:

- signs and symptoms
- course and prognosis
- treatments
- local care and support services
- support groups
- sources of financial and legal advice and advocacy
- medicolegal issues
- local information sources, including libraries and voluntary organisations.

The following actions were coded at time of index or up to formal diagnosis:

- anti-dementia medication prescribed
- medication review undertaken
- computed tomography (CT)/magnetic resonance imaging (MRI) scan requested.

Management in primary care

- Had antipsychotic medication been prescribed?

- Evidence of:
 - consent and capacity; evidence that the provisions of the MCA 2005 have been followed *and* evidence of recall, reasoning, decision-making, and, if relevant, agreement from next of kin, carers or other consultees?
 - care plan
 - BPSD addressed and managed
 - advance statements
 - living will (advance decision to refuse treatment)
 - LPA
 - preferred priorities
 - direct payments/personal budgets, functional abilities, activities of daily living (ADL) or the use of global assessments
 - discussion about carers' needs.

Information was given by the practice to either the carer or patient or both, on:

- local care and support services
- sources of financial and legal advice and advocacy
- medicolegal issues.

No attempt was made to measure the number of times a particular action – for example, record of contact with carers – was recorded, but only whether or not such contact was recorded in the pre-intervention and/or post-intervention periods by a member of the practice.

Measurement of unmet needs in patients and carers

Unmet needs were captured using a structured interview schedule with carers, developed by the research team in a previous trial.²¹

Consent

People with dementia were identified by practice managers and their lead clinician checked whether or not they fulfilled the inclusion criteria. Before seeking consent from patients to participate in the study, practitioners were asked for their opinion about the capacity of the person with dementia to give informed consent to taking part in the study, using the MCA 2005¹⁷ as the framework for their judgement.

For patients judged as having decision-making capacity, the following information was posted to the person with dementia: (1) a covering letter explaining the involvement of the practice and signed by the lead clinician; (2) a participant information sheet; and (3) a response letter and prepaid envelope to be returned to the research team. A researcher arranged to see those patients with dementia and their carers who expressed an interest in participating in the study. This encounter took place at the preference of the carer, at the patient's home, in the GP practice or at the research team's offices at the Royal Free Hospital. Its purpose was to seek consent from the carer and consent/assent from the person with dementia, where possible, for their participation in the study and for allowing access to patient records.

For those judged by the lead clinician to lack capacity to give informed consent, a consultee (as defined in the MCA 2005¹⁷) was identified and consulted about possible involvement of the person with dementia in the trial. The relevant clinician wrote to the consultee, providing full information about the trial.

Figure 4 shows the process of identifying participants and how they were approached, recruited and consented/consulted about EVIDEM-ED.

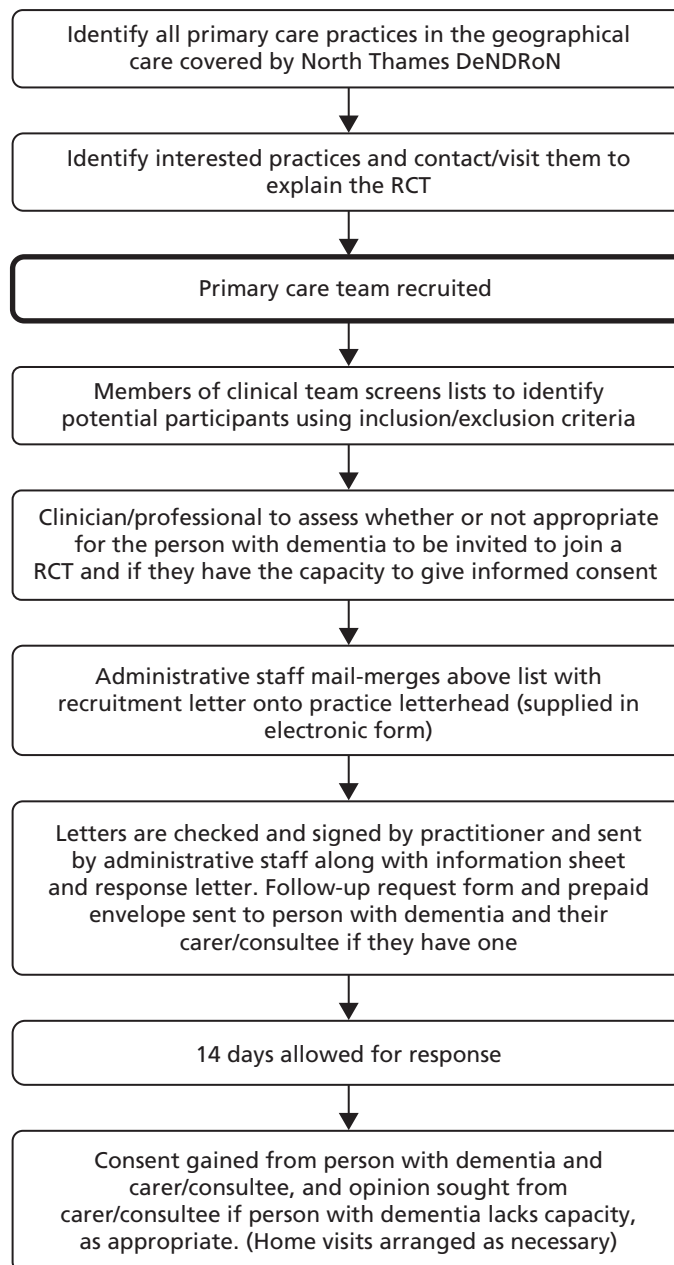


FIGURE 4 Flow chart of how participants were identified, approached, recruited and consented/consulted about EVIDEM-ED (2009–10).

Randomisation and masking

Participating practices were randomised to intervention or usual care arms by an independent researcher using a computer randomisation programme.⁴⁹ Independent clinicians undertaking record reviews could have deduced the allocation of the practices and could have become unblinded.

The process for obtaining participant informed consent was in accordance with the REC guidance, the MCA 2005¹⁷ and good clinical practice (GCP).

With the informed consent of the person with dementia or following discussion with their consultee, members of the research team examined medical records in the GP surgery, using the pro forma to guide data extraction. No personalised information was recorded or retained by the researcher, and each case was allocated a unique study number for the purposes of recording data. All other information was stored in accordance with the Data Protection Act (1998).⁵⁰

Statistical analyses

Primary outcome: number of reviews

Multilevel logistic regression modelling was used to compare the proportion of patients who had two or more reviews during the 12 months post intervention/randomisation (post period) between the usual care and intervention arms. Two-level random-effects models were fitted in order to take account of the cluster randomisation. The models adjusted for the proportion of patients within each practice with two or more reviews during the 12 months pre intervention/randomisation (pre period). Separate analyses of the dementia related reviews, opportunistic reviews and the total reviews were undertaken.

As sensitivity analyses, the above were repeated only for those patients with information available for the full 12-month pre and post periods.

Diagnoses

Multilevel Poisson regression modelling was used to compare the diagnoses rates, in those aged ≥ 65 years, between the intervention and usual care arms in the post period. The number of newly diagnosed patients was used as the outcome with the practice list size of those aged ≥ 65 years used as the exposure. Two-level random-effects models were fitted in order to take account of the cluster randomisation. The number of diagnoses during the pre period was adjusted for in the model.

Multilevel logistic regression modelling was undertaken to compare concordance with management guidelines in the post period between the intervention and usual care arms using two-level random-effects models. Models were adjusted for the concordance levels in the pre period.

Findings

Of 200 practices we approached, 23 agreed to participate and provided the required level of access and data. The practices came from 12 different primary care organisations in urban, semirural and rural areas. Practice enrolment was from 2008 to 2010. Practices received a mean of three workshops, including the needs assessment workshop at the beginning of the trial (range 2–4). These were staggered across the practices and took place from 2009 to 2011.

Practice information

Eleven practices were randomised to the intervention arm and 12 to the usual care arm. The number of patients with dementia per practice ranged from 5 to 123 in the intervention arm and from 6 to 108 in the usual care arm. The characteristics of the practices by arm of study are shown in *Table 3*. There was a slightly higher mean list size, a slightly higher mean deprivation score, and a slightly higher mean number of GPs in the intervention practices.

Patient information

A total of 1072 (intervention 512, usual care 560) patients had information available in their medical records at audit showing the number of reviews (dementia/opportunistic/total) in the 12 months (or a proportion of) before intervention or randomisation and/or the 12 months (or a proportion of) after. Of those, 61% ($n = 313$) were female in the intervention group and 70% ($n = 382$) were female in the usual care group. The mean age for those people with dementia in the intervention group was 83 standard deviation (SD) 8.7; minimum (min.) 33; maximum (max.) 104 years and 83 (SD 8.8; min. 55; max. 109) years for those in the usual care group.

TABLE 3 EVIDEM-ED: primary outcome analysis – practice characteristics by randomisation group

Variable	Summary measure	Usual care practices (n = 12)	Intervention practices (n = 11)
No. of GPs	Mean (SD)	4.6 (2.7)	5.1 (2.1)
	Median	5.5	5
	Min.	1	2
	Max.	9	9
List size	Mean (SD)	7892 (4684)	8382 (4711)
	Median	9239	6849
	Min.	1133	2682
	Max.	14,358	19,323
Deprivation score ^a	Mean (SD)	19.9 (10.0)	20.4 (7.6)
	Median	17.5	22.0
	Min.	7	8
	Max.	40	29
Care homes	No. of practices with patients residing in care homes	9	9
	Min. per practice	0	0
	Max. per practice	6	15
	Total no. homes per group	17	30

Max., maximum; min., minimum; SD, standard deviation.

a The Index of Multiple Deprivation (IMD)⁵¹ is a standard measure of deprivation at small area level across England.

The IMD is based on seven domains: income, employment, health and disability, education and skills, barriers to housing and services, living environment, and crime. The scores used in the indices are relative to each other and (in most cases) do not indicate an absolute value as such. For example, an IMD score of 40 does not mean that an area is twice as deprived as one with a score of 20, but it does mean that the area with the score of 40 is more deprived than the area with a score of 20.

Dementia management reviews

The mean total number of dementia management reviews (planned and opportunistic) for people with dementia in the intervention group in the period before randomisation was 0.89 (SD 0.92; min. 0; median 1; max. 4). For the period after randomisation it was 0.89 (SD 1.09; min. 0; median 1; max. 8).

For those people with dementia in the usual care group prior to the intervention, the mean total number of dementia management reviews (planned and opportunistic) was 1.66 (SD 1.87; min. 0; median 1; max. 12). For the period after intervention it was 1.56 (SD 1.79; min. 0; median 1; max. 11). This difference at baseline appears to have been due to one practice in the usual care group having medical responsibility for several care homes.

Primary outcomes

The numbers of each type of review for each patient in the pre and post periods were dichotomised for the primary analyses. These were classified according to whether the individual had < 2 or ≥ 2 dementia management reviews. A summary can be seen in *Table 4*.

TABLE 4 EVIDEM-ED: The percentage of patients, by group, with two or more reviews for each type of review in the pre and post periods

Variable	Usual care practice patients (%)	Intervention practice patients (%)
Dementia (pre)	15.1	4.9
Dementia (post)	9.6	6.1
Opportunistic (pre)	21.3	6.6
Opportunistic (post)	21.4	8.3
Total (pre)	39.0	18.2
Total (post)	35.9	19.8

Estimated ORs (odds of having two or more reviews in the intervention group vs. the usual care group), along with the *p*-values and 95% CIs for those with a full and partial data period are presented in *Table 5*.

There were no significant differences in recording of dementia management reviews for patients diagnosed by the current practice between the usual care and intervention arms.

Case detection

In order to get a realistic estimate of case identification that was comparable with studies published elsewhere we analysed rates of diagnoses by age group.

Pre period: in the pre-intervention/randomisation 12-month period, there were 239 newly diagnosed cases of dementia. Eleven of these (4.6%) were in people aged < 65 years. Of the 228 newly diagnosed cases in those aged ≥ 65 years, 99 were in the usual care practices and 129 in the intervention practices.

Post period: in the post-intervention/randomisation 12-month period there was a total of 169 newly diagnosed cases of dementia. Six of these (3.7%) were in people aged < 65 years. Of the 163 newly diagnosed cases in those aged ≥ 65 years, 78 were in the usual care practices and 85 in the intervention practices.

TABLE 5 EVIDEM-ED: Estimated ORs, *p*-values and 95% CIs by classification of dementia management review

Reviews (≥ 2 vs. < 2)	OR	95% CI	<i>p</i> -value
For all cases including proportion of data collection period pre and/or post			
Dementia	0.94	0.33 to 2.62	0.899
Opportunistic	0.96	0.53 to 1.74	0.890
Total	1.05	0.72 to 1.53	0.811
For full pre and post data period			
Dementia	0.83	0.32 to 2.10	0.688
Opportunistic	0.62	0.25 to 1.56	0.310
Total	0.83	0.52 to 1.33	0.444

The primary analysis considered diagnosis rates in those registered with the practice list and this was used as the denominator for the calculation of rates. For the usual care practices combined the total patient population was 15,699 compared with 11,541 for the intervention practices.

Table 6 shows the case detection rates in the pre-intervention/randomisation and the post-intervention/randomisation periods. These are displayed separately for the intervention practices (combined) and the usual care practices (combined). The rates by practice were also calculated and the min. and max. rates, across the practices, are also displayed in Table 6.

Case detection rates were unaffected by the intervention. The estimated IRR for the intervention compared with the usual care group from the multilevel Poisson regression modelling was 1.03; the *p*-value was 0.927 (95% CI 0.57 to 1.86).

Secondary outcome analysis

An in-depth study of the medical records of 167 people with dementia was carried out to capture the detail of clinical management before and after diagnosis. Nineteen of the 23 practices in the trial invited patients with dementia and/or their carers to permit analysis of medical records; four practices were unable to send invitations at baseline, for organisational reasons. The total number of people invited was 763, of whom 190 expressed an interest (25%) and, after further discussion with researchers, 167 (22%) allowed review of medical records. The medical records of some of the 167 participants were incomplete because they had joined their practice after the index consultation, or after diagnosis, and the previous records had not reached their new practice. One hundred and sixty-one had documentary evidence of a formal diagnosis, and 136 had documentary evidence of the index consultation and a formal diagnosis. Figure 5 shows the characteristics of the secondary outcome sample.

Symptoms were recorded at index consultation for 101 patients, and, of those, 39% had one or two symptoms, 45% had three or four symptoms, and 17% had five or more symptoms recorded.

TABLE 6 EVIDEM-ED: Detection rates for new cases of dementia in the pre and post periods by randomisation

Rates		Usual care practices (%)	Intervention practices (%)
Pre period	Combined	0.63	1.12
	Min.	0.00	0.17
	Max.	4.40	3.45
Post period	Combined	0.50	0.74
	Min.	0.00	0.00
	Max.	4.10	1.06

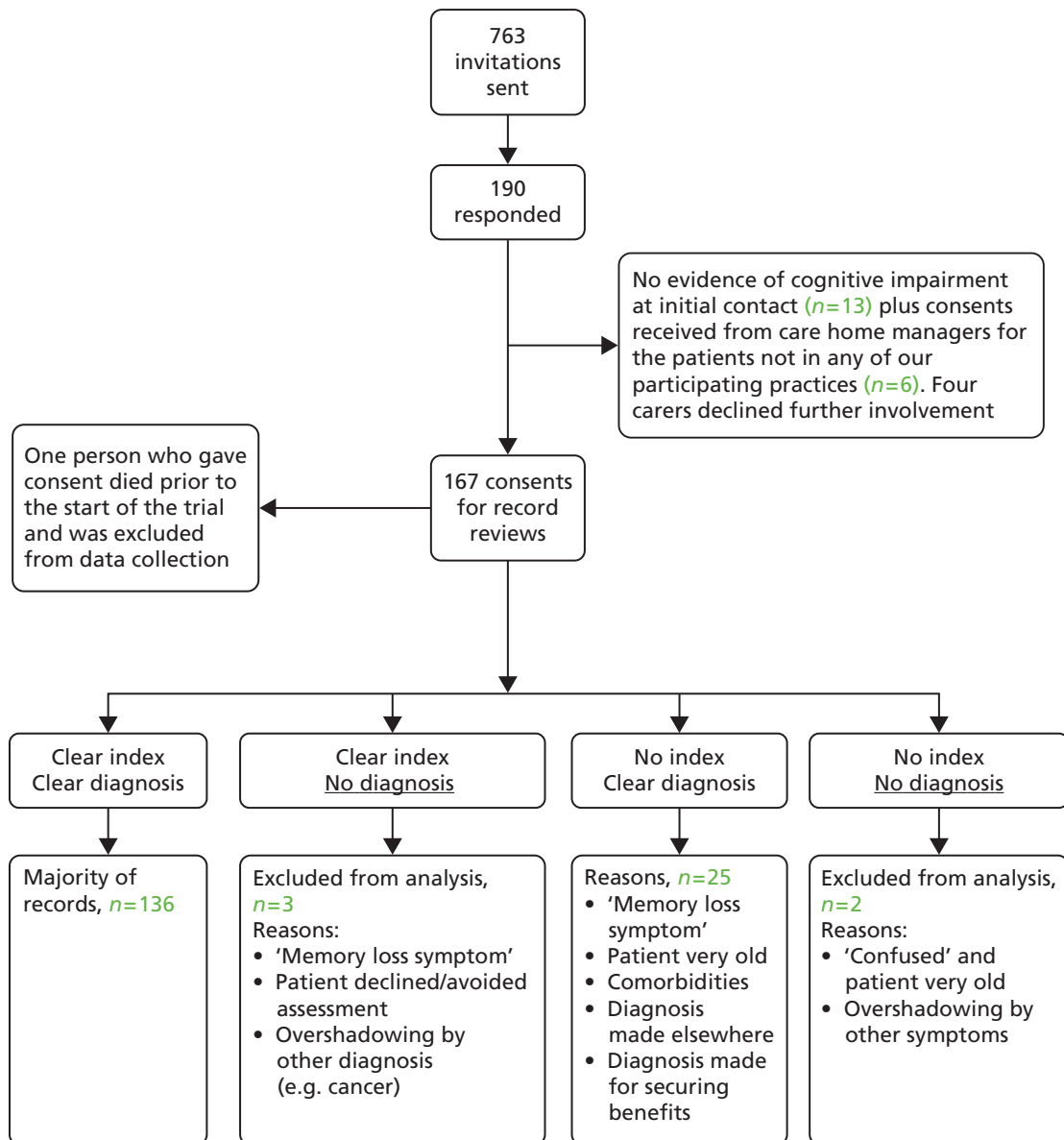


FIGURE 5 EVIDEM-ED: patient medical record data characteristics.

Comorbidity and repeat medication use

Forty-two members of the subset (25.3%) had 0–3 comorbidities recorded, 64 (38.6%) had 4–6 comorbidities and 60 (36.1%) had 7 or more comorbidities. Data on comorbidities were missing for one member of the subset. Six members of the subset (3.6%) had no repeat medications documented in the medical record, 59 (35.5%) had 1–5 medications, 82 (49.4%) had 6–10 medications and 19 (11.4%) had more than 10 medications. Data on repeat prescription of medication were missing for one member of the subset.

Table 7 shows the characteristics of dementia type by randomisation group.

TABLE 7 Patient baseline characteristics by randomisation group

Characteristics		Randomisation group			
		Usual care		Intervention	
Age, years	Mean	82		81	
	SD	8		8	
	Min.	57		60	
	Max.	102		97	
	<i>n</i>	97		64	
		<i>n</i>	(%)	<i>n</i>	(%)
Gender	Male	29	29.9	29	45.3
	Female	68	70.1	35	54.7
	Total	97	100.0	64	100.0
Location	Community	55	59.8	40	62.5
	Care home	37	40.2	24	37.5
	Total	92	100.0	64	100.0
Diagnosis	Senile dementia/dementia	28	28.9	12	18.8
	Alzheimer's disease	41	42.3	21	32.8
	Vascular dementia	13	13.4	17	26.6
	Dementia with Lewy bodies	0	0	3	4.7
	Mixed dementia	8	8.2	4	6.3
	Mild cognitive impairment	3	3.1	3	4.7
	Other	4	4.1	4	6.3
	Total	97	100.0	64	100.0

Concordance with diagnostic and management guidelines

Table 8 shows the concordance of medical records with guidelines about the diagnostic process in the 136 people with dementia for whom we had an index consultation and a formal diagnosis. Table 9 shows the concordance of medical records with guidelines about management after diagnosis in the same number of cases.

Two-thirds of patients were referred for specialist assessment at the index consultation. When referral to a specialist was documented at the index consultation, 58 (69%) were made to old age psychiatrists, 14 (17%) to memory clinics, four to neurologists (5%) and five (6%) to geriatricians. NICE guidelines for diagnostic work-up were adhered to in the majority of patients, with documentation of the blood screen, informant history and carer concerns, but not for cognitive function testing. Among those with cognitive test results documented, 30 (58%) were for the Mini Mental State Examination (MMSE),⁵² two (4%) were for the Six Item Cognitive Impairment Test (6CIT) and 19 (37%) were for the Abbreviated Mental Test Score (AMTS).

A locum reading the medical records of patients in the subset for the time period between index consultation and formal diagnosis would only occasionally learn what information had been given about signs and symptoms of dementia, the disease course and prognosis, the resources available locally that could provide support, and the relevant medicolegal concerns.

The number receiving cholinesterase inhibitors or memantine (Ebixa®, Lundbeck) ($n = 71$) was similar to the number with a formal diagnosis of Alzheimer's disease or mixed dementia ($n = 74$). Among those receiving anti-dementia medication, 56 (82%) received donepezil (Aricept®, Eisai & Pfizer), 7 (10%) received galantamine (Reminyl®, Janssen), 2 (3%) received rivastigmine (Exelon®, Novartis) and one received memantine. These medications were offered but declined by two patients.

TABLE 8 Frequency and percentage of individual actions concordant with guidelines for diagnosis (index consultation to formal diagnosis)

Diagnostic actions within primary care concordant with guidelines ($N = 136$)	n (%)
Request for blood tests documented (full or partial screen according to NICE guidelines)	76 (56)
Results of cognitive testing	53 (39)
Informant history documented	78 (57)
Referral to specialists at index consultation	87 (64)
Depression or psychosis considered	52 (38)
Carer concerns recorded	74 (54)
BPSD considered, apart from depression	42 (31)
Documentation of information given to carer or patient or both on:	
Signs and symptoms	5 (4)
Course and prognosis	0 (0)
Treatment option	18 (13)
Care and support available	20 (15)
Support groups available	7 (5)
Financial, legal and advocacy advice	11 (8)
Medicolegal matters	12 (9)
Local services (e.g. libraries, voluntary organisations)	4 (3)

TABLE 9 Numbers and proportions of the subset with documented management actions

Management actions (taken after formal diagnosis)	n (%)
Anti-dementia drugs prescribed	71 (52)
Medication review	56 (41)
Referred for CT/MRI scan	7 (5)
Prescribed antipsychotic drugs	26 (19)
Consent and capacity; evidence that the provisions of the MCA have been followed <i>and</i> evidence of recall, reasoning, decision-making and, if relevant:	33 (24)
Agreement from next of kin?	15 (11)
Care plan made	70 (52)
BPSD addressed and managed	101 (74)
Discussion of advance statements recorded	4 (3)
Discussion of living will (advance decision to refuse treatment) recorded	1 (1)
Discussion of LPA recorded	12 (9)
Preferred priorities for care (e.g. DNAR order)	12 (9)
Discussion of direct payments/personal budgets recorded	4 (3)
Functional abilities, ADL or global assessments documented	74 (54)
Discussion about carers needs	45 (33)
Evidence that information was given by the practice to either the carer or patient or both, on:	
Local care and support services	5 (4)
Sources of financial and legal advice and advocacy	6 (4)
Medicolegal issues	16 (12)
Local information sources, including libraries and voluntary organisations	3 (2)
DNAR, do not attempt resuscitation.	

One in five were prescribed antipsychotic medication, of which the most commonly used was quetiapine (Seroquel®, AstraZeneca) ($n = 13$, 52%), followed by amisulperide (patent expired 2008, multiple manufacturers/trade names) ($n = 4$, 16%), haloperidol (Haldol®, Johnson & Johnson) ($n = 2$, 8%) and risperidone (Risperdol®, Johnson & Johnson) ($n = 2$, 8%); six individuals received aripiprazole (Aripiprex®, Otsuka and Bristol-Myers Squibb) or olanzapine (Zyprexa®, Eli Lilly and Company).

One in four records showed that mental capacity had been assessed. The majority of records showed evidence of care planning, assessment of, and response to, BPSD and functional assessment.

A locum encountering these patients and reading their medical records would not know whether they had considered or made any decisions about advanced statements, 'living wills', Power of Attorney (POA), preferred priorities of care, use of direct payments or personal budgets, sources of support and medicolegal concerns, such as driving.

Concordance with diagnostic guidelines at baseline differed between those patients from practices subsequently allocated to intervention or usual care groups, as shown in *Table 10*.

TABLE 10 Baseline diagnostic concordance by randomisation group

Diagnostic action	Randomisation group					
	Usual care			Intervention		
	<i>n</i>	%	Total	<i>n</i>	%	Total
Dementia blood screen	47	81.0	58	29	69.0	42
Cognitive function test	34	58.6	58	17	39.5	43
Informant history considered	45	78.9	57	32	71.1	45
Referral made	50	87.7	57	37	84.1	44
Depression/psychosis considered	30	52.6	57	22	51.2	43
Carer concerns	47	81.0	58	26	60.5	43
BPSD recorded	27	47.4	57	15	34.9	43
Signs and symptoms	1	2.1	48	4	8.9	45
Course and prognosis	0	0.0	47	0	0.0	45
Treatment	13	27.7	47	5	11.1	45
Care and support	11	22.4	49	9	20.0	45
Support groups	3	6.1	49	4	9.1	44
Financial, legal and advocacy	7	13.7	51	4	8.9	45
Medicolegal matters	4	8.0	50	8	17.8	45
Local services	2	4.0	50	2	4.4	45
Anti-dementia drugs prescribed	40	66.7	60	31	58.5	53
Medication review	34	65.4	52	22	51.2	43

The data in this table relate to those people who received a diagnosis of dementia in the current practice. People who received a diagnosis prior to registration were excluded.

Concordance with management guidelines at baseline differed between those patients from practices subsequently allocated to intervention or usual care groups, as shown in *Table 11*. Concordance with management guidelines at follow-up is shown in *Table 12*.

Table 13 shows ORs (with 95% CIs, *p*-values and numbers included in each model) from models which take into account the practice clustering and are adjusted for baseline levels of concordance. ORs represent the odds of concordance for the intervention compared with usual care practices. There are only two statistically significant differences, both favouring the usual care group. Participants from practices in the intervention group were less likely to have details of valid patient consent, and of care plans, documented in their medical records.

Professionals' knowledge and skills analysis

Practitioners' knowledge about dementia

Knowledge about dementia was measured by a self-completed 14-item multiple-choice quiz, for questions which were drawn from two US instruments: the University of Alabama at Birmingham Alzheimer's Disease Knowledge Test⁵³ and the Alzheimer's Disease Knowledge Test.⁵⁴ The questions reflected the content of the educational intervention, and covered current and future prevalence, risk factors, diagnosis (including differential diagnosis), medication and management (see *Appendix 5*). Where necessary, wording was adapted to reflect development in knowledge about dementia or cultural differences.

TABLE 11 Baseline management concordance by randomisation group

Management action	Randomisation group					
	Usual care			Intervention		
	<i>n</i>	%	Total	<i>n</i>	%	Total
Prescribed antipsychotic drugs	18	25.4	71	8	12.9	62
Valid patient consent	20	28.2	71	12	20.3	59
Recall and reasoning	8	11.6	69	6	10.2	59
Care plan	40	59.7	67	30	50.0	60
BPSD mentioned/managed	58	81.7	71	43	71.7	60
Advanced statements	2	2.9	70	2	3.3	60
Living will	1	1.4	69	0	0.0	60
LPA	10	14.5	69	2	3.3	60
Preferred place of care	11	15.7	70	1	1.7	60
Direct payments	3	4.3	70	1	1.7	60
Functional abilities/ADL	52	74.3	70	22	36.7	60
Carer's needs	23	37.7	61	22	37.9	58
Care and support services	22	34.9	63	12	20.0	60
Support groups	0	0.0	64	5	8.3	60
Financial and legal advocacy	4	6.2	65	2	3.3	60
Medicolegal issues	10	15.4	65	6	10.0	60
Local services	3	4.8	63	0	0.0	60

TABLE 12 Follow-up management concordance by randomisation group

Management action	Randomisation group					
	Usual care			Intervention		
	<i>n</i>	%	Total	<i>n</i>	%	Total
Prescribed antipsychotic drugs	22	22.7	97	7	11.3	62
Valid patient consent	25	26.3	95	5	8.1	62
Recall and reasoning	18	20.0	90	3	4.8	62
Care plan	52	54.2	96	27	43.5	62
BPSD mentioned/managed	59	61.5	96	45	73.8	61
Advanced statements	5	5.2	96	3	4.8	62
Living will	2	2.1	95	2	3.2	62
LPA	8	8.3	96	4	6.6	61
Preferred place of care	13	13.5	96	5	8.1	62
Direct payments	3	3.2	94	2	4.0	50
Functional abilities/ADL	63	65.6	96	30	48.4	62
Carer's needs	25	27.5	91	18	30.5	59
Care and support services	15	16.9	89	7	11.7	60
Support groups	0	0.0	93	2	3.3	60
Financial and legal advocacy	2	2.1	95	1	1.7	60
Medicolegal issues	11	11.5	96	4	6.7	60
Local services	0	0.0	93	0	0.0	48

TABLE 13 Follow-up management concordance: results from multilevel modelling

Management action	OR (95% CI); <i>p</i> -value (<i>n</i>)
Prescribed antipsychotic drugs	0.75 (0.20 to 2.76); 0.664 (131)
Valid patient consent	0.18 (0.03 to 0.94); 0.042 (127)
Recall and reasoning	0.08 (0.01 to 1.24); 0.071 (121)
Care plan	0.44 (0.20 to 0.98); 0.045 (125)
BPSD mentioned/managed	1.65 (0.59 to 4.59); 0.339 (128)
Advanced statements	0.49 (0.07 to 3.35); 0.470 (128)
Living will (advance decision to refuse treatment)	0.58 (0.05 to 6.55); 0.659 (127)
LPA	0.52 (0.13 to 2.14); 0.363 (126)
Preferred place of care	1.17 (0.04 to 35.94); 0.926 (128)
Direct payments/personal budgets	1.39 (0.18 to 10.77); 0.756 (116)
Functional abilities/ADL	0.65 (0.24 to 1.79); 0.407 (128)
Carer's needs	1.10 (0.11 to 11.04); 0.938 (116)
Care and support services	0.74 (0.20 to 2.72); 0.646 (118)
Support groups	8857496 (0 to ∞); 0.995 (121)
Financial and legal advocacy	2310740 (0 to ∞); 0.995 (123)
Medicolegal issues	0.51 (0.15 to 1.81); 0.300 (123)
Local services	Unable to estimate as a result of all values being zero

A scoring system of 'correct' = +1, 'do not know' = 0, 'wrong' = -1 was adopted to maximise variance and to allow investigation of the mix of the three types of answer. These scores were transformed to give a theoretical range of -100 to 100⁵⁵ (see *Appendix 5*). The scores of GPs on knowledge skills and attitudes were compared with those obtained using the same instrument in the previous trial of educational interventions, in 2001–2.

Professional knowledge, skills and attitudes at baseline: general practitioners

Ninety-two GPs completed questionnaires at baseline, with very few missing data except for age. There were no statistically significant differences in knowledge, skills and attitudes between GPs in the two arms of the trial. Forty-six (50%) were women, and their age range was 26–65 years, mean = 37 years, median = 41 years.

Sixty-six (72%) were principals, 12 were salaried (13%), six were registrars (6.5%) and four were locums or categorised themselves as 'other' (8.5%). Sixty-one (66%) had worked in old age psychiatry, elderly medicine or general psychiatry.

Eleven (12%) had discussed the implications of the NDS¹⁸ in the practice, 16 (17%) had discussed the NDS in a professional development setting and seven (7.5%) had discussed it with specialist colleagues. Fifteen (7.5%) had been offered training in dementia diagnosis and/or management by local specialist services. Twenty-five (27%) had discussed the implications of the MCA 2005¹⁷ with their practice, 31 (34%) had discussed it in a professional development setting, and 15 (16%) had discussed it with a specialist colleague.

Confidence in reaching a diagnosis was similar to the earlier findings, but respondents were significantly more confident about advising on management of BPSD in 2009–10 than in 2001–2, as shown by *Table 14*.

At both time periods, about one in five GPs disagreed with the statement that much can be done to improve the quality of life of people with dementia or their carers. A similar proportion disagreed that families would rather be told the diagnosis as soon as possible (*Table 15*).

Respondents were significantly more likely to agree that dementia is best diagnosed by specialist services in 2009–10 than in 2001–2, although at both time periods only a minority agreed with this proposition.

The 2009–10 respondents were significantly less familiar with management of dementia-related symptoms, availability of services or how to access them, than respondents in 2001–2 (*Table 16*).

Differences between the two time points in perceived difficulties in diagnosis and management of patients with dementia are shown in *Table 17*. Not all questions were the same at the two time points.

TABLE 14 General practitioners' confidence in diagnosis and giving advice on symptom management

Confidence in:	2001–2	2009–10	p-value
Reaching a diagnosis	81 (64%)	63 (68.5%)	n.s.
Advising on BPSD management	40 (32%)	41 (45%)	0.03
n.s., not significant.			

TABLE 15 General practitioners' attitudes to dementia care^a

Attitude	Agreement ^b		p-value
	2001–2	2009–10	
Much can be done to improve the quality of life of carers of people with dementia	105/124 (84%)	74/92 (81%)	n.s.
Families would rather be told about their relative's dementia as soon as possible	99/120 (83%)	76/92 (83%)	n.s.
Much can be done to improve the quality of life of people with dementia	98/124 (77%)	77/91 (84%)	n.s.
Providing diagnosis is usually more helpful than harmful	79/122 (65%)	66/92 (72%)	n.s.
Managing dementia is more often frustrating than rewarding	46/124 (38%)	31/92 (34%)	n.s.
Dementia is best diagnosed by specialist services	41/125 (33%)	41/91 (44%)	0.03
Patients with dementia can be a drain on resources with little positive outcome	17/118 (14%)	11/92 (12%)	n.s.
It is better to talk to the patient in euphemistic terms	11/117 (9%)	15/92 (16%)	n.s.
There is little point in referring families to services as they do not want to use them	4/121 (3%)	4/92 (4%)	n.s.
The primary care team has a very limited role to play in the care of people with dementia	6/125 (5%)	9/92 (10%)	n.s.
n.s., not significant.			
a Ranked by level of agreement in 2001–2.			
b Combined 'strongly agree' and 'agree'.			

TABLE 16 General practitioners' perceived barriers to good practice in dementia care

Perceived barrier	2001–2	2009–10	p-value
Too busy/not enough time during surgery visits	98/118 (83%)	69/92 (75%)	n.s.
Lack of social service support available to practice	69/118 (58%)	54/92 (59%)	n.s.
Lack of funding within the practice	54/118 (46%)	35/92 (38%)	n.s.
Lack of team staff in the practice	60/118 (50%)	40/91 (44%)	n.s.
Unfamiliar with advances in the management of dementia related symptoms	53/119 (45%)	61/92 (66%)	< 0.001
Unfamiliar with available services to help keep patients at home	49/119 (41%)	57/92 (62%)	< 0.01
Unsure how to refer patients to available services to help keep them at home	29/119 (24%)	33/92 (36%)	0.04

n.s., not significant.

TABLE 17 General practitioners' perceptions of difficulties in dementia diagnosis and management^a

Perceived difficulty	Mean score	
	2001–2 (scale 1–7)	2009–10 (scale 1–6)
Responding to co-existing behaviour problems	4.6	3.7
Discussing the probable diagnosis:	4.5	3.6
With the co-ordinating support services for carers and people with dementia	4.3	–
With the co-ordinating support services for people with dementia	–	3.8
With the co-ordinating support services for carers	–	3.8
Responding to the family's concerns:	3.9	–
Getting information about support services for carers and people with dementia	3.8	–
Getting information about support services for people with dementia	–	4.1
Getting information about support services for carers	–	4.2
Responding to co-existing psychiatric problems	3.8	3.9
Discussing the probable diagnosis with the family	3.5	3.3
Reaching a probable diagnosis yourself	3.4	3.3
Getting information about anti-dementia medication	3.4	3.5
Getting specialist assessment services advice by telephone	2.8	3.5

a On a score of 1 (not at all difficult) to 6/7 (very difficult), $n = 123-6$ (ranked).

A consistent one in five respondents in 2009–10 cannot answer the questions, suggesting that they are not engaged with patients with dementia (*Table 18*).

Nearly four in five GPs responding in 2009–10 thought that dementia prevalence would double by 2021, and 41% estimated the average caseload as ≥ 21 . The overestimation on both questions is consistent with findings from 2001–2 (*Table 19*).

Respondents in 2009–10 were significantly less likely to answer correctly the questions about the effect on anti-dementia drugs (cholinesterase inhibitors) and the treatment of depression in patients with dementia.

TABLE 18 General practitioners' views of available resources for dementia care

Resource	Available and satisfactory		Available but not satisfactory		Needed, but not available		Not needed		Cannot say	
	2001–2, n = 126	2009–10, n = 92	2001–2	2009–10	2001–2	2009–10	2001–2	2009–10	2001–2	2009–10
Information about what old age psychiatry services offer	67 (59%)	33 (36%)	34 (30%)	31 (34%)	10 (9%)	15 (16%)	0 (0%)	0 (0%)	14 (11%)	13 (14%)
Protocol for assessment and investigation of a patient with possible dementia	27 (32%)	28 (30%)	10 (12%)	24 (26%)	43 (51%)	22 (24%)	2 (2%)	1 (1%)	43 (34%)	17 (18.5%)
Brief screening instrument for early identification	46 (48%)	37 (40%)	12 (13%)	19 (21%)	31 (33%)	15 (16%)	3 (3%)	1 (1%)	32 (25%)	19 (21%)
Nurse with mental health training working in association with the practice	37 (34%)	2 (2%)	8 (7%)	4 (4%)	54 (50%)	64 (70%)	7 (7%)	4 (4%)	19 (15%)	18 (20%)
Shared care protocol for cholinesterase inhibitors	–	10 (11%)	–	13 (14%)	–	37 (40%)	–	7 (8%)	–	25 (27%)
Information about benefits (attendance allowance, council tax, etc.)	48 (46%)	13 (14%)	26 (25%)	17 (18.5%)	25 (24%)	37 (40%)	3 (3%)	6 (6.5%)	23 (18%)	18 (20%)

–, no equivalent 2001–2 data.

TABLE 19 Numbers and percentages of respondents giving correct answers on the dementia knowledge quiz

Question	Correct <i>n</i> (%)		<i>p</i> -value
	2001–2, <i>N</i> = 126	2009–10, <i>N</i> = 92	
1. A GP with a list of 1500–2000 people can expect to have the following number of people with dementia on their list: <ul style="list-style-type: none"> ● 1–6 ● 7–11 ● 12–20 ● ≥ 21 	48 (38)	32 (35)	n.s.
2. By 2021, the prevalence of dementia in the general population in the UK is expected to: <ul style="list-style-type: none"> ● decrease slightly ● remain approximately the same ● increase slightly ● nearly double 	14 (11)	16 (17)	n.s.
3. One of the risk factors for the development of Alzheimer’s disease is: <ul style="list-style-type: none"> ● atherosclerosis ● age ● nutritional deficiencies ● exposure to aluminium 	71 (58)	55 (60)	n.s.
4. All of the following are potentially treatable aetiologies of dementia except: <ul style="list-style-type: none"> ● hypothyroidism ● normal pressure hydrocephalus ● Creutzfeldt–Jacob disease ● vitamin B₁₂ deficiency 	107 (86)	71 (77)	n.s.
5. A patient suspected of having dementia should be evaluated as soon as possible as: <ul style="list-style-type: none"> ● prompt treatment of dementia may prevent worsening of symptoms ● prompt treatment of dementia may reverse symptoms ● it is important to rule out and treat reversible disorders ● it is best to institutionalise a dementia patient early in the course of the disease 	108 (86)	73 (79)	n.s.
6. Which of the following procedures is required to definitely confirm that symptoms are due to dementia? <ul style="list-style-type: none"> ● MMSE ● Post mortem ● CT scan of the brain ● Blood test 	25 (21)	14 (15)	n.s.
7. Which of the following is not a necessary part of the initial evaluation of a patient with possible dementia? <ul style="list-style-type: none"> ● Thyroid function test ● Serum electrolytes ● Vitamin B and folate levels ● Protein electrophoresis 	110 (87)	84 (91)	n.s.
8. A sudden onset of confusion, disorientation and inability to sustain attention – this presentation is most consistent with the diagnosis of: <ul style="list-style-type: none"> ● Alzheimer’s disease ● acute confusional state ● major depression ● vascular dementia 	121 (96)	85 (92)	n.s.

continued

TABLE 19 Numbers and percentages of respondents giving correct answers on the dementia knowledge quiz (*continued*)

Question	Correct <i>n</i> (%)		<i>p</i> -value
	2001–2, <i>N</i> = 126	2009–10, <i>N</i> = 92	
9. Which of the following is nearly always present in dementia? <ul style="list-style-type: none"> • Loss of memory • Loss of memory and incontinence • Loss of memory, incontinence and hallucinations • None of the above 	115 (92)	85 (92)	n.s.
10. Which of the following clinical findings best differentiates vascular dementia from Alzheimer's disease? <ul style="list-style-type: none"> • Word-finding problems • Short-term (2-minute span) visual memory loss • Stepwise disease course • Presence of depression 	89 (71)	68 (74)	n.s.
11. The effect of anti-dementia drugs is to: <ul style="list-style-type: none"> • temporarily halt the disease in all cases • temporarily halt the disease in some cases • temporarily halt the disease in some cases but often causing liver damage • permanently halt the disease in some cases 	114 (91)	72 (78)	< 0.01
12. Which statement is true concerning the treatment of dementia patients who are depressed? <ul style="list-style-type: none"> • It is usually useless to treat them for depression because feelings of sadness and inadequacy are part of the disease • Treatments of depression may be effective in alleviating depressive symptoms • Antidepressant medication should not be prescribed • Proper medication may alleviate symptoms of depression and prevent further intellectual decline 	91 (72)	53 (58)	0.01

n.s., not significant.

Carers' perceptions

Participants

Ninety carers of patients with dementia expressed interest in being interviewed about the quality of dementia care. Of these, 84 gave consent for two interviews, one at baseline and then again 12 months later. Six carers who had expressed interest did not consent to an interview, either because of the death of the person with dementia or because they changed address and could not be contacted.

Depending on the preference of the carers, the interviews took place in the following places: the carer's home ($n = 23$, 27.4%); the patient's home ($n = 4$, 4.8%); carer and patient's home ($n = 46$, 54.8%); the GP practice ($n = 6$, 7.1%); carer's place of work ($n = 3$, 3.6%); and the research department at University College London - Royal Free Hospital ($n = 2$, 2.4%). All participants received a copy of the signed and dated consent forms, and the original was retained in the Trial Master File. A third copy was filed in the PWD's medical notes at their GP practice. The interviews took, on average, 98 (SD 33, range 30–205) minutes to complete.

A structured interview schedule was used, derived from the instrument used in the previous trial,⁵⁶ and is shown in *Appendix 6*. Interviews were tape recorded with permission, and transcribed.

Results

Carer and patient characteristics

Of the 84 carers who completed interviews, 63 (75%) were women and 21 (25%) men. Their age ranged from 36 to 88 years, with a mean age of 66 years. More than one-third were spouse carers (wives 36%, husbands 13%) and 44% were adult children (daughters 33%, sons 11%), with the remaining 7% of carers being sisters or daughters-in-law.

Their relatives with dementia had been diagnosed, on average, 43 months prior to interview (SD 42.9 months, range 1–168 months) and 79 of the people with dementia (94%) lived in their own home. See *Table 20* for further sociodemographic information of dementia patients and their carers. *Table 21* shows that the care recipients had substantial functional losses and a high prevalence of BPSD.

According to carer reports, almost half of the sample taking anti-dementia medication had Alzheimer's disease ($n = 25$, 46.3%), compared with 10% ($n = 3$) of those not on medication.

Table 22 shows that the majority of carers recalled receiving advice or support in only 6 of 15 domains: home adaptations, the care recipient's driving, benefits and grants, legal concerns, respite (day care) and in how they were coping. Despite the requirements of an annual dementia review, which should include the assessment of carer needs, only half of the carers included in the study had been asked how they were coping and 60% had not been asked about their fears or anxieties.

TABLE 20 Demographic information of carers and the people with dementia whom they were supporting ($n = 84$)

Demographic information	Patient: mean (SD, range)	Carer: mean (SD, range)
Age (years)	80.5 (9, 57–97)	65.7 (12.6, 36–88)
Time since diagnosis (months)	43 (42.9, 1–168)	–
Age of leaving school (years)	15.3 (1.6, 11–18)	16.65 (2.5, 13–29)
Demographic information	Patient: n (%)	Carer: n (%)
Further education (e.g. diploma, university)	25 (29.8)	44 (52.4)
Gender		
Female	44 (52.4)	63 (75)
Male	40 (47.6)	21 (25)
Marital status		
Widowed	40 (47.6)	–
Married/co-habiting	41 (48.8)	72 (85.7)
Single	1 (1.2)	8 (9.5)
Divorced	2 (2.4)	4 (4.8)

continued

TABLE 20 Demographic information of carers and the people with dementia whom they were supporting (*n* = 84) (*continued*)

Demographic information	Patient: <i>n</i> (%)	Carer: <i>n</i> (%)
Ethnic status		
White – UK	68 (81)	73 (86.9)
White – Irish	2 (2.4)	3 (3.6)
White – other	7 (8.3)	3 (3.6)
Black – Caribbean	1 (1.2)	1 (1.2)
Black – African	2 (2.4)	–
Black – other	–	1 (1.2)
Indian	3 (3.6)	3 (3.6)
Bangladeshi	1 (1.2)	–
Employment status		
Working full time		9 (10.7)
Working part time		12 (14.3)
Unable to work for health reasons		1 (1.2)
Homemaker		4 (4.8)
Retired		51 (60.7)
Other (e.g. freelance)		7 (8.3)
Relationship with patient		
Wife		30 (35.7)
Husband		11 (13.1)
Daughter		28 (33.3)
Son		9 (10.7)
Other (e.g. sister, daughter-in-law)		6 (7.2)
Type of dementia		
Alzheimer's disease	29 (34.5)	
Vascular	10 (11.9)	
Lewy body	4 (4.8)	
Pick's disease	2 (2.4)	
Mixed (e.g. Alzheimer's disease and vascular)	9 (10.7)	
Dementia	14 (16.7)	
Other (e.g. unclear)	16 (19)	
Place of residence		
Own home (with or without spouse)	79 (94)	
With relative	5 (6)	

TABLE 21 Percentage of needs and/or symptoms reported by carers, among people with dementia ($n = 84$)

Type of disability	Yes, n^a (%)	No, n^a (%)
Able to manage personal care	42 (50.6)	41 (49.4)
Able to manage medication	13 (16.7)	65 (83.3)
Able to prepare food	21 (26.6)	58 (73.4)
Mobility within the house	64 (79)	17 (21)
Mobility outside the house	43 (55.1)	35 (44.9)
Able to cope with toileting	56 (67.5)	27 (32.5)
Able to do shopping	12 (14.8)	69 (85.2)
Able to do housework	20 (25)	60 (75)
Able to manage money and bills	8 (9.8)	74 (90.2)
Verbally aggressive	37 (45.1)	45 (54.9)
Physically aggressive	15 (18.3)	67 (81.7)

a Because of missing data/'not applicable', not all figures add up to $n = 84$.

TABLE 22 EVIDEM-ED: overall receipt of advice and support given to carers and people with dementia by primary care team ($n = 84$)

Type of advice – been asked/given advice about:	Yes, n^a (%)	No, n^a (%)
How to manage verbal aggression	6 (16.2)	31 (83.8)
How to manage physical aggression	4 (26.7)	11 (73.3)
What to tell a relative re. diagnosis	6 (7.4)	75 (92.6)
Keeping a relative independent	13 (15.5)	71 (84.5)
Home adaptations and equipment	46 (58.2)	33 (41.8)
The care recipient's driving	22 (55)	18 (45)
Benefits/grants	45 (54.2)	38 (45.8)
Costs of services	27 (32.1)	57 (67.9)
Legal aspects	44 (52.4)	40 (47.6)
Day care	44 (53)	39 (47)
Respite options	29 (37.2)	49 (62.8)
How the carer is coping	44 (52.4)	40 (47.6)
Fears and anxieties	33 (39.8)	50 (60.2)
Future care plans and expectations	13 (15.7)	70 (84.3)
Reference material	40 (48.2)	43 (51.8)

a Because of missing data/'not applicable', not all figures add up to $n = 84$.

Fifty-four of the 84 carers reported that the person they care for was taking cholinesterase inhibitors. Comparison of advice and support received between the groups taking/not taking cholinesterase inhibitors is shown in *Table 23*. The carers of those patients taking cholinesterase inhibitors reported significantly more advice about the care recipient's driving, significantly more enquiries about their own coping and significantly more discussion about their fears and anxieties.

Qualitative results

Questions with open-ended responses were included in the interview. *Box 2* displays a summary of three themes arising; perceptions of support from primary care, expectations of primary care, and the need for proactive care. Full analysis of the qualitative data will be reported in a separate publication.

Overall, few carers had contact with primary care and had relatively low expectations of their GP. However, those who did have contact with the practice were generally satisfied with the care they received.

TABLE 23 EVIDEM-ED: between-group prevalence (being on or off anti-dementia medication) of being given advice and support from health-care professionals

Been asked/given advice about:	On cholinesterase inhibitors (<i>N</i> = 54), ^a <i>n</i> (%)		Off cholinesterase inhibitors (<i>N</i> = 30), ^a <i>n</i> (%)		χ^2 ; <i>p</i> -value
	Yes	No	Yes	No	
How to manage verbal aggression	5 (20.8)	19 (79.2)	1 (7)	12 (92)	n.s.
How to manage physical aggression	3 (30)	7 (70)	1 (20)	4 (80)	n.s.
What to tell a relative about diagnosis	6 (11.8)	45 (88.2)	0 (0)	30 (100)	n.s.
Keeping a relative independent	9 (16.7)	45 (83.3)	4 (13.3)	26 (86.7)	n.s.
Home adaptations and equipment	28 (57.1)	21 (42.9)	18 (60)	12 (40)	n.s.
Relative driving	20 (66.7)	10 (33.3)	2 (20)	8 (80)	6.599; < 0.025
Benefits/grants	32 (60.4)	21 (36.6)	13 (43.3)	17 (56.7)	n.s.
Costs of services	18 (33.3)	36 (66.7)	9 (30)	21 (70)	n.s.
Legal aspects	32 (59.3)	22 (40.7)	12 (40)	18 (60)	n.s.
Day care	29 (54.7)	24 (45.3)	15 (50)	15 (50)	n.s.
Respite options	17 (34)	33 (66)	12 (42.9)	16 (57.1)	n.s.
How the carer is doing	35 (64.8)	19 (35.2)	9 (30)	21 (70)	9.372; < 0.002
Fears and anxieties	26 (49.1)	27 (50.9)	7 (23.3)	23 (76.7)	5.292; < 0.025
Future care	8 (15.1)	45 (84.9)	5 (16.7)	25 (83.3)	n.s.
Reference material	29 (54.7)	24 (45.3)	11 (36.7)	19 (63.3)	n.s.

n.s., not significant.

^a Because of missing data/'not applicable'; not all figures add up to *n* = 54; *n* = 30.

BOX 2 Common themes about dementia support management and examples**Theme 1: perceptions of support from primary care**

They kind of, I mean you get the proactivity in terms of coming in and have the blood tests, because she's got diabetes etc. But we didn't really get any dementia help from him [the GP]. And, you know, to be honest, when she had these water infections and we'd ring and say, 'Oh look she's really bad,' they really didn't come and see her. They said, 'Well there's not a lot that we can do for her really.' And even when she went to hospital, they said, 'Well why don't you just ring 999?'

Daughter, 55, of care home resident, not on cholinesterase inhibitors

I did go and see the GP; I mean they were always very nice. And if they came to see mum here, and they'd always, you know, sometimes they'd say to me, 'How are you?' you know. You know, while they, you know, as we were showing them out etc., you know, 'Are you okay? I know it's hard.' But, and then once when I was really feeling not well myself, I did go and see the GP just to have some blood tests and things, you know, because I was really at a bit of a low ebb. And, you know . . . we chatted about the caring.

Daughter, 55, of care home resident, not on cholinesterase inhibitors

Wife: No, nothing at all. The bottom line is, I don't think, then again I don't think anybody can do anything for us, for me. We'll just have to help ourselves.

Interviewer (I T-B): And in terms of support then, how is that for you?

Wife: There is no support.

Wife, 66, husband living at home, on cholinesterase inhibitors

Yes we've been in and out of there [the practice]. And he's brilliant, I have to say . . . Yes, he's been a brilliant support, you know . . . It is, I must admit, you know, a couple of times he's said, 'And how are you?' you know, and I think that's just so nice really.

Daughter, 47, mother living in her own home, on cholinesterase inhibitors

Well it was mum's GP that said really you do need to get this Power of Attorney done, and a couple of times I've been, he's said, 'Have you done it yet, have you done it yet?' And I said, 'I will do,' and he said, 'Honestly,' he said, 'If your mum goes into hospital and I'm not around, you know, they won't listen to you.' And he is lovely. He really is. But then you talk to nearly anybody in the town and he's caring right the way across the board, you know, right through the young . . . He's lovely and he sits there and, you know, he says to mum, he held her hand the other day and he said, 'You know what's the matter with you,' he said, 'You worry too much.' And she said, 'I know, I've always been the same.' And he said, 'I know.' And she just said, you know, 'Thank you so much.' And I thought that goes such a long way.

Daughter, 47, mother living in her own home, on cholinesterase inhibitors

Daughter-in-law: No, no. I don't find them very helpful at all actually.

Interviewer (I T-B): And what about for you as carers, do they ever ask you if you're okay or if you need anything?

Daughter-in-law: No never.

Daughter-in-law, 52, mother-in-law living in her own home

BOX 2 Common themes about dementia support management and examples (continued)

Theme 2: expectations of primary care

Well I think the GP could have put me in touch with social services a bit quicker because I was fighting to get mum some care, because I was doing it all myself. And I think the GP could have been a bit more sympathetic or as he's seen her probably over the years, he could have shared the experience. But he didn't. He, it was just, all I ever got from him was, 'Take her home, make her comfortable. What do you want me to do? Do you want me to put her in a home? Do you want me to do this?' All the things I didn't want him to do.

Daughter, 50, mother living in her own home, not on anti-dementia medication

Interviewer (IT-B): *Is there anything else you would say to her GP that they could improve?*

Daughter: *Well, to take it a bit more seriously, I think. I think there is a matter of fact isn't it? Yes, and just to, you know, be able to help people that don't understand dementia at all. You know, if you don't, I mean the first time I'd heard of it was when mum got it. And then I still didn't understand what it was all about. You don't know what to ask, do you? I remember sitting in the surgery thinking, 'Well what do I ask next? Is she going to get better?' They never said to me that she wasn't going to get better.*

Daughter, 50, mother living in her own home, not on anti-dementia medication

So I guess they can only do so much. And they were always very nice and we talked to them on the phone, etc.

Daughter, 55, of care home resident, not on cholinesterase inhibitors

The bottom line is, I don't think, there again I don't think anybody can do anything for us, for me. We'll just have to help ourselves.

Wife, 66, husband living at home, on cholinesterase inhibitors

Theme 3: proactive care

Yes you're very loathe because you're always conscious that the doctor's time is valuable, you know you've already waited an hour to actually see them past the appointment time and you're very grateful you're not being given the bum's rush. But you don't think to say, 'You know, is there anything locally that mum could go to?' because you think it's 'the doctor'.

Daughter of care home resident, (carer, age unknown), no longer on cholinesterase inhibitors

I can only, I don't know really. I mean they, they always seem quite independent of everything else. And I know they've got a lot of demands on them. Again I suppose if they worked with a key worker so they, they did their visits or they – and the idea of them looking at reviewing such a vulnerable person's health proactively does seem quite a good idea. I don't know how that fits in with the opportunity cost of resourcing and expenses.

Son, 58, mother living in own home, on cholinesterase inhibitors

So ideally that's what I would like. I would like some sort of, I don't know how they could do this, but they should be, I would like them to have some sort of recognition that all people who are carers are really under a huge strain that cannot be seen. And I mean, you know, I mean I know – I don't want preferential treatment for me, but I want preferential treatment for carers.

Wife, 72, husband living at home, not on cholinesterase inhibitors

Discussion

The EVIDEM-ED trial builds on an earlier study,²¹ and developed and tested an intervention customised to the educational needs of individual practices. The deliverables from this programme include an educational intervention for general practice and practice nursing, combining timely dementia diagnosis and psychosocial support around the period of diagnosis, with components appropriate to later stages of the disease trajectory. It also includes electronic resources on the same themes, together with shared care guidelines for medication use.

The English policy imperatives and financial incentives for dementia diagnosis and management have created an ideal environment for a trial of an educational intervention designed to improve clinical practice in primary care – the educational intervention as developed following the Medical Research Council (MRC)'s recommendations for complex interventions,⁵⁶ with strong elements of co-design to gain the insights and experiences of a range of practitioners.³⁷ The ENA deployed in this trial is an example of a strategy aimed to improve quality of care by overcoming the translation block that obstructs the diffusion of clinical guidelines and knowledge into practice.⁵⁷

In this study we found no significant improvement in case identification or documentation of dementia management reviews after an educational intervention tailored to practice educational needs. This is despite the financial gain to practices for increasing the number of cases identified and reviewed annually. There are several possible reasons for this.

The intervention may have been too weak to change practice. More workshops may have been needed, with reinforcement or mentoring of practitioners over longer periods of time. This level of educational input was not practicable in this trial, and we doubt that it would be feasible in real-world primary care organisations.

Physicians have a limited ability to accurately self-assess their competence.⁵⁸ Although the ENA was designed as a group process to offset this tendency, more external assessment may have been needed to truly tailor the intervention to needs.

Practitioners' knowledge, skills and attitudes in 2009–10 were similar to those recorded using the same instrument in 2001–2. Differences in responses between the two time periods suggested that GPs were less confident about diagnosis and overall clinical management of dementia in 2009–10 (with BPSD as an exception).

Carers' recall of advice given to help them manage the person with dementia suggested that a large minority had not received the information recommended by the NICE dementia guidelines.^{36,59} However, carers of patients taking cholinesterase inhibitors reported more advice on some aspects of care than those whose care recipients did not take this medication.

Carers' generally positive attitudes towards general practice, despite their limited contacts with the care recipients' GPs, is similar to findings from the earlier trial.⁶⁰

Limitations of the study

It is possible that the medical records did not capture important changes in the quality of management after the educational intervention, which were not captured in our evaluation of secondary outcomes, but our creation of a category of 'opportunistic dementia review' fitted with clinical practice and allowed a generous interpretation of clinical activity. Many patients with dementia joined or left during the pre and post periods, truncating the data collection time so that the length of follow-up may have been too short to capture a difference. The number of dementia management reviews was higher in the non-intervention group at baseline; this could be the consequence of one practice in the usual care group having medical responsibility for several care homes. Distribution of newsletters and guidelines to usual care arm practices may have had an effect on their patients' behaviour.

The study took place in south east England with practices that were innovative early adopters, not typical general practices, and local educational programmes that had been developed to implement the NDS may have influenced practice activities, although we found no evidence of this. The volunteer practices were probably different from others, in that they wanted to take part in a pilot educational programme about dementia. However, the results of this study have wider implications, particularly about the value of tailoring educational interventions.

The intervention was developed in ways consistent with current understanding of how effective interventions are made. Nevertheless, there may have been deficiencies in the development process. For example, the views of people with dementia and their family carers may not have had sufficient weight. Some professional perspectives may have been too powerful; the absence of response from expert panel members to the ENA questions themselves could be a sign of this. The expert group may not have used the expert panel's critical comments sufficiently, resulting in an oversimplification of the ENA. Finally, the expert tutor may have had an effect on the use of the ENA and the 'filling' of the educational prescription, even although we used a participant observer to avoid idiosyncratic interpretations of the group discussions.

Conclusions

This study suggests that a tailored educational intervention aimed at GPs does not improve dementia case identification or documentation of clinical management for people with dementia, even when policy pressure encourage changes in clinical practice and the reimbursement system rewards it.

Implementation studies

There was considerable demand for the EVIDEM-ED intervention even before the results of the RCT were available. Its use has been tested as follows:

- Thames Valley Health Innovation and Education Cluster ran sessions with 13 practices in 2011. The sessions aimed to improve GP knowledge around dementia, and to improve care for patients and their carers. The sessions were facilitated by a group of five postgraduate psychology students from the University of Reading, who received 1 day of training on small group facilitation and the use of the training tool.
- Cambridge Community Mental Health Team ran sessions, for which a consultant in old age psychiatry acted as a group facilitator.
- Central and North West London (CNWL) NHS Foundation Trust demonstrated the approach to specialist registrars in old age psychiatry, so that they could test it in general practices.
- NHS Wales has run two training sessions for GPs in the use of ENA.
- Two research projects using the EVIDEM-ED approach have been submitted for funding, one from Johns Hopkins Medical School in the USA and the other from the University of Auckland in New Zealand.

Research capacity building

Three academic GP registrars have learned research skills by working within the EVIDEM-ED project: Dr Louise Pealing, Dr Tamar Koch and Dr Alexandra Davidson.

Dr Sarah Voss in Swindon obtained funding for a parallel project on promoting person-centred care in general practice for people with dementia and their families. Details of this initiative are reported elsewhere.⁶¹ This nested project was funded by the Alzheimer's Society and its outputs have been incorporated into EVIDEM-ED's learners' manual (see: www.EVIDEM.org.uk).

Changes to protocol

No changes to the original protocol were made.

List of appendices

Appendix 1 Chapter 1: Findings from literature review of interventions in primary care designed to alter clinical practice with patients with dementia.

Appendix 2 Chapter 1: Advisory and steering group membership.

Appendix 3 Chapter 1: Diagnostic and management processes identified by the expert team.

Appendix 4 Chapter 1: Changing clinical practice in dementia: elements of a training programme – for primary care team.

Appendix 5 Chapter 1: General practitioner questionnaire.

Appendix 6 Chapter 1: Carer semi-structured interview schedule.

Appendix 7 Chapter 1: Medical records data extraction tool – baseline (time 1).

Chapter 2 EVIDEM-E: exercise as a therapy for behavioural and psychological symptoms of dementia – a randomised controlled trial of clinical effectiveness and cost-effectiveness

Abstract

Background Exercise could be beneficial for some BPSD.

Objectives To review the evidence and cost-effectiveness about exercise and BPSD, and to design and test a simple dyadic exercise regimen.

Study overview (1) Literature review: a rapid appraisal of the literature showed that exercise programmes for people with dementia have been poorly conceptualised. It is unclear which aspects of physical activity produce best outcomes. (2) RCT: a pragmatic, randomised, controlled, single-blind, parallel-group trial of 12 weeks of tailored walking for community-dwelling individuals with dementia who had BPSD, and for their carers. A total of 906 people with dementia were invited; 131 were randomised [64 treatment as usual (TAU), 67 intervention], and 57 TAU and 59 in the intervention arm were analysed. The primary outcome was change in the Neuropsychiatric Inventory⁶² (NPI) score.

Results There was no significant between-group difference in NPI score at week 12 [adjusted difference in means (intervention minus control) = -0.41, 95% CI -7.37 to 4.32; $p = 0.6$]. Caregiver's burden, as measured by the Zarit Burden Interview (ZBI), doubled by week 12 for the TAU group but decreased in the intervention group (OR = 0.18, 95% CI 0.05 to 0.69; $p = 0.01$). Average cost of the exercise intervention was £284 per dyad. Within a subsample, the exercise intervention had a significantly higher cost from a societal perspective (mean difference £2728.60, $p = 0.05$) but a non-significantly lower cost from a health and social care (HSC) perspective.

Conclusion Regular simple exercise does not improve the BPSD but does attenuate rising caregiver burden.

Background: why this study was necessary

Dementia is associated with a cluster of non-cognitive symptoms and behaviours that are an integral part of the syndrome. Commonly described by some clinicians as BPSD, they include disturbed perception, thought content, mood or behaviour.⁶³ Although recognised as core to the phenomenology of dementia in Alzheimer's disease seminal case studies,⁶⁴ these symptoms have received relatively little attention from the research community. This is surprising given that > 80% of people with dementia will experience BPSD at some point during the course of their illness.⁶⁵ BPSD have long been commonly associated with reduction in the quality of life for the person as well as their carers;⁶⁶ increase of caregiver stress,⁶⁷ higher costs of care,⁶⁸ and premature moves to long-term care facilities.⁶⁹

Although there is some evidence supporting the treatment of BPSD with antipsychotic drugs, there have been increasing concerns over the safety of these drugs for people with dementia.⁷⁰ Several studies have indicated that there is a long-term risk of mortality in patients with dementia who take antipsychotic medication.^{71,72} There are few other safe pharmacological interventions with a proven evidence base.

Non-pharmacological alternatives that have been reported to have a positive effect include music therapy, bright light therapy, behavioural interventions and exercise.⁷³ As well as the obvious physical impact, exercise has been demonstrated to have a positive effect on cognitive symptoms and mood.^{74,75} Interventions such as exercise may offer a safer effective alternative to pharmacological treatment, could empower individuals with dementia and may reduce carers' burden.

Heyn *et al.*⁷⁶ carried out meta-analysis of exercise interventions for people with dementia and reported data on 30 trials of exercise. The authors analysed trials that included exercise regimens promoting strength, cardiovascular fitness or flexibility and analysed them for functional, cognitive or behavioural outcomes. They found a positive effect of exercise on behavioural outcomes (effect size = 0.54; 95% CI 36 to 72).

However, the trials included in the meta-analysis do not provide a full picture of the effectiveness of exercise for BPSD for a number of reasons. First, there was considerable heterogeneity among the interventions, and exercise was often combined with other behavioural interventions; consequently, it is difficult to isolate the impact that exercise had on behavioural outcomes. Second, some exercise regimens were complex and required a degree of physical fitness that would preclude many older adults with complex physical problems and moderate or significant dementia from performing them. These complex exercise regimens were potentially unsustainable without the support of trained therapists. The relatively high cost of delivering specialist input for such regimens may prevent such interventions being used more widely. Finally, most trials included in the analysis were relatively small, with only two reporting samples including > 100 participants.

Because of this limited evidence base, we designed a pragmatic, randomised, controlled, single-blind, parallel-group trial to evaluate the effectiveness of a simple exercise regimen as a therapy for BPSD.

Research questions:

1. What is the current evidence around the effects of exercise on BPSD, and how can this evidence shape the design of this trial?
2. Does a simple dyadic exercise regimen improve outcomes for people with BPSD and their carers?
3. What are participants' views about, and experiences of, the dyadic exercise regimen?

Study methods and findings

Components of the study

The first question was addressed through a review of the literature; this informed the focus and design of the clinical trial to answer the second and third research questions (ISRCTN01423159). As a consequence of unforeseen difficulties with recruitment, a fourth question arose: Why is it difficult to recruit participants from a seemingly large population and supportive clinical service? To answer this question we added a small substudy that incorporated a focus group with recruiting clinicians.

Literature review

Methods

A rapid appraisal approach was adopted to inform the design and implementation of a RCT of exercise as therapy for BPSD. This review, rather than systematically aggregating data, has adopted a critical interpretive approach,⁷⁷ the purpose of which is to construct theories grounded in research, develop an understanding about the potential effect of exercise on BPSD and to generate practical methods to evaluate these effects. This broad aim led to the generation of three research questions: (1) Does exercise ameliorate BPSD?; (2) How has exercise been conceptualised and how does this relate to the findings? and (3) What are the main limitations and methodological shortcomings of recent studies? Full details of the methods used in this literature review were published.⁷⁸

Inclusion/exclusion criteria

Although the aim of this review was to be as inclusive as possible with the current relevant literature, we recognised the importance of setting boundaries concerning papers to include.⁷⁷ Studies and review articles were selected that met the following criteria:

1. Individual studies must measure the efficacy of exercise as a therapy for BPSD. Exercise is defined as physical activity that is a planned, structured and repetitive programme.
2. Review articles must examine intervention studies assessing the efficacy of exercise as a therapy for BPSD.
3. Papers must have been published in peer-reviewed journals using relevant keywords appearing as an important factor in the title or abstract. Studies examining combined interventions (i.e. combining exercise with another psychosocial intervention) were excluded, as these are unable to establish the absolute effect of exercise.

The database search was constructed using the following strategies and searched up to January 2011.

- MEDLINE, EMBASE, PsycINFO and PubMed were searched using a combination of keywords: 'physical activity and dementia/Alzheimer's disease', 'exercise and dementia/Alzheimer's disease', 'non-pharmacological interventions and dementia', 'exercise, sleep disturbance and dementia/Alzheimer's disease', 'exercise, apathy and dementia/Alzheimer's disease', 'exercise, aggression and dementia/Alzheimer's disease', 'exercise, wandering/repetitive behaviours and dementia/Alzheimer's disease', 'exercise, depression/mood and dementia/Alzheimer's disease'.
- Other sources were also searched including reference lists and book chapters.

Results

Seven hundred and twenty-three articles were screened, of which 16 met the inclusion criteria. Of these, 10 were review articles and six were additional papers not included in these reviews (see the PRISMA chart in *Figure 6* for the derivation of the selected papers). We examined each paper included in the reviews to assess their inclusiveness and their contribution to answering our three questions.

1. *Does exercise reduce BPSD?* Using very stringent inclusion criteria, the Cochrane review by Forbes *et al.*⁷⁹ concluded that there is insufficient evidence of the effectiveness of physical activity programmes on affective symptoms in older persons with dementia to warrant commissioning new services or decommissioning existing ones. They argue that until further methodologically robust studies are conducted and published, making firm recommendations for clinical practice about the importance, type and duration of exercise as a therapy for BPSD will not be possible. The existing research literature, although thin, does offer insights into potential effects of physical activity on BPSD and hints at the impact (or not) of exercise on behavioural and psychological symptoms not included in the Cochrane review (e.g. sleep disruptions, wandering, repetitive behaviours, anxiety and apathy).
2. *How has exercise been conceptualised and how does this relate to the findings?* Exercise programmes for people with dementia have been poorly conceptualised and it is unclear which aspects of physical activity (e.g. type and duration) provide better results than others. We need to understand further what behavioural and psychological symptoms respond and to what type of physical activity intervention, and how exercise may work, for whom and under what circumstances. Indeed, exercise may affect various BPSD in different ways. The current evidence cautiously indicates that its effect on some symptoms (e.g. agitation, anxiety) may be more rapid than on others (e.g. depression).
3. *What are the main limitations and methodological shortcomings of recent studies?* The methodological shortcomings of current work in this area are substantial – very few studies have robust methodologies. Few use randomised controlled designs and few have a sample size with enough power. In addition, many studies have short follow-up periods, which could potentially produce a type 2 error, that is, an effect of exercise on some symptoms may not be evident after only a short period. Many also rely on findings from

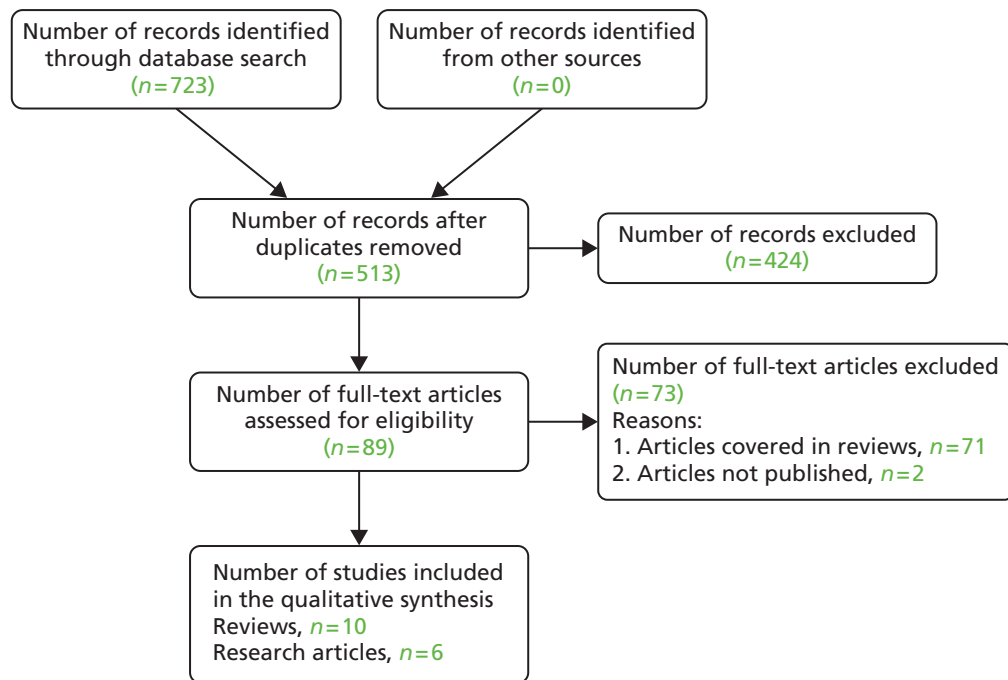


FIGURE 6 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart describing the search process of finding articles examining the efficacy of exercise on BPSD.

mixed dementia groups while ignoring the potential differences between different types of dementias. Moreover, the intervention itself was often a heterogeneous one using different modalities of exercise (i.e. strength building, cardiovascular fitness or flexibility) and/or combined with other interventions (e.g. carer education). In such instances it remains unclear which particular components of an intervention are effective.

Trial objectives

Objectives

Primary objective

To determine the effectiveness of a dyadic exercise regimen delivered through a programme of incremental walking for treating BPSD (as defined by NPI scores) compared with TAU.

Secondary objectives

To determine the effect of this dyadic exercise regimen on (1) the quality of life of people with dementia; (2) psychotropic medication usage; (3) moving to a residential care facility (care home); (4) mortality levels; and (5) caregivers' perceived level of burden. We also carried out an economic evaluation of the intervention.

Method

Trial design

We conducted a pragmatic, randomised, controlled, single-blind, parallel-group trial of a dyadic exercise regimen (tailored walking) for community-dwelling individuals with dementia who had BPSD, and for their carers. Individuals with a diagnosis of dementia, or suspected dementia, who had a carer who was willing and able to be a co-participant in the exercise regimen, were eligible for recruitment.

After screening and consent, participants were randomly allocated to one of two arms: the intervention arm, which received an individually tailored regimen of walking (see below for details) in addition to TAU or the control arm which received TAU only. TAU included home care, attendance at day-care facilities, visits by health professionals, hospital clinic visits, receipt of medication, respite care and so on. The trial protocol is shown in *Appendix 8*.

Both the intervention and TAU arms were assessed for all outcomes at weeks 6 and 12. Further telephone contact took place at 26 weeks to assess adverse events (AEs), mortality, change in domiciliary status and adherence to exercise regimen. The consent procedure, standard operating procedure for monitoring AEs, risk assessment tools and risk management pathway are shown in *Appendices 9–13*.

An independent randomisation officer (RO) assigned participants using a computerised algorithm and informed the participants, the participant's GP and exercise therapist of allocation status. Other study personnel were kept blind to randomisation status.

Recruitment and baseline assessment of participants

Participants with a clinical diagnosis of dementia or 'suspected dementia' with at least one significant BPSD defined by the NPI⁶² (excluding the domains of delusions and hallucinations) were eligible for the trial (*Figure 7*). Diagnosis of dementia was confirmed using *International Classification of Diseases, Tenth Edition (ICD-10) Diagnostic Criteria for Research (DCR-10)*.⁸⁰ A risk assessment was performed to assess the suitability of participants for the intervention at baseline. This assessment included measurement for risk of falls using the Falls Risk Assessment Tool (FRAT)⁸¹ and Timed Unsupported Steady Standing (TUSS) assessment.⁸²

Interventions

Physical exercise was delivered as an individually tailored regimen of walking, designed to become progressively intensive and last between 20 and 30 minutes. This was facilitated by a registered exercise professional qualified in Instructing Physical Activity and Exercise [National Vocational Qualification (NVQ) Level 3] and delivered to participants in the intervention arm of the trial in and around their own home. The exercise therapist facilitated physical exercise in the participant-carer dyad with the expectation that the dyad would perform the exercise regimen regularly and independently of the therapist at least five times per week. In order to attempt to control for the social effects of the therapist contact, the exercise therapist provided input for only the first 6 weeks of the trial, but participants were requested to continue exercising for 12 weeks. The intervention protocol is shown in *Appendix 16*.

The intervention group dyad was asked to complete a visual analogue scale, the Rate of Perceived Exertion (RPE).⁸³ Perceived exertion is based on the physical sensations that a person experiences during physical activity, including increased heart rate, increased respiration or breathing rate, increased sweating and muscle fatigue. Although this is a subjective measure, a person's exertion rating may provide a fairly good estimate of the actual heart rate during physical activity.

All participants were asked to record their daily activities throughout the 12 weeks of participation using a diary that was designed to meet the specification of this study (see *Appendices 14 and 15*).

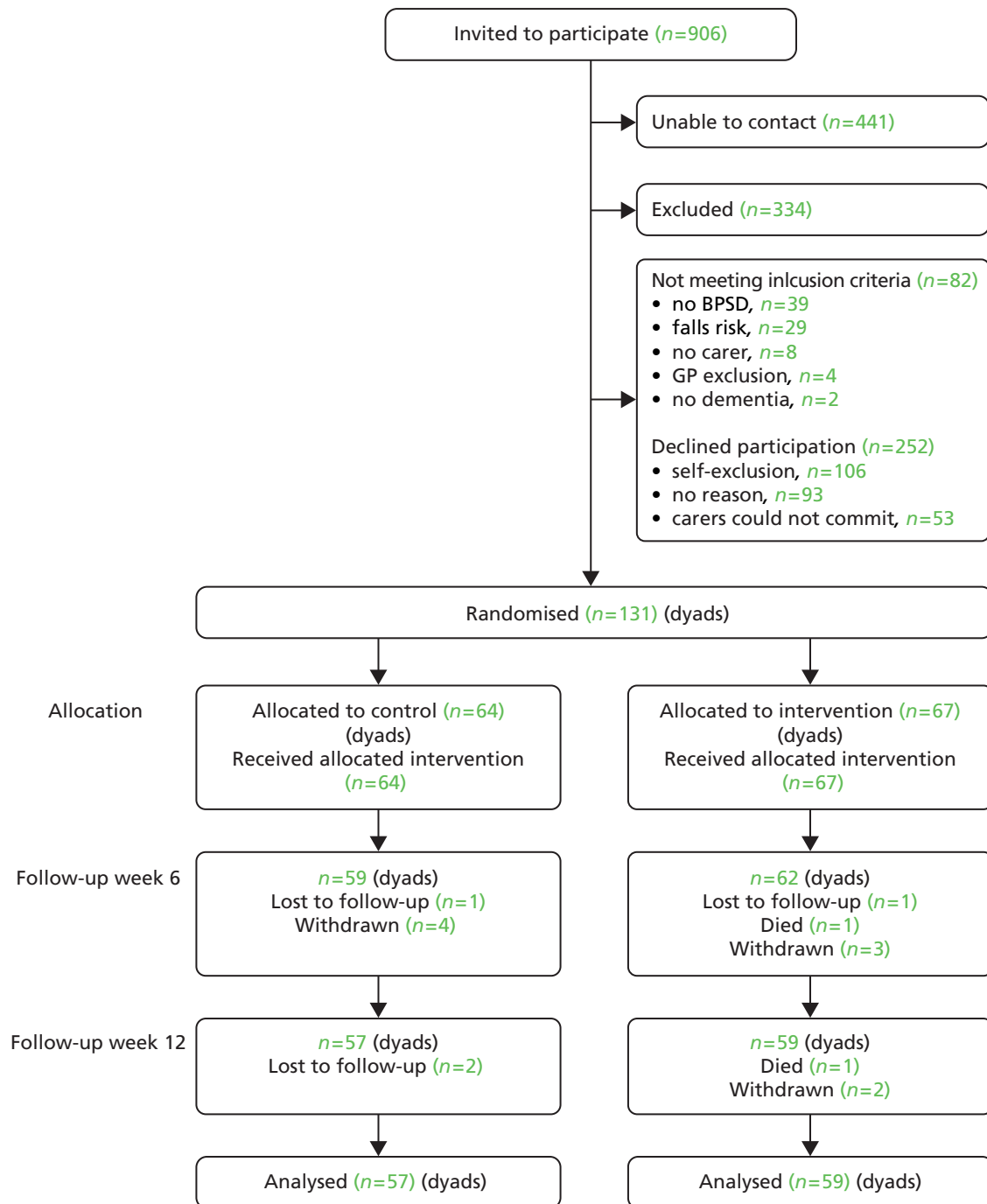


FIGURE 7 EVIDEM-E: CONSORT diagram.

Setting

This study was conducted in inner city, urban and semirural locations in and around London. Recruitment began in EVIDEM's host trust, with approaches to memory clinic teams and community teams working with older adults to identify and approach people with dementia who would fit the trial's inclusion and exclusion criteria (see below), and progressively expanded the range of potential recruitment sources, which included:

1. North Thames DeNDRoN, which has a registry of people with dementia interested in participating in research (DemReg).
2. GP practices working with other projects in the EVIDEM programme.
3. Memory assessment services and community mental health services in six NHS Trusts: CNWL NHS Foundation Trust, West London Mental Health NHS Trust, East London NHS Foundation Trust, Surrey and Borders Partnership NHS Foundation Trust, Barnet, Enfield and Haringey Mental Health NHS Trust and South Essex Partnership University NHS Foundation Trust.
4. Self-referral in response to publicity about the trial through various media channels, including television and radio [British Broadcasting Corporation (BBC)], websites (EVIDEM and Alzheimer's Society), local support groups (Housing 21 and Alzheimer's Society's Memory Cafés), carer information events ('Service user network information day' and 'Admiral Nurses Carer Information Day') and newsletters, for example the Alzheimer's Society's 'Living with Dementia'.

The EVIDEM-E team held a focus group to identify barriers to recruitment, and the outcomes of these are reported below (see *Findings*) and also in a research letter in the *International Journal of Geriatric Psychiatry*.⁸⁴

Outcome measures

All outcomes were measured at baseline and after 6 and 12 weeks of participation.

The primary outcome measures were the behavioural and psychological symptom scores measured by the NPI⁶² at 12 weeks' follow-up (*Table 24* provides a full description of outcome assessment).

Secondary outcome measures were:

1. participants' mental health measured using the General Health Questionnaire (GHQ)⁸⁵
2. participants' quality of life measured using Dementia Quality of Life (DEMQOL)-Proxy⁸⁶
3. carers' burden measured using the short ZBI⁸⁷
4. service use and costs, measured using the Client Service Receipt Inventory (CSRI).⁸⁸

Participants' level of physical activity and compliance with the intervention were measured by carers using daily diaries and the RPE scale,⁸³ and blood pressure and heart rate monitoring were carried out by the researcher. Domiciliary change and mortality at 26 weeks was ascertained by the researcher over the telephone.

Sample size

Assuming 80% of participants in the TAU group will have BPSD measured by the NPI at the 12-week follow-up, and based on an anticipated between-group (TAU minus intervention) absolute risk difference of 30% in the proportion of people with improved BPSD (defined as at least three-point improvement), we calculated that a sample size of 146 participants would provide 90% power to detect this difference with a 5% (two-sided) significance level, allowing for an anticipated 20% attrition rate.

TABLE 24 Administration of outcome measures

Day	Administrator	Intervention/assessment
0	RW	ICD-10, MMSE, NPI, demographics, CSRI, DEMQOL-Proxy, GHQ, ZBI, medication, vital signs
0	Randomisation	Allocation and diaries
1–2	Exercise therapist	RPE timed walk, diary ^a
3–4	Exercise therapist	RPE timed walk ^a
5–8	Exercise therapist	Telephone contact – advice and guidance ^a
6–8	Exercise therapist	RPE timed walk ^a
13–17	Exercise therapist	Telephone contact – advice and guidance ^a
17–28	Exercise therapist	Telephone contact as needed ^a
40–46	Independent researcher	NPI, diary reminder
40–46	RW	DEMQOL-Proxy, GHQ, ZBI, medication, vital signs
40–46	Exercise therapist	RPE timed walk ^a
80–88	Independent researcher	NPI, diary reminder
80–88	RW	DEMQOL-Proxy, GHQ, ZBI, medication, vital signs
80–88	Exercise therapist	RPE timed walk ^a
90–99	RW	Collection of diaries
182–196	RW	Telephone contact, check for change of status (residence and mortality)

CSRI, Client Service Receipt Inventory; DEMQOL-Proxy, Dementia Quality of Life tool; GHQ, General Health Questionnaire; RW, research worker.

^a Intervention group only.

Randomisation

With consent to participation, individuals were randomly allocated to receive TAU or exercise in addition to TAU (intervention). The randomisation ratio for the two groups was 1 : 1 (intervention : TAU). Randomisation was performed by the central co-ordinating centre using a computer algorithm of a simple randomisation protocol. A RO performed the randomisation and communicated notifications to participants, carers and the therapist, but not the research worker (RW).

Concealment of individual's group allocation was preserved until individuals had committed to the study. The nature of the intervention rendered it impossible for participants to be blind to allocation. Although it was difficult for the RW to be blind to the allocation of participants because of their involvement in patient recruitment and assessments, several strategies were implemented to minimise unblinding of the RW. The efficacy of blinding was assessed at each time point using a three-point Likert-type scale polarised by the two arms and including a 'not sure' level as the centre rating. Telephone assessments were used when possible to reduce the likelihood of the RW observing treatment. For the statistical analysis of participants' data, the statistician, the RW and principal investigator remained blind to the study group allocation of the participants.

Analytic methods

An analysis plan was agreed and locked before analysis began. The randomisation code was not revealed until analysis had been completed. Descriptive statistics for the baseline demographic and the outcome data are presented for each group. Categorical data are presented as numbers and percentages, and continuous data as means, SDs and ranges.

Continuous outcomes were compared using analysis of covariance (ANCOVA), which included the relevant baseline scores.

Participants were categorised into two groups: those who had a clinically significant reduction in BPSD (NPI score) of three points or more, and those who did not. We used binary logistic regression to analyse the difference in the proportions of those who had a clinically significant reduction in NPI score between the TAU and intervention groups at 12 weeks.

All analyses were undertaken using the statistics package SPSS™ version 20 [Statistical Package for the Social Sciences (SPSS), IBM Ltd., Armonk, NY, USA: www-01.ibm.com/software/uk/analytics/spss/] before the breaking of the randomisation key and the analyses were carried out blindly by the RW.

Economic analysis

Resource use and cost measures

Data on utilisation of care and support services were captured through the CSRI,⁸⁸ completed with the assistance of the RW. The CSRI was completed twice (baseline and 12 weeks), on each occasion asking about service use retrospectively over the previous 3 months. Data were collected on all HSC services, equipment and adaptations, medication and unpaid carer inputs.

Unit costs used were drawn, where possible, from the Personal Social Services Research Unit (PSSRU) compendium for 2011⁸⁹ and reflect long-run marginal opportunity costs. The *British National Formulary* database was used to obtain medication costs.⁹⁰ Market sources were used to estimate costs for equipment and adaptations to homes when these were not available in the PSSRU compendium. Although most unit costs were found at 2011 prices, in other cases available figures were adjusted to the 2011 price level. When services would continue to provide a benefit for > 1 year, costs were annuitised using the HM Treasury recommended annual discount rate of 3.5%.⁹¹ Unpaid care costs were estimated using an hourly rate equal to the National Minimum Wage, under the assumption that this was a potential opportunity cost for the unpaid carers.

Cost-effectiveness analyses

Cost-effectiveness analyses were conducted from two perspectives: HSC and societal. A HSC perspective considers those costs incurred by organisations providing HSC. A societal perspective considers costs incurred by all members of society collectively. In this instance, the difference between the two perspectives is the inclusion of informal (unpaid) carer costs in the societal perspective only. The main cost-effectiveness analyses from each perspective compared the exercise regimen and control on cost and mean difference in composite NPI score. Secondary cost-effectiveness analyses compared the exercise regimen and control on cost and each of the following outcomes in turn: the ZARIT caregiver burden inventory (ZBI), DEMQOL-Proxy, GHQ and a measure of quality-adjusted life-years (QALYs) generated from DEMQOL-Proxy scores. Scores on the outcome variables for which lower scores show better outcomes have been reversed in order to have a more intuitive interpretation for the economic analysis. For each cost-effectiveness analysis, there were four potential outcomes.

The exercise regimen is:

- i. more effective (has superior outcomes) and less expensive than usual care
- ii. less effective and more expensive than usual care
- iii. both less expensive and less effective than usual care, or
- iv. both more expensive and more effective than usual care.

Strong dominance of one intervention over another is described in cases (i) and (ii), and the decision of whether or not to implement the new intervention is typically straightforward, although the potential presence of measurement error must be considered. For cases (iii) and (iv), the decision-maker must weigh up the differences in outcomes and costs before choosing whether or not to implement the exercise regimen. The value or weight attached to differences in outcomes will play a part in deciding whether or not to proceed with implementing the new intervention. In such cases, the typical approach would first involve the

calculation of the incremental cost-effectiveness ratio (ICER), $ICER = \Delta C / \Delta E$, where ΔC is the mean cost difference between (in this case) the exercise regimen and control, and ΔE is the difference in mean outcome.

Each ICER was estimated with the Seemingly Unrelated Regression (SUR)⁹² model using Stata version 13 (StataCorp LP, College Station, TX, USA, <http://stata.com/>). Each cost and outcome measure, in turn, was regressed on treatment allocation, controlling, respectively, for cost and outcome at baseline. In sensitivity analysis, we controlled additionally for participant age at baseline, gender, ethnicity, marital status, education level, whether or not living in a care home, MMSE⁵² score at baseline, carer's age and gender. Regression models were bootstrapped with 1000 replications in order to address possible data skewness. Multiple imputation (using 10 imputed data sets) was used to deal with missing values in some outcomes and covariates.⁹³

The formula net benefit (NB) = $\lambda \times \Delta E - \Delta C$ was used to calculate NBs, which, in addition to using mean cost and outcome differences as with ICER calculations, used a range of hypothetical values of willingness to pay (λ) for an additional unit on a given outcome measure. Cost-effectiveness acceptability curves (CEACs) were then plotted for the primary outcome (NPI) using the NB values calculated for each value of willingness to pay within the range of £0–10,000. This showed the probability of the exercise regimen being cost-effective over the values of willingness to pay considered.

The economic analysis was conducted using Stata version 13.

Protocol changes

No significant protocol changes have been made to this trial (see *Appendix 8*).

Ethical arrangements

This study was approved by Outer North East London REC (ref. 09/H0701/67), and nine minor amendments were requested and approved.

Findings

Description of the sample

Recruitment and follow-up began in 2010 and ended in 2012. One hundred and thirty-one participant dyads were randomised to receive either the exercise regimen in addition to TAU (intervention) or TAU only (control) (see *Figure 7*). Eighty-nine per cent of dyads completed the trial, with seven and eight dyads lost from the TAU group and the intervention groups, respectively. The sample (people with dementia and carers) was predominantly female (women 163: men 99). Participants with dementia were typically older than the carer participants (78.85 ± 7.1 years vs. 63 ± 16.2 years). Most of the participants with dementia were living at home and were being cared for by partners or adult children. Alzheimer's disease was the most prevalent type of dementia ($n = 82$, 62.6%), and most participants had been diagnosed within the previous 2 years ($n = 73$, 56%). Report of a fall in the previous year was more common for people with dementia (80%) than for carers (34%). Quality of life for people with dementia at baseline as measured by the DEMQOL-Proxy was relatively good (101.3 ± 13.9). Behavioural and psychological symptoms as measured by the NPI [30.6 (SD 17.7), range 4–80] were similar to that reported in the original validation paper.⁸¹ Participants were dichotomised according to validated thresholds for 'caseness' relating to psychological well-being (GHQ) (range 0–84, threshold ≥ 23)⁸⁴ and for caregiver burden (ZBI) (range 0–28, threshold ≥ 24).⁹⁴ Thirty-six carers (27%) reached the validated threshold for 'caseness' relating to psychological well-being (GHQ)⁸⁴ and 25 (19%) for caregiver burden (ZBI).⁹⁴ Heart rate and blood pressure readings were generally within the normal range in our sample. *Table 25* provides the descriptive analysis.

TABLE 25 Sociodemographic statistics (baseline)

Participant	Control (N = 64)		Intervention (N = 67)	
	n	Mean ± SD (range)/frequency (percentage)	n	Mean ± SD (range)/frequency (percentage)
Person with dementia				
Age, years	64	78 ± 7.4 (58–99)	67	79 ± 6.8 (64–97)
Gender: female	64	39 (60.9)	67	35 (52.2)
Ethnicity: white	64	50 (78.1)	67	56 (83.6)
Marital status: married	63	45 (71.4)	67	46 (68.6)
FRAT score: ≥ 2	64	36 (56.3)	67	27 (40.3)
Living: private residence	64	57 (89.1)	67	59 (88.1)
Years' education	60	11.92 ± 5.9 (0–36)	63	12.1 ± 4.1 (6–23)
MMSE	64	14.9 ± 8.7 (0–29)	67	16.3 ± 7.4 (0–30)
Alzheimer's disease	59	38 (64.4)	65	44 (67.7)
Years since diagnosis: ≤ 2 years	61	38 (64.4)	59	35 (54.7)
Carer				
Age, years	59	60.9 ± 17 (22–88)	53	65.4 ± 14.9 (27–89)
Gender: female	64	39 (60.9)	67	50 (74.6)
FRAT score: = 0	64	46 (71.9)	67	40 (59.7)
Relationship: 'partner or spouse'	64	35 (54.7)	67	42 (62.7)
Carer distress (NPI)	64	11.9 ± 8.1 (0–39)	67	11.8 ± 8.9 (0–38)

Exercise uptake

Self-reported walking time (diary) appeared to differ between the groups. The TAU group increased walking by just over 2 minutes at week 6 in comparison with week 1, but by week 12 their reported walking time had decreased by almost eight minutes in comparison with week 6. Participants in receipt of the intervention reported increasing their walking time by 6 minutes at week 6 and retained this change at week 12.

Analysis of primary outcomes

Adjusting for baseline NPI scores, there was no significant difference in NPI score at 12 weeks ($\beta = -0.41$; $p = 0.6$, 95% CI -7.37 to 4.32), where ' β ' represents the difference in mean NPI scores (intervention minus TAU groups) at week 12. In addition, there was no significant difference in the proportions of participants reaching a clinically significant reduction of three or more points of NPI score at week 12 compared with baseline between the TAU and intervention groups (OR = 1.41; $p = 0.36$, 95% CI 0.67 to 3.01) (Table 26).

TABLE 26 EVIDEM-E: primary analysis

Control frequency (%)	Intervention frequency (%)	OR ^a	95% CI	p-value
33/57 (57.9%)	39/59 (66.1%)	1.41	0.67 to 3.01	0.36
Mean ± SD	Mean ± SD	β^b		
25.6 ± 16.6	23.9 ± 20.6	-1.53	-7.37 to 4.32	0.60

a OR of improvement (reduction) of composite NPI score of three or more points between baseline and weeks 6 and 12. Scoring at or above the validated threshold for 'caseness' at week 12.

b ANCOVA of the adjusted difference in mean NPI scores (intervention minus control) at week 12.

Analysis of secondary outcomes

Caregiver's burden as measured by the ZBI doubled by week 12 for the TAU group participants but decreased from 23% to 17% for those in the intervention group (OR = 0.18; $p = 0.01$; 95% CI 0.05 to 0.69). There were no statistically significant differences between the groups at week 12 regarding carers' mental health (GHQ), carers' distress (NPI) and quality of life of participants with dementia (DEMQOL-Proxy) (Table 27).

Follow-up at week 26

No major changes were reported at the 26-week follow-up. Four individuals had moved from their family homes to care homes. Three of those individuals were in the control group and one in the intervention group (OR = 0.38; $p = 0.42$; 95% CI 0.04 to 3.85).

Three deaths were reported at week 26: two from the control group and one from the intervention group. This difference was not significant (OR = 1.76; $p = 0.55$; 95% CI 0.28 to 11.07).

No significant difference was reported in receipt of antipsychotic medication (OR = 1.48; $p = 0.68$; 95% CI 0.23 to 9.52).

TABLE 27 EVIDEM-E: secondary analysis

Outcome	Week	Control frequency (%)	Intervention frequency (%)	OR ^a (95% CI)	<i>p</i> -value
NPI	Baseline	64	67		
	6	32/56 (57.1)	39/62 (62.9)	1.27 ^a (0.61 to 2.66)	0.52
GHQ	Baseline	46/63 (73)	48/67(71.6)		
	6	24/57 (42.1)	16/62 (25.8)	0.42 ^b (0.18 to 1.00)	0.05
	12	24/56 (43)	17/55 (31)	0.59 ^b (0.24 to 1.43)	0.19
ZBI	Baseline	52/62 (83.9)	50/65 (76.9)		
	6	14/55 (25.5)	14/59 (23.7)	0.48 ^b (0.14 to 1.67)	0.25
	12	18/56 (32)	10/57 (17.5)	0.18 ^b (0.05 to 0.69)	0.01
		Mean \pm SD	Mean \pm SD	β^c	
NPI	6	26.6 \pm 17.5	25.7 \pm 20.5	-0.81 (-6.08 to 4.45)	0.76
DEMQOL-Proxy	6	101.1 \pm 14.9	103.6 \pm 11.9	1.27 (-2.33 to 4.86)	0.49
	12	101 \pm 13.5	104 \pm 10	2.62 (-0.78 to 6.02)	0.09
NPI carer distress	6	11.07 \pm 7.2	11.5 \pm 8.5	-0.06 (-2.25 to 2.14)	0.96
	12	9.98 \pm 5.9	10.9 \pm 9.3	1.14 (-1.31 to 3.58)	0.76

a OR of improvement (reduction) of composite NPI score of three or more points between baseline and weeks 6 and 12.

b Scoring at or above the validated threshold for 'caseness' at weeks 6 and 12.

c ANCOVA of the adjusted difference in means (intervention minus control) at weeks 6 and 12.

The denominator of week 6 and week 12 data varies as result of participant availability.

Qualitative data

Diaries were returned by 90 (69%) participant dyads: 52 (78%) from the intervention group and 38 (60%) from the TAU group. Participants in both groups reported positive and negative aspects of walking outside, and barriers that affect this activity. Weather was reported as the main factor that affected walks. Participants reported that during the walks they enjoyed the nature, socialisation, gaining a sense of achievement, feeling independent and feeling less agitated (for the person with dementia). Some of the disadvantages reported were overexertion, physical pain, feeling alone, difficult terrain and noise. Planned walks were cancelled because of unfavourable weather conditions, poor health, carer unavailability, PWD feeling agitated, and being busy indoors.

It was not possible to perform further detailed analyses nor draw conclusions from the diaries contents because of variation in completion.

Recruitment

With early recruitment low and an obvious incongruity between verbal support and limited promotion of the study, we invited clinicians (team managers, nurses, occupational therapists, physiotherapists and psychologists) to a focus group to discuss their perceptions of research, impediments to their role as recruiters, and potential solutions to the study's recruitment difficulties.

The group described how clinicians are increasingly challenged by patients 'informed about the latest research'. The group indicated they often had to provide counter evidence in response to 'headline', and sometimes 'sensationalised' research conclusions. Together with patients' limited understanding of varying quality in research and the importance of clinical judgement for each individual, this could have (in the group's view) an adverse impact on the patient-clinician relationship. When recruiting to research, the group felt responsible – as the source of the research invitation – for assuming a degree of accountability for the research project's value and conduct (Box 3, quotation a). This responsibility was experienced as unreasonable, as they often had no part in the study's design and administration, and so there was a risk that recruiting might be perceived as potentially unrewarding, or worse, detrimental to patients. Although the group perceived the value of research, they also identified several concerns about recruiting their patients to EVIDEM-E (see Box 3, quotes b–d).

BOX 3 Findings from the focus group on recruitment to the trial

a. Clinician accountability for research

What if they agree due to your relationship with them, when you've said this thing is going to be great . . . ?

b. Overburdening 'vulnerable' individuals with voluminous Participant Information Sheets/invitation

I was just wondering if you could take it (information pack) out and talk them (participants) through, rather than this big pack arriving. I'd be thinking 'wow' I thought I was just going out on a walk . . .

c. Anxiety over the patients' feelings after researcher withdrawal

From our perspective they have participated in research . . . but they got nothing to say: thank you very much. I think that kind of puts people off.

BOX 3 Findings from the focus group on recruitment to the trial (continued)

d. Concern that participants would be dissatisfied when allocated to a control group

I'm thinking about when putting someone forward, they've agreed to go forward with it, only for them not to be put in the category where they actually get the intervention. I think this maybe holds people [professionals] back from encouraging people [clients].

We have to tell the client what is it they get out of this . . . what if they go on the control group and get nothing?

e. Low priority in individual clinical context

A lot of people just want practical advice and support . . . if someone is, let's say, incontinent. What can I do, what can I put in place? It's the practical solution to a problem that they have. And even if we say that we bring experience, knowledge and information that doesn't really matter because there is something that is going on at that time that needs to be sorted.

I don't see it as likely that patients that will be offered some sort of treatment will ask: 'why are you saying this is the best treatment?' and ask for a justification. Many of our patients would be grateful because what they are looking for is an outcome, they are not interested how we get there. They just want positive outcome.

f. Continuation of treatment: themselves to be trained to deliver the EVIDEM-E intervention

I think it would be really useful if we could do it (exercise intervention) ourselves and have a go. With proper training and under you observing it, I don't see a reason why we couldn't.

Would it be possible, not as part of the trial, simply a form of walking with somebody who has got some sort of behavioural problems, and we can try it out after being trained by your exercise therapist.

g. Feedback provided face to face to participants

You need to talk to people. The feedback is very important, whether it (the study) has success or not. At the end they (participants) should be given some feedback.

h. Provision of carer respite

There is a lot going on for carers at that particular time. And I think that whilst in their heart of hearts they might want to be involved and participate, but if the services are not going in to enable them to have a good night sleep, or maybe incontinence worry is a primary concern . . . A lot of times carers will actually say: I want a break. I want someone to physically do it (walking) for me. I've been up all night, they've been going to the toilet, they are restless, agitated, they ask repetitive questions. And it will be really nice that while the therapist takes them out the carer can put their feet up for 10, 15, 20 minutes. That's the expectation of the carer, that someone will do that. That'll be the motivation.

i. Tangible rewards

What's in it for us?

Understandably, recruitment was regarded as a low priority in consultations and all too easily 'slipped off the radar' (see *Box 3*, quote e1). However, the group did suggest ways to enhance recruitment to EVIDEM-E (see *Box 3*, quotes f–i). All three suggestions aimed to enhance the participants' experience opposed to theirs as recruiters, and the first suggestion involved increasing clinician workload.

Recruitment to the trial improved when alternative mechanisms were tried, including recruitment from a registry of patients and carers held by North Thames DeNDRoN Dementia Register study (DemReg). Eight participants were recruited to the trial in the first 6 weeks of working with the DemReg registry.

Description of the economic analysis subsample

Complete CSRs were received from 74 dyads at baseline and 67 dyads at the 12-week follow-up. However, depending on the outcome variable, the matching sample for the economic analysis varied from 49 to 52 dyads. Using multiple imputation techniques we were able to achieve a sample size of 52 dyads (22 control; 30 intervention). Hereafter, our findings on service use, costs and cost-effectiveness are based on the 52 dyads in this subsample, which is just less than half of the sample available for the main outcome analysis (116 dyads).

Table 28 presents descriptive statistics for the economic analysis subsample. We tested if the economic analysis subsample was significantly different from the original sample of 131 dyads by using the Wilcoxon rank-sum test for continuous variables and the Fisher's exact test (or Pearson's chi-squared test when appropriate) for binary variables. We found no significant differences between the 'economic subsample' and the full sample at 95% level of confidence, although a p -value of 0.07 was found for the difference in MMSE score at baseline. Using the same method we compared the intervention and control groups, and, again, did not find any significant baseline difference at 95%, with the smallest p -value (again equal to 0.07) being associated with the 'primary education or less' variable, implying that people included in the final economic analyses sample were perhaps less likely to have a limited education.

Average intervention cost per dyad

Total intervention cost was calculated by multiplying unit cost per visit (£60) or unit cost per telephone call (£10) by the number of contacts between the exercise professional and each dyad. Average intervention cost per dyad was £284 (range £190–320).

Cost analyses

In *Table 29* we present service utilisation rates by people within the study by treatment group and overall. At baseline, there were no significant differences in use of services by treatment group. Overall, at baseline, 12% of people with dementia made use of accommodation services, 58% hospital services and 71% community services. Most sample members (85%) reported use of unpaid care.

At 12 weeks' follow-up, overall proportions remained fairly similar. However, the two treatment groups seem to have separated in terms of use of hospital services: more than 70% of the control group reported using hospital or similar services compared with only 47% of the intervention group, although this difference is not significant ($p = 0.09$). For other service categories, as at baseline, the Fisher's exact test did not show any significant differences.

TABLE 28 Economic analyses subsample descriptive statistics

Variable	Treatment group						p-values				
	Control			Intervention			Total				
	n	Mean	SD	n	Mean	SD	n	Mean	SD	Control vs. intervention	Estimation sample vs. original sample
Age, years	22	78.4	9.07	30	78.6	7.6	52	78.5	8.2	0.66	0.91
Carer's age, years	19	62.2	17.11	25	63.6	16.4	44	63.0	16.5	0.88	0.96
MMSE	22	17.5	8.17	30	13.6	7.4	52	15.3	7.9	0.07	0.58
NPI	22	32.9	19.06	30	31.6	19.2	52	32.1	19.0	0.89	0.62
ZBI	21	17.0	7.74	29	19.0	9.0	50	18.1	8.5	0.34	0.19
DEMQOL-Proxy	22	100.7	16.28	30	103.6	12.5	52	102.4	14.2	0.82	0.29
Utility score (based on DEMQOL-Proxy)	22	0.71	0.15	30	0.72	0.15	52	0.72	0.14	0.62	0.71
GHQ	22	19.7	10.88	30	17.9	9.1	52	18.7	9.8	0.53	0.87
	n	%	Cases	n	%	Cases	n	%	Cases		
Gender: female	22	59.1	13	30	53.3	16	52	55.8	29	0.78	0.89
Carer's gender: female	22	68.2	15	30	66.7	20	52	67.3	35	1.00	0.90
Ethnicity: white	22	81.8	18	30	90.0	27	52	86.5	45	0.44	0.18
Married or in a civil partnership	22	68.2	15	30	73.3	22	52	71.2	37	0.76	0.62
Living alone	22	31.8	7	30	26.7	8	52	28.8	15	0.76	0.66
Paid carer	22	4.5	1	30	6.7	2	52	5.8	3	1.00	1.00
Living in a care home	22	9.1	2	30	13.3	4	52	11.5	6	1.00	0.98
Primary education or less	21	4.8	1	28	3.6	1	52	3.8	2	1.00	0.07
Further education	21	9.5	2	28	17.9	5	52	13.5	7	0.68	0.18
Dementia severity	22	50.0	11	28	28.6	8	50	38.0	19	0.15	0.67
	22	31.8	7	28	35.7	10	50	34.0	17	1.00	0.78
	22	18.2	4	28	35.7	10	50	28.0	14	0.22	0.86

TABLE 29 Economic analyses subsample service utilisation patterns

Variable	Treatment group: no. and percentage using services						Fisher's exact test
	Control		Intervention		Total		<i>p</i> -value
Pre baseline (3 months)							
Residential care/accommodation	2	9	4	13	6	12	1.00
Hospital services	14	64	16	53	30	58	0.57
Community services	14	64	23	77	37	71	0.36
Equipment and adaptations	12	55	20	67	32	62	0.40
Day services	8	36	13	43	21	40	0.78
Medications	22	100	29	97	51	98	1.00
Unpaid care	19	86	24	80	43	83	0.72
<i>n</i>	22	100	30	100	52	100	
Follow-up (1–3 months)							
Residential care/accommodation	1	5	3	10	4	8	0.63
Hospital services	16	73	14	47	30	58	0.09
Community services	12	55	21	70	33	63	0.38
Equipment and adaptations	12	55	14	47	26	50	0.78
Day services	10	45	12	40	22	42	0.78
Medications	22	100	29	97	51	98	1.00
Unpaid care	18	82	26	87	44	85	0.71
<i>n</i>	22	100	30	100	52	100	

Table 30 displays baseline and 12-month follow-up service use costs.

The summary statistics suggest that a sizeable proportion of total HSC service costs is related to use of accommodation services, which, at baseline, resulted in a higher cost on average for the intervention group, although the difference was not significant (tested using an adjusted regression model with 1000 bootstrap replications).⁹³ Apart from accommodation, hospital and community services displayed the highest aggregate costs. Total HSC costs appeared to be higher for the intervention group (£3205) than the control group (£2655), although this difference was not significant. At baseline, the intervention group was found to have higher costs, on average, than the control group, even when considering the provision of unpaid care (£6500 vs. £7800), leading to an average societal cost of £9200 for the control group and £11,000 for the intervention group.

At follow-up, accommodation costs were more similar between the two groups than at baseline, whereas the average cost of hospital care appeared to be higher in the control group than the intervention group, although the difference was not significant. Interestingly, for both groups there was reduction in HSC service costs (£1984 vs. £1838), largely due to reduction in use of paid accommodation. The only adjusted difference found to be significant ($p = 0.04$) relates to the use of medications, which was higher for the intervention group.

Provision of unpaid care was greater, and hence more costly, in the intervention than the control group (£8400 vs. £5800). This difference may not be surprising given the nature of the intervention. Total societal cost, including intervention and provision of unpaid care, was £10,500 for the intervention group compared with £7800 for the control group, although after adjustment for baseline covariates this difference was not significant.

TABLE 30 Costs incurred by the economic analyses subsample

Variable	Control (n = 22)			Intervention (n = 30)			Total (n = 52)			Bootstrapped test: adjusted p-value			
	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean		SD	Min	Max
Pre-baseline costs (£)													
Accommodation	951.7	3080.3	0	10,468	1300.9	3478.1	0	13,182	1153.2	3288.8	0	13,182	072
Hospital services	513.6	747.8	0	2566.0	577.5	1248.9	0	5217.0	550.4	1057.4	0	5217.0	0.83
Community services	575.5	1108.9	0	4355.3	682.4	1010.9	0	3061.6	637.2	1044.2	0	4355.3	0.72
Equipment and adaptations	68.2	135.7	0	502.5	112.0	158.6	0	459.1	93.4	149.5	0	502.5	0.30
Day services	270.2	550.0	0	2,055.6	259.6	492.5	0	1778.9	264.1	512.3	0	2055.6	0.94
Medications	275.7	194.3	3	882.8	272.8	177.0	0	691.3	274.0	182.7	0	882.8	0.96
Total HSC	2654.8	3756.8	315.7	16,121	3205.1	3595.1	129.4	13,747	2,972.3	3638.2	129.4	16,121	0.61
Unpaid care	6563.3	4953.9	0	15,366	7812.1	6273.3	0	24,870	7283.8	5733.3	0	24,870	0.42
Total societal	9218.2	5647.8	465.9	21,113	11,017	5719.5	691.3	25,145	10,256	5704.5	465.9	25,145	0.24
12-month follow-up costs (£)													
Accommodation	632.7	2967.7	0	13,919	697.0	2361.4	0	10,468	669.8	2607.4	0	13,919	0.80
Hospital services	461.0	937.2	0	4425.7	146.7	255.9	0	898.0	279.7	650.7	0	4425.7	0.08
Community services	270.4	707.0	0	3229.0	390.5	782.2	0	3919.9	339.7	746.5	0	3919.9	0.65
Equipment and adaptations	103.0	189.7	0	710.4	89.0	160.3	0	641.5	94.9	171.7	0	710.4	0.25
Day services	270.5	519.5	0	1,937.0	229.1	476.8	0	1541.7	246.6	490.7	0	1937.0	0.78
Medications	246.3	169.4	6	672.8	285.2	172.9	0	783.7	268.7	170.9	0	783.7	0.04
Total HSC	1983.8	3080.5	85.7	14,528	1837.5	2511.8	118.4	11,367	1899.4	2738.7	85.7	14,528	0.41
Intervention	0	0	0	0	284.0	43.2	190.0	320.0	163.8	145.4	0	320.0	–
Total HSC plus intervention	1983.8	3080.5	85.7	14,528	2121.5	2509.7	417.5	11,627	2063.2	2737.5	85.7	14,528	0.76
Unpaid care	5820.7	6750.9	0	28,626	8411.6	5727.0	0	24,570	7315.5	6251.9	0	28,626	0.24
Total societal plus intervention	7804.5	6859.0	85.7	29,735	10,533	5890.7	532.5	29,271	9378.7	6399.7	85.7	29,735	0.31

Cost-effectiveness analysis

In *Table 31* we report the incremental costs and incremental effects for the primary and secondary outcomes.

Incremental cost-effectiveness ratios would typically be calculated by dividing incremental costs by incremental benefits, but these have not been presented in *Table 31* because neither incremental costs nor incremental effects were significantly different between trial arms. From a HSC perspective, we found that incremental costs were negative, that is, the intervention group had lower costs than the control group (about £170 less) and incremental effects were positive, that is, the intervention group achieved better outcomes. Although none of these differences were significant at the 95% level, for illustrative purposes we note that, from a societal perspective, the ICER for the NPI outcome measure was £421. *Figures 8* and *9* show CEACs for the primary outcome measure (NPI) from a HSC and societal perspective, respectively.

From a HSC perspective (see *Figure 8*) the CEAC suggests that, at a willingness to pay of £500 per incremental improvement in outcome (i.e. per 1-point difference in NPI score), the exercise regimen is cost-effective with probability of > 80%. From a societal perspective (see *Figure 9*), the ICER was £421 per incremental difference in NPI score. If a reduction of at least eight points in the NPI score can be considered clinically meaningful⁹⁵ then this result suggests that the cost of achieving a meaningful improvement is £3368.

Table 32 presents results for a sensitivity analysis that, in addition to baseline costs and baseline outcomes, also controlled for participant age at baseline, gender, ethnicity, marital status, education level, whether living in a care home, MMSE score at baseline, carer age and gender. This analysis gave results that are consistent with the main analysis.

TABLE 31 Incremental costs and effects (controlling for baseline costs and outcome)

Perspective	Incremental cost (£, 2010–11): mean, 95% bootstrap CI			Incremental effect: mean, 95% bootstrap CI			ICER
	Mean	Upper CI	Lower CI	Mean	Upper CI	Lower CI	
HSC: 0–12 weeks							
NPI	-168.6	-1232.8	895.6	4.07	-4.65	12.79	Intervention dominant
ZBI	-170.8	-1234.6	893.1	1.54	-1.78	4.86	
DEMQOL-Proxy	-165.6	-1251.7	920.6	2.87	-1.94	7.68	
QALY (DEMQOL-Proxy)	-169.7	-1240.0	900.5	0.0055	-0.0031	0.0140	
GHQ	-173.6	-1235.8	888.6	4.19	-0.55	8.93	
Societal: 0–12 weeks							
NPI	1686.4	-1407.1	4780.0	4.01	-4.72	12.73	421
ZBI	1641.1	-1497.8	4780.0	1.56	-1.75	4.86	1055
DEMQOL-Proxy	1635.9	-1520.9	4792.6	2.82	-1.97	7.61	580
QALY (DEMQOL-Proxy)	1565.8	-1592.6	4724.2	0.0055	-0.0031	0.0140	286,440
GHQ	1657.3	-1471.8	4786.4	4.23	-0.50	8.97	392

Note: Positive variations in the incremental effects represent improved outcomes. Minor differences in incremental effects between perspectives are a consequence of the incremental cost-and-effect equations being jointly estimated with the SUR method.⁹²

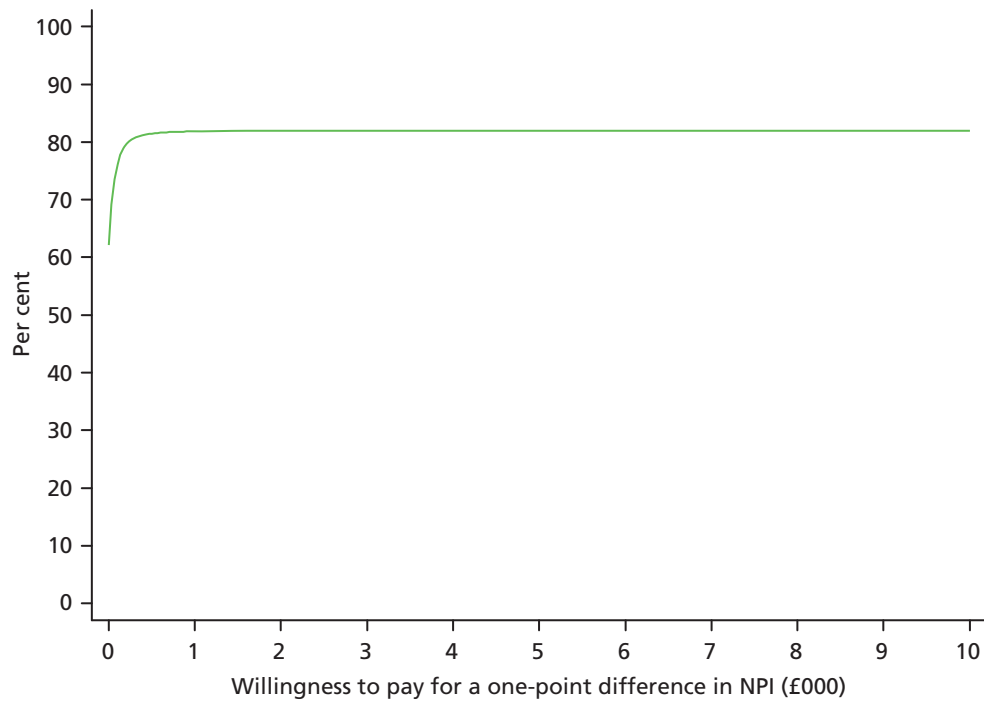


FIGURE 8 Cost-effectiveness acceptability curve: exercise regimen vs. usual care; HSC perspective, with effectiveness measured on the NPI scale.

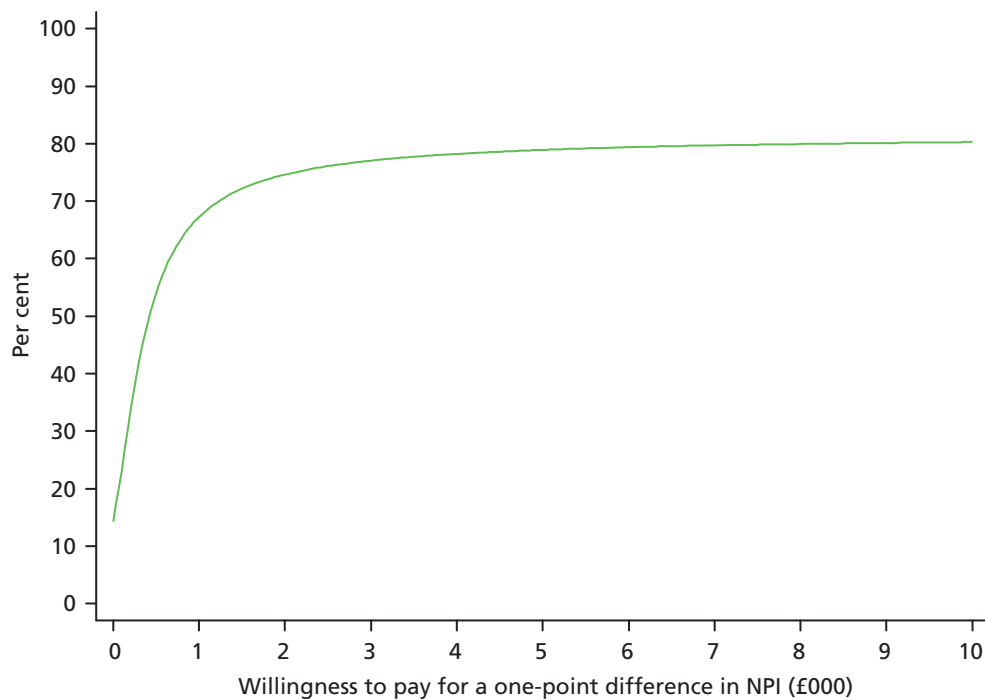


FIGURE 9 Cost-effectiveness acceptability curve: exercise regimen vs. usual care; societal perspective, with effectiveness measured on the NPI scale.

TABLE 32 Incremental costs and effects (controlling for sociodemographics, baseline costs and outcome)

Perspective	Incremental cost (£, 2010–11): mean, 95% bootstrap CI			Incremental effect: mean, 95% bootstrap CI			ICER
	Mean	Upper CI	Lower CI	Mean	Upper CI	Lower CI	
HSC: 0–12 weeks							
NPI	–159.6	–1267.8	948.5	2.46	–7.59	12.50	Intervention dominant
ZBI	–155.9	–1254.7	942.9	0.56	–3.90	5.02	
DEMQOL-Proxy	–156.5	–1256.3	943.3	2.55	–3.32	8.41	
QALY (DEMQOL-Proxy)	–156.7	–1257.4	944.1	0.0066	–0.0026	0.0157	
GHQ	–155.5	–1250.6	939.5	4.00	–1.92	9.91	
Societal: 0–12 weeks							
NPI	1,018.8	–2331.0	4368.7	2.42	–7.54	12.39	421
ZBI	992.5	–2384.6	4369.6	0.58	–3.86	5.02	1,711
DEMQOL-Proxy	978.1	–2403.7	4359.9	2.46	–3.40	8.33	397
QALY (DEMQOL-Proxy)	954.0	–2444.5	4352.4	0.0065	–0.0025	0.0155	146,437
GHQ	1,004.8	–2349.2	4358.8	4.07	–1.79	9.93	247

Note: Positive variations in the incremental effects represent improved outcomes. Minor differences in incremental effects between perspectives are a consequence of the incremental cost-and-effect equations being jointly estimated with the SUR method.⁹²

Discussion

Summary of the main findings

The study comprised three inter-related components: a literature review; a RCT; and some qualitative exploration of experiences of the conduct and participation in the trial. In the literature review we described the limited, but promising, evidence to support the use of exercise as a therapy for BPSD. The main shortcoming in the reported literature was the limitations of the research methods in the existing evidence base, something we sought to address with our RCT. The findings from the literature review were used to design a methodologically robust trial of an exercise programme for the purpose of ameliorating BPSD. Our main finding was that the exercise programme did not produce a significant clinical benefit for BPSD in this population. Importantly, however, we did find that caregiver burden was significantly better at the end of the trial for those in receipt of the exercise programme. Finally, significant – and unexpected – challenges of recruiting to the trial via clinicians were explored in a focus group. Clinicians reported significant anxieties recruiting to our relatively ‘low-risk’ trial that were most readily overcome through the use of a well-defined systematic recruitment and feasibility tool.

Towards a research agenda: from the literature to a randomised controlled trial

Behaviours that challenge caregivers – particularly agitation, psychosis and sleep disturbance – are often central to predicting institutionalisation, probably because of the reported negative impact for caregivers.^{96–98} Research that identifies optimal physical activity modalities, frequency, intensity and duration for persons with different types and severity of dementia has been lacking and will be important to inform commissioners of the value of exercise programmes in this population.

Appropriateness, safety and motivation to participate are critical to the success of exercise programmes, and may be particularly complex for older adults with dementia. For example, adherence may be influenced

by the nature of dementia itself. Particular symptoms, such as apathy, may have a proportionally greater impact (relative to other BPSD) on adherence, which could be further impacted upon by context⁷⁶ (e.g. paid carers often view apathy differently to unpaid carers).

Exercise appears to be beneficial in reducing some BPSD, especially depressed mood and agitation, and may also improve sleep and reduce 'wandering'. However, research into the efficacy of exercise with the therapeutic aim of improving other important symptoms, such as anxiety, apathy and repetitive behaviours, was weak. Although some studies suggest that walking for at least 30 minutes, several times per week, may enhance outcomes, the beneficial effect of exercise type, its duration and frequency are unclear. Indeed, studies examining the effect of daily exercise had more favourable outcomes.

Results from the trial

Although overall BPSD were lower at week 12 in the group that received the exercise in comparison with the TAU group, this difference was not statistically significant. This is not consistent with the meta-analysis reported by Heyn *et al.*⁷⁶ There are three possible explanations for this: first, exercise is not a clinically effective therapy for BPSD; second, our exercise regimen has not had sufficient intensity to effect an impact on the participants; or, third, the effect size is smaller than we anticipated.

Importantly, our secondary analyses revealed a significant benefit for carers by attenuating burden across the trial duration. This is important as caregiver burden is strongly linked to use of health, social and medical services by both the person with dementia and their caregiver.⁶⁵⁻⁶⁸ Given the absence of impact on behavioural and psychological symptoms, it is unclear why caregivers from the TAU group reported having a significant worsening of burden in comparison with those in receipt of the intervention. The increase may have been due to worsening burden because of BPSD, differential physical burden between the two groups (there was a slightly higher number of physical conditions in the TAU group at baseline) or unhappiness among carers about not being randomised to the intervention. Conversely, participation in exercise in the intervention group may have attenuated the perception of burden.

The economic evaluation looked at costs and cost-effectiveness. At 12 weeks, average costs from a societal perspective for the group following the exercise regimen were non-significantly higher than for the control group getting TAU. From a HSC system perspective, costs for the exercise group were non-significantly lower.

When considering cost-effectiveness for each outcome measure there were no significantly different incremental costs or incremental effects. The sensitivity analysis conducted (adjusting for baseline sociodemographic variables) generated findings that were consistent with the main analyses.

Recruitment to clinical trials

Researchers aim to work to high professional standards of GCP and require all study participants to be consenting volunteers, who are aware of their right of refusal without fear of detriment. When people lack capacity, ethics committees require rigorous protocols to safeguard participants' wishes and welfare. We believe that all people, whether they have dementia or not, should have the right to participate in research. We recognise that people take part for many reasons, including altruism and a sense of purpose. Within a society that often patronises and demeans older people, many clinicians and researchers are passionate advocates of enlarging patient choice. In our experience people who are not interested in participating in research have a range of direct and indirect ways of showing this. Despite all of these safeguards, clinicians appear apprehensive about recruiting even for relatively low-risk studies like EVIDEM-E. Therefore, we support recent calls to quantify clinicians' impact on recruitment and test ways of improving accruals.⁹⁹ We also agree more is needed to understand the experience of participating as a 'control'. The response from the teams was positive, but actual recruitment was much slower than anticipated. Six participants were recruited to the trial through memory clinics and community mental health teams over a 6-month period from a patient population exceeding 2000 people with dementia.

There are several ways in which researchers can incentivise clinicians' involvement in research. The focus group indicated their involvement should bring tangible reward for individual clinicians and participants. It was not enough, in the group's view, that NHS trusts financially gain through involvement with research – how these resources enhance frontline clinical services should be made explicit. Encouraging a sense of ownership is a well-established tool for engendering investment, and we attempted this by including clinicians on our advisory groups. However, it is likely that a more widespread and involved approach is needed to improve practitioner engagement. Consulting clinicians on dissemination strategies might help them see the pathway from project to practice more clearly. Finally, developing flexible quick guides to recruitment may instil confidence when discussing individual projects with patients.

The approaches suggested by the focus group would all maintain clinicians at the centre of the recruitment process. An alternative could be direct contact between researchers and patients, which could potentially resolve many recruitment challenges for clinician and researcher while improving patient choice. In collaboration with the North Thames DeNDRoN, we helped to develop a registry of people with dementia who were interested in research ('DemReg'),¹⁰⁰ which appears to be an efficient recruitment mechanism. This registry is discussed in detail in *Chapter 6* of this report.

Strengths of the trial design

The process of designing the study was challenging to the research team. It saw the project team – supported by an independent steering group – attempt to strike a balance between achieving a feasible and sustainable intervention that could be widely adopted in the target population while maintaining scientific rigour in its evaluation.

Strengths of this study include the relatively large sample size, with low attrition rates; use of well-validated outcome measures; a pragmatic exercise programme that does not require specialist training or equipment; and efforts to control for the impact of therapist contact.

The trial design addressed other important factors: a more homogeneous sample in terms of diagnosis, severity of disease and mobility; a sample size with sufficient power to detect an effect (positive or negative) of clinically significant magnitude; and blinded and objective outcome ratings.

Limitations of the study

Careful consideration was given to blinding the researcher to the allocation status of the participants. The single-blind design left study personnel vulnerable to unmasking group allocation during data collection with participants. To mitigate this impact we decided to include a second, independent, researcher who collected our primary outcome data (NPI) at 6 and 12 weeks. However, a risk remained that the dyad would divulge information about the group to which they have been allocated. The efficacy of maintenance of blinding was assessed at each time point, by personnel collecting data who recorded the arm to which they believed each dyad was randomised.

Separating the effect of psychosocial contact (from the exercise therapist) from the exercise intervention has proved to be the biggest challenge in our study. We addressed this problem by introducing two periods during the intervention: 1–6 weeks, whereby the participants in the intervention group were trained and supported by an exercise therapist, and 6–12 weeks, when participants were encouraged to continue exercising but had no contact with the therapist. Although we tried to control for contacts between participants and the exercise therapist, we could not control for the social contact between the person with dementia and their carer. Dyadic walking may have encouraged not only physical activity, but also psychosocial support from the carer as well.

We used outcome measures that are well validated and widely used in research with individuals with dementia. We also gave considerable thought to the issue of measuring physical activity. Particular consideration was given to the use of equipment by the participants to record their individual activities, for example GPS (Global Positioning System) receivers and pedometers. However, we decided not to use such instruments in order to avoid excessive intrusion, and to prevent the instruments affecting exercise behaviour in their own right. Similarly, participants' levels of physical activity was evaluated through measurements of the participants' self-reported RPE. The intervention delivered by the therapist centred on monitoring and increasing activity intensity utilising the RPE, and so could be provided only to the exercise group.

Assessing physical activity with minimum intrusion to study participants is challenging and we relied on participants' self-reports through daily dairies. Self-report is prone to information bias, especially when participants are not blinded to their group allocation.

The economic evaluation adopted a HSC perspective for some analyses and a societal perspective for others to ensure that unpaid carer inputs were not overlooked. A range of outcome measures was examined, including QALYs generated from a dementia-specific measure. A limitation of the economic analyses was the sample size, which was 50% lower than the sample for the main outcomes analysis because service-use data were not collected. This loss of statistical power limits the conclusions that can be drawn. Another possible limitation is that only 85% of study participants provided information about support received from unpaid carers, yet we know that all sample members had a carer. It is difficult to estimate accurately the amount of time an unpaid carer spends with someone with dementia.

Conclusions

There are two key implications that we can draw from this study. First, recruitment of people with dementia via clinical sources is resource intensive and research registers can significantly increase the efficiency of this process. This is critical to ensure that large clinical trials are feasible. Second, regular walking is not effective at reducing BPSD but does seem to attenuate rising caregiver burden. We cannot be sure whether this was because of the exercise per se, increased psychosocial effect between carer and person with dementia or a placebo effect. Neither incremental costs nor incremental effects (for any outcome measure considered) were significantly different between the intervention and control groups, which suggests that the exercise regimen is unlikely to be cost-effective. Further research should seek to confirm our findings and clarify the active component.

Building research capacity

The exercise therapist (James Lee) used data from this study towards his undergraduate degree; he received the Bob Finney Memorial prize for this work and graduated with first-class honours. The RW (Arlinda Cerga-Pashoja) has registered for a Doctor of Philosophy (PhD) and passed her MPhil–PhD viva in 2011. In addition, David Lowery worked in a postdoctoral capacity and contributed to an expert therapy development group of another National Institute for Health Research (NIHR)-funded research programme (WHELD) on behalf of the EVIDEM group. The study team members have also contributed in delivering educational programmes to the CNWL staff through summer schools.

Voluntary RWs have given an invaluable input in the EVIDEM-E study. Nine volunteers helped with data entering, designing databases and collecting outcomes. They gained research experience and had the opportunity to be trained in GCP.

Changes to protocol

No changes from the original protocol were made.

List of appendices

Appendix 8 Chapter 2: Research protocol EVIDEM-E study.

Appendix 9 Chapter 2: Consenting protocol – standard operating procedures.

Appendix 10 Chapter 2: Standard operating procedure for monitoring of adverse events.

Appendix 11 Chapter 2: Risk assessment and management tool.

Appendix 12 Chapter 2: Serious adverse event reporting form.

Appendix 13 Chapter 2: Risk management pathway.

Appendix 14 Chapter 2: Diary – intervention group, example page.

Appendix 15 Chapter 2: Diary – control group, example page.

Appendix 16 Chapter 2: Intervention protocol.

Chapter 3 EVIDEM-C: promoting continence and managing incontinence with people with dementia living at home

Abstract

People with dementia experience persistent problems with toileting and incontinence, which are difficult to manage, problematic for carers and one factor in the decision to move to a care home. There is little clinical guidance for primary care professionals tailored to this population. This series of studies, shaped by MRC framework¹⁰¹ for the development of complex interventions, investigated (1) the incidence of the problems for people with dementia living in their own homes; (2) the published evidence for management; (3) the experience; and (4) the strategies and issues faced by people with dementia, their carers and the professionals trying to support them, as well as the feasibility of testing different designs of continence pads and tools to aid primary care nurses in tailoring their advice, management and support.

The study has added new evidence about the incidence, experience and management of toileting difficulties (TDs) and incontinence for this population. The reasons for the toileting and incontinence problems are multifactorial, and a mosaic of strategies is required to both reveal the problems and manage them in ways that are acceptable to the person with dementia and family members. This study suggests that there are strategies and responses that primary care professionals and others can utilise to encourage greater openness, thereby lessening the taboo of incontinence within the stigma of dementia. It remains to be seen if these approaches, combined with more emphasis of effective containment of excreta, will influence decisions about relocation of people with dementia to care homes.

Introduction

Dementia is one of the most disabling, distressing and burdensome diseases. Supporting people with dementia and their family carers to live in their own homes is a major HSC policy objective in the UK^{102,103} and in other countries.^{104–106} There are many dimensions to the problems faced by people with dementia and their family carers as the dementia progresses.^{107,108} Many are well understood and the strategies required from HSC services are recognised.^{102,103} However, toileting problems and incontinence in people with dementia are problems which are poorly understood and for which there is little guidance for HSC professionals working in community settings.

Background: the overall need for the EVIDEM-C study

Family carers have reported incontinence as the most problematic symptom to manage.¹⁰⁹ Incontinence contributes significantly to both family and carer burden associated with supporting a person with dementia,¹¹⁰ and also to the decision to seek residence in a group or care home.¹¹¹

Dementia is a clinical syndrome with a trajectory of progressive loss in cognition and abilities in undertaking ADL, including personal toileting and physical functioning.¹¹² BPSD¹¹³ can manifest as inappropriate voiding and toileting behaviours.¹¹⁴ Extrinsic factors, such as attitudes of ‘therapeutic nihilism’ (i.e. attitudes of nothing can be done to help) by professionals and unadapted environments compound these impairments.¹¹⁵

The high prevalence of incontinence in people with dementia who are resident in care homes is well documented,¹¹⁶ as are the research and guidance for managing the problems for people living in these settings.¹¹⁷ However, international estimates suggest over two-thirds of all people with dementia live in their own homes.^{118,119} In reviewing clinical and social care guidance for best practice in managing toileting and incontinence problems in people with dementia living at home, and supporting their family carers, it became evident that there was a significant knowledge deficit.

There are internationally agreed definitions of types of urinary incontinence (UI) and faecal incontinence (FI).¹²⁰ 'Functional incontinence' is a term sometimes used when factors outside the lower urinary tract (such as environmental features or cognitive impairment) result in incontinence. Although internationally agreed algorithms for assessment and treatment of UI and FI inform national clinical guidance, the guidance on incontinence management either pointed to the evidence gaps for frail older people¹²¹ or excluded people with cognitive impairment.¹²² Available guidance on primary care management of dementia did not refer to incontinence management.¹²³ The NICE and SCIE guidelines on supporting people with dementia and their carers did not review evidence on incontinence management, offering the view that combined interventions are more likely to support and maintain independence in the person with dementia.¹²⁴

Against this background EVIDEM-C (2007–12) investigated the promotion of continence and management of UI and FI in people with dementia living in their own homes. The specific research questions it addressed were:

1. What is the prevalence of different types of incontinence problems experienced by people with dementia, living at home?
2. What is the evidence for different strategies and interventions in managing incontinence in people with dementia living at home?
3. What are the perceived factors that support or detract from the use of different strategies and interventions from the perspective of informal carers, people with dementia, generalist and specialist health-care staff, social workers and social care?
4. What are the experiences, strategies, impact and cost consequences of managing incontinence problems in people with dementia living at home, and how do they change over time?
5. What are the feasibility and acceptability of developing specific interventions to promote continence and manage incontinence with people with dementia and their carers at home?

In addition, the study aimed to develop educational materials for those working in community and primary care settings to assist in the promotion of continence and management of incontinence in people with dementia living at home.

The research approach and design

The research approach was one of critical realism¹²⁵ which allows an integration of both subjective and objective research approaches. In taking this approach, the multifaceted nature of the issues and problems in promoting continence and managing incontinence in the home, as well as the perspectives of multiple and diverse stakeholders, was examined in the light of the evidence of effectiveness. This research approach allowed the study to acknowledge the complexity of the issues. The EVIDEM-C study drew on the MRC Framework¹⁰¹ for developing complex interventions in stepwise phases. The study had four interlinked phases:

1. Reviewing the evidence about prevalence and effective interventions (see *Phase 1: reviewing the evidence for incidence, prevalence and effective strategies*, below)
2. Exploring the experiences and strategies used by people with dementia and their carers to manage incontinence, and the impact and consequences of that incontinence (see *Phase 2: exploring the experience, strategies, impact and consequences*, below)
3. Testing the feasibility of an identified intervention (see *Phase 3: investigating the feasibility, effectiveness and acceptability of an identified strategy*, below)
4. Developing educational resources (see *Phase 4: developing and testing resources for practice*, below).

The overall protocol can be found in *Appendices 17–23* and research instruments and tools are provided in *Appendices 26–34*. The study was supported by an advisory group, which brought different types of expertise (carers, professionals – primary care, dementia specialists and continence specialists) to inform and help shape the study. It was chaired by a former carer of a person with dementia. Patient and public involvement representatives were present at every meeting, and performed co-production roles in shaping the research activities, such as agreeing the intervention to be tested in Phase 3, reviewing research materials, such as interview topic guides, and assisting in recruitment of participants.

Phase 1: reviewing the evidence for incidence, prevalence and effective strategies

In this phase, three reviews were undertaken and a nested study of a secondary data analysis of a primary care database was carried out to establish the prevalence and incidence of incontinence in people with dementia. Each is presented below.

A systematic review of the evidence about prevalence

Although the presence of incontinence symptoms is well documented in people resident in care homes,¹¹⁶ there is currently little evidence available for clinicians, commissioners and service planners concerning the scale of the problems in the larger population of people with dementia living at home.

Methods

Aims and objectives

To identify the prevalence of UI and FI experienced by people with dementia, living at home.

Study design: a systematic literature review

Search procedure

We searched the following electronic databases: MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, British Nursing Index (BNI) and The Cochrane Library [including Database of Abstracts of Reviews of Effects (DARE) and National Technical Information Service (NTIS)], from 1 January 1990 to 1 September 2008, and then searches were updated to 2012 week 13 (4 April). In addition, 'lateral searching' techniques¹²⁴ were used for key authors and cited references. Search terms are given in *Table 33*.

TABLE 33 Search terms for studies of prevalence

Area	Search terms (Medical Subject Headings and keywords)
Population characteristics	exp Fecal Incontinence/or exp Urinary Incontinence/ exp Delirium, Dementia, Amnesic, Cognitive Disorders/or exp Dementia/ dementia.mp. exp Aged
Setting	Community dwelling.mp Community.mp
Research field of enquiry	Exp prevalence Prevalence.mp. Exp Needs assessment

Screening as per the inclusion and exclusion criteria (*Table 34*) and data extraction were undertaken by two researchers. Judgements of risk of bias in the studies¹²⁷ used criteria recommended for prevalence studies.¹²⁸ A narrative analysis was undertaken because of the heterogeneity in the included studies.

Results

The PRISMA³³ flow diagram in *Figure 10* reports the results of the search. From 427 references, eight studies^{129–136} met the inclusion criteria and are summarised in *Table 35*. No studies reported incidence. Seven studies provided prevalence rates as findings that were incidental to their primary question. Study populations, size of sample and assessment tools were varied, including the Care Needs Assessment Pack for Dementia (CareNap-D),¹³⁸ Cognitive Performance Score (CPS),¹³⁹ the ICD-10,⁸⁰ the UK Office of Population Censuses and Surveys (OPCS) Disability Survey 1985¹⁴⁰ and the MMSE.⁵² Assessment of risk of bias found that all studies had some aspect that was judged to be a risk; this has been reported in full elsewhere.¹³⁷ The reported prevalence rates are presented in *Table 36*. The prevalence of UI ranged from 1.1% in a general community population to 38% in those receiving home care services.

TABLE 34 Inclusion criteria for prevalence studies

Criteria	
Inclusion	Community-based observational studies Data on UI and/or FI in people with cognitive impairment or dementia Resident in their own homes English language
Exclusion	Studies not reporting empirical data of UI and/or FI Settings of hospital, nursing homes, cares homes, group homes Excluded people with dementia or cognitive impairment Data from the population of interest not identifiable in the results Published in languages other than English

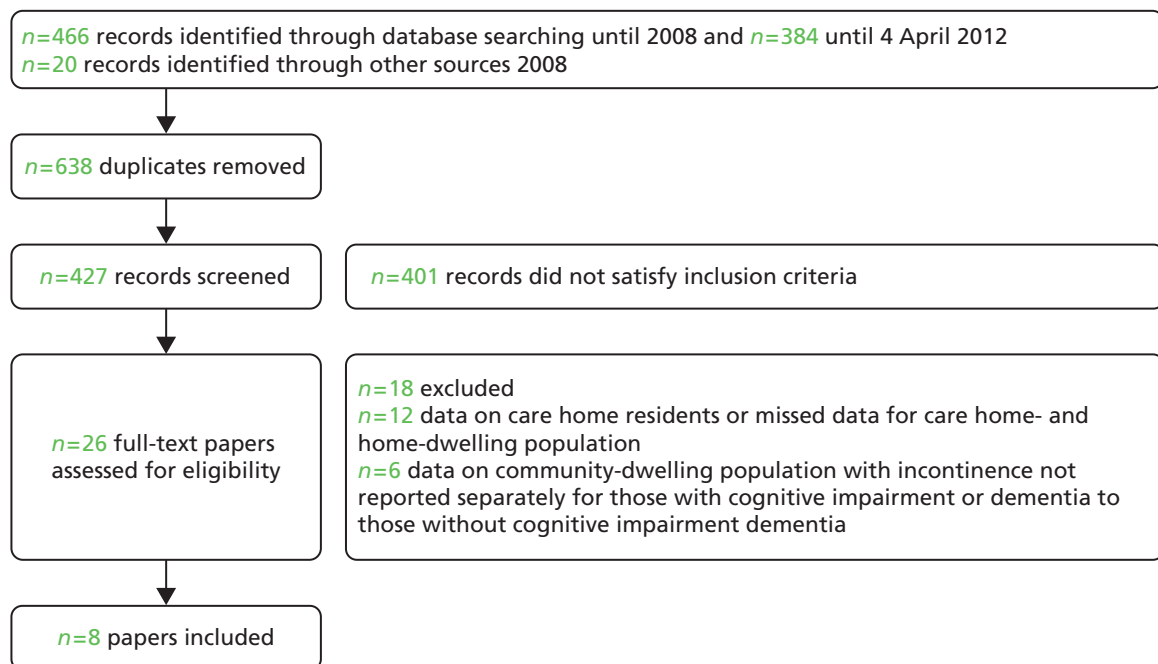


FIGURE 10 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram of search results for prevalence studies.

TABLE 35 Studies with prevalence data (adapted from Drennan *et al.*¹³⁷)

Study author, year, location	Population	No. with cognitive impairment or dementia and method of assessment	Method of assessment of UI and FI
Chung, ¹²⁹ 2006, Hong Kong	Convenience sample recruited from the Alzheimer's Disease Association, memory clinics and outpatient clinics <i>n</i> = 197 Mean age 77 years; 64% female	197 with a confirmed diagnosis of dementia or Alzheimer's disease	UI/FI determined by self and carer report to researcher using an amended CareNap-D ¹³⁸
Landi <i>et al.</i> , ¹³⁰ 2003, Italy	Patients enrolled in home health-care programmes and Silver Network Home Care Project <i>n</i> = 5372 Mean age 78.6 (SD 9.5) years; 59% female	In text, number not given but states 30% with moderate to severe cognitive impairment, determined by CPS ¹³⁹ (CPS > 2)	UI determined by a single self-report question with five-point scale as part of the enrolment assessment to the home care service completed by a health professional (GP, geriatrician, nurses)
Meaney <i>et al.</i> , ¹³¹ 2005, Ireland	Patients, consecutively referred, attending an old age psychiatry outpatient clinic, meeting ICD-10 criteria and living in the community <i>n</i> = 82 Mean age 76 (SD 7.8) years; 55 = female, 27 = male	82 with ICD-10 ⁸⁰ diagnosis of dementia	UI/FI determined by self and carer report to project nurse using (CareNap-D) ¹³⁸
Mohide <i>et al.</i> , ¹³² 1988, Canada	Patients receiving home care services aged > 16 years <i>n</i> = 2801 Mean age not given; number by sex not given	Number not given Method of determining cognitive disabilities not given	UI determined by study developed continence assessment form completed by health professional (unspecified)
Nakanishi <i>et al.</i> , ¹³³ 1997, Japan	A randomly selected (unspecified) sample of community residing people aged > 65 years from a computerised sex-age register in one city <i>n</i> = 1405 Mean age not given; number by sex not given	Number not given Dementia determined by intellectual functioning subscale of OPCS Disability Survey 1985 ¹⁴⁰	UI and FI determined by self-report using OPCS Disability Survey 1985 ¹⁴⁰ to welfare commissioners
Ouslander <i>et al.</i> , ¹³⁴ 1990, USA	Community-residing patients with a dementia diagnosis attending a community facility whose family carers volunteered for 'help with stress and burden' <i>n</i> = 184 Mean age: incontinent 76.28 (SD 8.10) years; continent 75.84 (SD 7.73) years Number by sex not given	A total of 184 with a clinical diagnosis of dementia	UI determined by report of carer to unspecified researcher Part of study developed memory and behaviour checklist

continued

TABLE 35 Studies with prevalence data (adapted from Drennan *et al.*¹³⁷) (continued)

Study author, year, location	Population	No. with cognitive impairment or dementia and method of assessment	Method of assessment of UI and FI
Rait <i>et al.</i> , ¹³⁵ 2005, UK	General practice registered patients, aged > 75 years, approached as part of a RCT of the methods of assessment of older people; computer randomised to universal or targeted arm <i>n</i> = 15,051 (subjects in universal arm) of whom 14,621 completed MMSE ⁵² 47% aged 75–79 years, 61.5% female	<i>n</i> = 2682 with cognitive impairment determined by MMSE ⁵² < 23/24	UI once a week or more often single question by self-report to research nurse
Teri <i>et al.</i> , ¹³⁶ 1989, USA	Patients with diagnosis of an Alzheimer's disease-type dementia attending a geriatric clinic selected (from case notes) as meeting criteria of diagnosis (aged between 55 and 85 years and community residing) for the study <i>n</i> = 56 Mean age 71 (range 55–85) years 43% female, 57% male	56 with a clinical diagnosis of Alzheimer's disease-type dementia	UI and FI determined by report by caregivers to trained interviewer; no tool specified

CPS, Cognitive Performance Score; OPCS, Office of Population Censuses and Surveys.

TABLE 36 Reported prevalence rates of UI and FI (adapted from Drennan *et al.*¹³⁷)

Study	Reported UI and FI rates				
	UI				FI
	Unspecified frequency	≥ 1 per day	≥ 1 per week	Night only	
Chung 2006 ¹²⁹	–	–	–	21% of 197	18% of 197
Landi <i>et al.</i> 2003 ¹³⁰	38% of 5372 Relative risk of UI in those with a CPS 2–4 compared with CPS 0–1: 2.03 (95% CI 1.88 to 2.18), and in those with a CPS > 4 compared with CPS 0–1: 2.97 (95% CI 2.78 to 3.18)	–	–	–	–
Meaney <i>et al.</i> 2005 ¹³¹	34% of 82	–	–	34% of 82	27% of 82
Mohide <i>et al.</i> 1988 ¹³²	10% of 2801	–	–	–	–
Nakanishi <i>et al.</i> 1997 ¹³³	1.1% of 1405	–	–	–	0.9% of 1405
Ouslander <i>et al.</i> 1990 ¹³⁴	–	24% of 184	11% of 184	–	–
Rait <i>et al.</i> 2005 ¹³⁵	–	–	8.8% of 2465	–	–
	–	–	Relative risk of UI in people with MMSE score < 24 compared with MMSE score ≥ 24: 2.03 (95% CI 1.73 to 2.36)	–	–
Teri <i>et al.</i> 1989 ¹³⁶	–	–	11% of 56	–	7% of 56

Prevalence of FI ranged from 0.9% in a community population to 27% in a sample attending an old age psychiatry outpatient clinic.

Discussion

This review found no studies reporting incidence and a wide variation in reported prevalence rates of UI and/or FI in people with dementia living in their own homes. This is explained, in part, by the variety of populations and assessment tools, and the lack of uniformity in criteria for defining incontinence and dementia. These methodological challenges in assessing prevalence rates have been well documented for both incontinence¹¹⁶ and dementia,¹⁴¹ including the issues of underreporting through embarrassment and stigma. Consequently, nearly all of the studies may have underestimated prevalence. The rates were incidental findings in nearly all studies and the one study designed to address the prevalence question of interest had a small population, identified through carers who identified themselves as experiencing high levels of stress.¹³⁴

To our knowledge, this is the first review addressing this question of prevalence. The greatest weakness of the study is the search strategy, which may have overlooked other studies with incidental prevalence findings in studies, and the exclusion of studies not reported in the English language. The study is reported in more detail elsewhere.¹³⁷

Conclusion

There is currently no definitive evidence of incidence or prevalence of UI or FI in people with dementia living at home, and further research is required to establish population-level data.

A cohort study of the incidence and management of incontinence in primary care

The absence of robust data on prevalence or incidence of incontinence in people with dementia living in the community led the research team to undertake a nested study investigating these questions and management strategies in primary care.

Methods

Aims and objectives

To investigate the incidence of UI and FI in community-dwelling people aged 60–89 years with dementia, and management strategies in primary care.

Study design

A cohort study of patient data from The Health Improvement Network (THIN), a UK general practice patient database.¹⁴²

Procedures

We compared two cohorts: all adults with dementia aged 60–89 years with at least 6 months' data from 1 January 2001 to 31 December 2010, and a stratified (by age and gender) random sample of four times as many adults without dementia. IRRs, adjusted for potential confounders (age, gender and comorbidity), were calculated using multilevel Poisson regression.

Ethical arrangements

The NHS South-East Multicentre REC approved the scheme for THIN to obtain and provide anonymous patient data to researchers, and scientific approval for this study was obtained from the THIN Scientific Review Committee¹⁴² in October 2011.

Results

There were 1,246,963 eligible participants from 487 general practices, of whom 54,816 entered the dementia cohort and 205,795 were selected for the non-dementia cohort. During the 10-year follow-up, incontinence (urinary, faecal and double) was newly recorded for 8987 (16%) people with dementia and 23,083 (11%) without dementia. *Table 37* reports the incidence of UI and FI per 1000 person-years at risk (PYAR) in men and women with and without dementia. The IRRs, adjusted for age, sex and comorbidity, for UI were 3.2 (95% CI 2.7 to 3.7) in men and 2.7 (2.3 to 3.2) in women. The IRRs for FI were 6.0 (95% CI 5.1 to 7.0) in men and 4.5 (3.8 to 5.2) in women.

Fifteen and 18% of people with and without dementia respectively were prescribed medication for UI. Crude and adjusted IRRs are shown in *Table 38*.

The incidence of catheterisation could be analysed in 47,066 people with UI over 163,735 PYAR. The IRRs comparing people with dementia to those without are given in *Table 38*. The results in full are presented elsewhere.¹⁴³

Discussion

Dementia is associated with at least a doubling in the incidence rate of incontinence (any type) in community-dwelling primary care patients. To our knowledge this is the first report of incidence of incontinence from the clinical records of community-dwelling people with dementia.

Patients aged 60–89 years with UI and dementia received drug treatments at more than twice the rate of patients without dementia but of the same sex, age and comorbidity. This difference was attenuated with age but remained evident. There is some evidence to suggest that, in general, older adults may not receive optimum treatment for UI.^{144,145} Indwelling urinary catheters were recorded at more than double the rate in women with dementia, compared with those without dementia of the same age and comorbidity. The difference was attenuated with comorbidities but not age. Indwelling catheters are associated with discomfort and risk of infection among other problems.^{146,147} The clinical reasoning for the greater use of drug treatment and indwelling catheters in this population needs investigation.

TABLE 37 Incidence of UI and FI in people with and without dementia (adapted from Grant *et al.*¹⁴³)

Type of incontinence	Men		Women	
	Without dementia: rate per 1000 PYAR (95% CI)	With dementia: rate per 1000 PYAR (95% CI)	Without dementia: rate per 1000 PYAR (95% CI)	With dementia: rate per 1000 PYAR (95% CI)
Urinary	19.8 (19.4 to 20.3)	42.3 (40.9 to 43.8)	18.6 (18.2 to 18.9)	33.5 (32.6 to 34.5)
Faecal	3.1 (2.9 to 3.3)	11.1 (10.4 to 11.9)	3.6 (3.5 to 3.8)	10.1 (9.96 to 10.6)

TABLE 38 Comparison of unadjusted and adjusted IRRs and 95% CIs of drug treatment and catheterisation for people with dementia to those without (adapted from Grant *et al.*¹⁴³)

Incidence of action	Crude IRR (95% CI)	IRR adjusted for sex, age and comorbidity (95% CI)
Incidence of drug treatment for UI		
Both sexes	1.3 (1.2 to 1.4)	2.2 (1.4 to 3.7)
Incidence of long-term catheterisation		
Men	1.3 (1.2 to 1.4)	1.6 (1.3 to 1.9)
Women	1.9 (1.8 to 2.1)	2.3 (1.9 to 2.8)

The study has a number of limitations. The data are from primary care clinical records, kept for that purpose rather than the questions of this study. The different general practices do not record uniformly all types of information regarding the patient, for example, treatment or non-pharmaceutical supplies from other health-care services. Despite this the data provide insights not offered elsewhere.

Conclusions

This large cohort study establishes the incidence of incontinence among people with dementia living in the community. The incidence of incontinence is more than double – and for some age groups treble – for people with dementia compared with people without dementia of the same age, gender and comorbidity. The clinical reasoning in the primary care management of UI in people with dementia requires further investigation.

A systematic review of interventions and strategies

Urinary and faecal symptoms from underlying pathology in the genitourinary system have established pharmacological and/or surgical treatments.¹²⁰ Conservative interventions (i.e. non-pharmacological and non-surgical⁸⁶) are also important. Incontinence problems in people with dementia are multifactorial¹¹⁶ and many aspects require conservative management. This review addressed the question: what is the evidence for effectiveness of conservative interventions for the prevention or management of incontinence in community-dwelling people with dementia or cognitive impairment?

Methods

Aims and objectives

To identify and assess the empirical evidence for the effectiveness of conservative interventions for the prevention or management of incontinence in community-dwelling people with dementia or cognitive impairment.

Study design

A systematic literature review.

Search procedure

We searched electronic databases: MEDLINE, EMBASE, CINAHL, PsycINFO, BNI, Care.data and The Cochrane Library [including DARE, NTIS and System for Information on Grey Literature in Europe (SIGLE)], Social Science Citation Index (SSCI), AgeInfo, National Research Register (NRR), PapersFirst (conference presentations), and the specialised register of the Cochrane Effective Practice and Organisation of Care (EPOC) Group, Dissertation Abstracts, DH and similar websites. The databases were searched from their start date to 2012 week 13 (4 April). In addition 'lateral searching' techniques¹²⁶ were used for key authors and cited references. Search terms were used in combination (*Box 4*). Abstracts were screened by two researchers for inclusion. For ambiguous abstracts the full text was retrieved and read. Data were extracted against predefined categories by one researcher and confirmed by a second.

Inclusion and exclusion criteria

Inclusion Interventional studies addressing problems of incontinence (UI and/or FI) experienced in people with dementia or cognitive problems in the setting of the person's home, and reporting in the English language.

Exclusion Papers not reporting empirical, observational data of interventions or strategies addressed at problems of incontinence; settings of hospital, nursing homes, care homes or group residential homes or populations; papers excluding people with cognitive impairment or dementia or where they were included but not identifiable in the results; papers not published in the English language.

BOX 4 Search terms for conservative intervention studies

Fl or UI.
Delirium, dementia, amnestic, cognitive disorders or dementia.
Aged.
Elderly.
Caregivers.
Caregiver burden.
Spouses.
Family.
Significant other.
Home care services.
Housebound patients.
Community living.
Community dwelling.
Home nursing.
Ambulatory care.
Ambulatory care nursing.
Self care.
Home nursing, professional.
Home health care.
Home health agencies.
Homemaker services.
Community health services.
Social support.
Volunteer workers.
Toilet facilities.
Occupational therapy.
ADL.
ADL or adl.
Toilet.
Toilet training.
Attitude to health.
Adaptation, psychological.
Behaviour therapy.

Results

The search results are presented in the PRISMA flow diagram (Figure 11) and three papers¹⁴⁸⁻¹⁵⁰ met the inclusion criteria. Each study was assessed for risk of bias.¹²⁷ Because of the heterogeneity of the interventions and outcomes it was not appropriate to undertake a meta-analysis, and a narrative summary of findings is presented. The characteristics of the three studies are presented in Table 39.

Two studies were described as exploratory and pilot studies, recruiting fewer than 20 dyads.^{148,150} All had a control group, although one reported no data on these people.¹⁴⁸ All had risk of bias to the internal validity, presented previously in detail.¹⁵⁰ The interventions were advice and education aimed at the family carer, for them to act upon. Two included education for toileting: prompted voiding (PV)¹⁴⁸ and an individualised toileting schedule,¹⁵⁰ together with other aspects of continence education. The interventions involved between weekly¹⁴⁹ and monthly¹⁵⁰ contact with the health professional for the duration of the study. Toileting schedule advice was the least acceptable to carers in the occupational therapist (OT) intervention study.¹⁴⁸ The study of individualised scheduled toileting presented statistics indicating a significant reduction in UI in the intervention arm¹⁴⁹ but on our re-analysis of the data provided this was not confirmed.¹⁵¹ Using the intention-to-treat method the PV study found no statistical differences between groups on any UI outcome but noted there were clinically significant reductions in episodes of UI for some patients.¹⁵⁰ The results in full detail have been published previously.¹⁴⁸

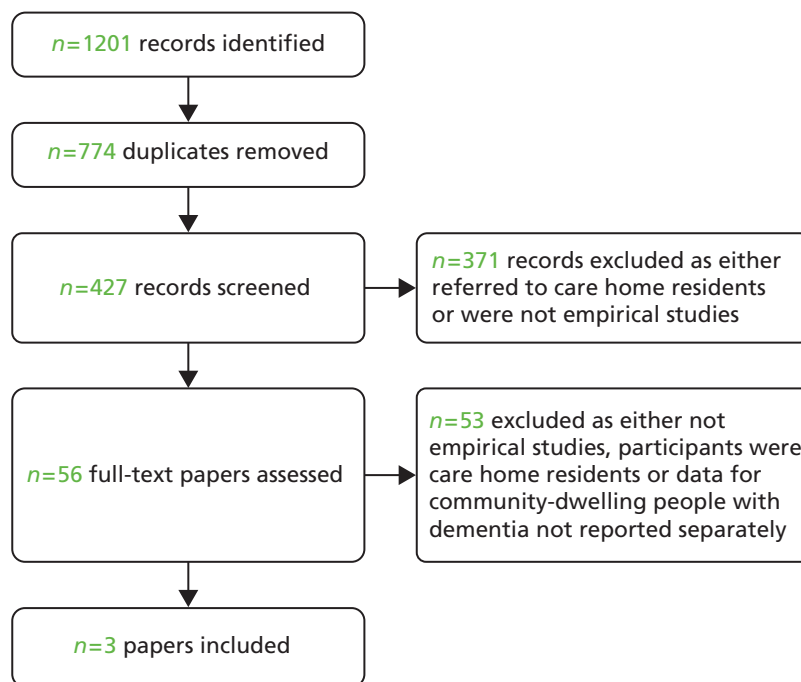


FIGURE 11 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram of the results of search for conservative intervention studies.

TABLE 39 Characteristics of the included studies of conservative interventions (adapted from Drennan *et al.*¹⁵¹)

Authors, year, location	Research question or aim	Study design	Participants	Intervention	Control
Gitlin and Corcoran, ¹⁴⁸ 1993, USA, community	To test the effectiveness of an intervention to expand caregiver problem-solving and use of environmental solutions for problems with bathing and incontinence	Randomised two-group experimental pilot study	Recruited spouse carers residing with a spouse diagnosed with moderate Alzheimer's disease via network of social service agencies Thirty-seven spouse carers recruited and 17 randomly assigned (unspecified) to the treatment group	Five visits by OT over 3 months using a framework from the competence-environmental literature. Visit 1, problem identification and review of current strategies; visit 2, identification of environmental influences, education and development of plan; visit 3 implementation of plan; visit 4 expansion of plan; visit 5 review and closure	An attention control group receiving home-making services
Jirovec and Templin, ¹⁴⁹ 2001, USA, community	To determine if functional incontinence, i.e. urine loss caused by factors outside the lower urinary tract, could be reduced in memory-impaired incontinent elders who had an individualised toileting programme (IST)	Two-by-two mixed design analysis by variance (group by time)	Recruited by advertisement for carers of 'memory-impaired' elders Total $n = 118$ dyads recruited Seventy-seven randomly assigned to intervention (38 to bimonthly follow-up and 38 to 6-month follow-up) and 41 to control At 6 months 74 remained in study (44 intervention group and 30 control), i.e. 37% attrition rate; 14 carers found that participating 'was too much for them', two carers became ill or could not be reached; 19 elders moved to a nursing home; nine people died	<ol style="list-style-type: none"> 1. IST carers recorded usual voiding patterns (most around every 2 hours) and agreed an IST schedule. Not specified if IST day only or night too 2. Carers taught about age-related bladder changes to understand urgency in toileting behaviours 3. Carers taught about the importance of insuring adequate fluid intake 4. Home environments assessed for obstacles to urine control and advice given 5. Pamphlet of teaching protocol, written at sixth-grade level, left with carer 6. Monthly telephone calls to review toileting schedule and difficulties, keep carers alert to intervention strategies, ensure carers offered elders six to eight glasses of fluid a day and retain in study 	Control group paid US\$25 per visit Monthly telephone calls to maintain commitment to study and provide 'friendly visits'

Authors, year, location	Research question or aim	Study design	Participants	Intervention	Control
Enberg <i>et al.</i> , ¹⁵⁰ 2002, USA, community	To examine the short-term effectiveness of PV in cognitively impaired housebound older adults	Exploratory study Prospective, controlled crossover design, for which the usual care controls crossed over to the intervention following the 8-week observation	Participants recruited via Home Health Nursing Services had to have a MMSE ³² score of < 24 and a resident carer Recruited patients = 19 and carers = 16 Nine randomised to the intervention and 10 to control Six of nine in the intervention group completed the intervention (two died and one carer became ill)	Prompted voiding instruction to carers in 8-weekly sessions in patients' homes by NPs. PV described as a behavioural therapy by which carers approached patients every 2 hours to ask if wet or dry, to check and to praise if dry. Patients were also asked if they would like to use the toilet. Those asking for the toilet were helped to get there and those not asking were encouraged to do so Carers also encouraged to eliminate caffeine from care recipient's diet. If they had enuresis caregivers were encouraged to limit fluids in the evening	The NPs visited every 1–2 weeks to provide 'socialisation' (attention control) of an average of 35 minutes without discussing incontinence

IST, individualised scheduled toileting; NP, nurse practitioner; OT, occupational therapist; PV, prompted voiding.

Discussion

Only three studies¹⁴⁶⁻¹⁴⁸ of conservative interventions were found, dating from over a decade ago. Two were described as exploratory and pilot studies and all had some risk of bias to internal validity. None provided evidence of effectiveness of the interventions. All three provided evidence as to the difficulties in recruiting to such studies. All three provided evidence as to issues in acceptability and feasibility for some carers in agreeing with and implementing the professional advice or instruction.

The review has limitations in that while the search was designed to be comprehensive, criteria such as English language only may have resulted in the omission of some studies. However, to our knowledge this is the first systematic review addressing the question of evidence of effective interventions for this population group. Previous reviews have not differentiated between evidence from community-dwelling or within-an-institution populations although much of the evidence relates to those within care homes,^{152,153} or has not drawn on a systematic approach.¹⁵⁴ This lack of attention to the very different environments (both physically and in availability of people to help) of an individual's home from a care home is apparent in many clinical guidelines.^{155,156}

Conclusions

There is little evidence of effective interventions for managing incontinence in people with dementia living at home. There is an urgent need for both research and clinical guidance for health professionals tailored to the setting in which the majority of people with dementia live.

A review of English community health services continence policies and clinical guidance

Local clinical guidelines for incontinence, produced by specialist continence services, are an important source of evidence to guide clinical practice for primary care professionals, particularly community nurses. A major part of district nurses' and community nurses' work is in supporting older people with incontinence problems who live at home.¹⁵⁷ Specialist continence services include nurses who work closely with a lead medical consultant, and across primary care, acute care and in care homes, although there is wide variation in provision.¹⁵⁸ In the absence of nationally available clinical guidelines, as described in the introduction to this chapter, this review sought to understand the extent to which local guidelines had been tailored to address the needs of people with dementia or cognitive impairment. The advisory group considered this an important review in light of the findings of the early parts of Phase 2 (see *Exploring the experience, strategies, impact and consequences*, below).

Methods

Aims

To investigate if the clinical guidance for incontinence management provided by specialist continence services in England addresses the problems and issues experienced by people with dementia living at home and their carers.

Study design

A review by documentary analysis¹⁵⁹ of clinical policies and guidance from a sample of at least 25% of specialist continence services covering 152 PCT areas and distributed across the 10 Strategic Health Authority regions of England. Documents were obtained through internet searches on public domain NHS websites and requests to specialist continence nurses identified through a national directory.¹⁶⁰ The framework for analysis was designed in conjunction with the advisory group.

Ethical arrangements

The NHS Research Ethics Service (NRES) advised that this was a service evaluation not requiring NHS ethics committee review. The study followed university research ethics requirements.

Results

Ninety-eight documents from 38 local community health service specialist continence services, located across all 10 strategic health authority areas, were obtained and analysed.

Of the 38 local services, 19 (50%) made no mention of dementia or cognitive impairment in their documents. Only in the documents of three services were nurses offered detailed guidance about the management of incontinence for people with dementia at home. The remaining 16 organisations provided guidance that mentioned dementia or cognitive impairment in assessment processes, but there was very little evidence of any subsequent advice or mechanism for producing specifically tailored care plans, such as a dementia care pathway. Only one organisation specified that the service user should be given any information about the consultation, and that was a copy of the referral form for incontinence pads with delivery information on it.

Ten (26%) of the 38 local organisations referred to a leaflet entitled *Continence in the Confused Elderly* (anonymous) to be given to family carers. The carers in the advisory group reviewed this leaflet and concluded that it had deficiencies in content, information, tone and style. People with dementia were identified as a special case in the documentation of only one service, which warranted the provision of additional continence products. Only one service made reference to addressing the problems of delivery of NHS continence pads to people with dementia living alone at home.

Discussion

Fifty per cent of sampled organisations had clinical guidance on incontinence which made no mention of dementia. A small minority provided examples of good practice. These good practice examples focused on person-centred assessment and responsiveness to the described problems, an approach advocated for some time in the care of people with dementia generally,¹¹⁵ and by gerontological nurses and dementia specialists.¹⁶¹ A more detailed discussion of the results has been published previously.¹⁶²

To our knowledge, this is the first study exploring the local guidance to primary care professionals in meeting the continence needs of people with dementia living at home. The study has limitations in that the representativeness of the documents is unknown, although the geographical spread, method of requesting from specialist nurses and internet searches would suggest that the variety has been captured.

Conclusion

Local clinical guidance on incontinence management rarely addresses the specific needs of people with dementia living at home or their carers. There is much room for improvement and providing evidence-based guidance to frontline staff on the specific problems of people with dementia and their carers. This review led the advisory group to prioritise for Phase 4: the development and testing of dementia specific continence assessment tools and guidance for the use of primary care nurses working with people with dementia living in their own home. The review also pointed to the importance of the involvement of carers of people with dementia in continence service developments.

Phase 2: exploring the experience, strategies, impact and consequences

In Phase 2, interlinked primarily qualitative studies were undertaken. All four studies were informed by the background and rationale described in the introductory section of this chapter, and these will not be repeated in each of the following sections. For each study therefore the details of the methods, results, discussion and conclusion only are given here.

The views of people with dementia

We could find no accounts from the perspective of the person with dementia on issues of incontinence. The purpose of this study was to investigate the PWD's perceptions of managing problems of incontinence.

Methods

The study approach was in the interpretative tradition¹⁶³ and the design was of qualitative guided conversations, a recommended research technique for use with people with dementia.¹⁶⁴ A purposive sample of people with dementia was recruited through primary care, specialist community mental health services and voluntary organisations. Conversations were taperecorded with permission, transcribed and thematically analysed,¹⁶⁵ using NVivo™ version 8, 2008 software package (QSR International, Warrington, UK: www.qsrinternational.com/default.aspx).

Ethics

The ethical issues we considered were capacity to consent, within the guidance of the MCA;¹⁷ assessment of continuing consent during the conversation and non-verbal signs of wishing to finish; and preparing researchers to manage distress and act on information that might suggest that a vulnerable adult was being neglected or harmed. A favourable opinion was given by Camden and Islington NHS local REC (08/H0722/60 2008) (see *Appendix 24*).

Results

It took a period of 1 year to recruit seven people with mild to moderate dementia and UI problems. They described a range of problems from urgency (which they could not respond to in time) to nocturnal enuresis. All described feelings of shame and humiliation as in this example:

There's always the fear and sometimes I don't get there in time and I find myself with wet pyjamas and it's personally very embarrassing.

Man with dementia 04

Strategies included planning activities outside the house only when they knew they could access toilets, accepting help from their spouse (although this sometimes caused tension) and using a variety of absorbent materials for containment, for example towels. Descriptions of the use of incontinence pads included problems of fit and acceptability, as in this example.

I'm so small you know, and I've been cutting them [incontinence pads] and the whole flat is covered in bits of, what do you call it, small pieces, fluff, every day fluff . . . they're so big, I've got to cut them.

Woman with dementia 01

Strategies also included using euphemisms in describing the problems, using humour to overcome embarrassment and trying to protect family members from spillage by clearing up or dealing with urine or wet clothes themselves. The detailed results are reported elsewhere.¹⁵⁸

Discussion

To our knowledge, this is the first study reporting people with dementia's perceptions of these problems of incontinence. The descriptions of embarrassment and shame are no different from those given by other adults.¹⁶⁶ The desire to protect spouses or other family members from the 'pollution of bodily waste'¹⁶⁷ has not been reported before and may have two unintended consequences. The first is that it may increase family carer stress if the person cannot appropriately deal with leakage and excreta. The second is that the family carer may not understand the motivation for such acts and interpret these as the need to protect their dignity by concealment from everyone, including health professionals who could potentially help. Although the study has limitations through size and difficulty in recruitment, it does provide insights that have not been reported previously.

Conclusion

People with dementia are able to describe in detail their experiences and management of incontinence. Their desire to protect their own dignity, but also protect others, may lead to unintended consequences and delays in seeking wider help for such problems.

Views of family carers on the problems of incontinence and effective strategies to manage them

We could find no study investigating family carers' strategies for managing incontinence. The purpose of this study was to investigate family carers' perceptions of the range of incontinence problems and their strategies for managing them.

Methods

The research approach was in the interpretative tradition.¹⁶⁴ A purposive sample of family carers of people with dementia, living in their own homes, was recruited through primary care, specialist community mental health services and voluntary organisations. Qualitative semi-structured interviews (SSIs), based on an open-ended topic guide,¹⁶⁸ were conducted either face to face or by telephone, recorded by tape, transcribed and thematically analysed,¹⁶⁴ using NVivo™ version 8, 2008 software package.

Ethics

Researchers were prepared to manage participant distress appropriately, and also situations that might suggest a vulnerable person was being neglected or harmed. A favourable review was given by Camden and Islington NHS local REC (08/H0722/60 2008).

Results

Thirty-two carers were interviewed. They described a range of problems from supporting the person to remain independent in toileting, through to dealing with inappropriate behaviours, to containing and managing incontinence. Key themes were identified: active problem-solving, protecting the dignity of the person with dementia, problematic responses from health services and unintended consequences. All carers actively used problem-solving strategies but sometimes these were not acceptable or understood by the person with dementia, particularly as the dementia progressed. Most carers reported protecting the person's dignity by not seeking health professionals' help, often until the point of crisis.

I didn't want people to know about her not managing and incontinence . . . I felt her dignity, you know . . . She was so in herself a very dignified lady . . . If she'd have known she'd have been horrified.

Husband c6

Once the carer had decided to seek help, the responses from health professionals were reported to be often less than helpful, and carers reported local health service policies on access to continence products to be inconsistent and often inappropriate to their circumstances. A few carers reported strategies for managing toileting and incontinence that had the potential for distress and harm to the person with dementia. These findings are reported in full elsewhere¹⁶⁹ in a paper that was awarded the Royal College of General Practitioners' Research Paper of the Year 2011, in the category of dementias and neurodegenerative diseases.

Discussion

The reluctance to seek help for toileting and incontinence problems by carers of people with dementia as they seek to preserve their dignity and personhood¹¹⁵ has not been reported before, although the low rate of seeking help for incontinence symptoms is well documented in older adults.¹⁷⁰ The variability and sometimes inappropriate responses of primary care professionals has not been reported previously, to our knowledge. Management strategies were mediated by their acceptability to both the PWD, the carer and other family members. A key influence in carers' management strategies was to ensure that excreta were well contained, an important goal identified by expert panels for incontinence management in frail older people.¹¹⁷ Although the study has limitations because of its sample size, the diversity of the population and the sampling until saturation in data ensured depth and breadth in the findings.

Conclusions

There is a wide range of types of incontinence problems that change over time, and carers managing them are often poorly supported by primary care professionals. Primary care professionals could be more proactive in enquiry, repeated over time, about toileting and incontinence problems; alert to strategies that have the potential for negative effects; and develop their repertoire of referrals, advice and information to reduce crisis and problems.

Views of primary care, social care and specialist mental health staff in community settings on effective strategies

We could find no studies reporting HSC professionals' perceptions of effective strategies for the management of incontinence in this population. The aim of this study was to investigate the perceived range of problems and effective strategies.

Method

The study design was in the interpretative tradition using qualitative individual and group interviews,¹⁷¹ with HSC professionals purposively sampled to ensure a range of generalist and specialist community services, disciplines, grades of staff and those with qualifications regulated through legislation and those without. Participants were approached through organisations that had agreed to participate in the EVIDEM programme and at EVIDEM educational events; these were mainly in north and central London and Hertfordshire. Data were recorded in field notes and in flip charts kept as part of the group discussions, transcribed to electronic documents and thematically analysed.

Ethics

The NRES advised us that the study did not require review as it was a service evaluation. The study followed university research ethics requirements.

Results

We recruited 140 participants from a wide range of staff groups (*Table 40*), and they took part in 30 individual interviews and group interviews. Collectively, they described a wide range of toileting and incontinence problems, with a wide range in the number of problems reported. Some informants mentioned only one or two types of problems, whereas dementia specialist staff, such as the Admiral Nurses, described greater numbers of both physical problems and dementia-related problems.

TABLE 40 Staff participating in interview by professional groups

Staff group	No.
Dementia specialist social care staff	40
LA social workers and care managers	14
Continence nurse specialists	9
GPs	3
Admiral Nurses (specialist dementia care nurses)	10
Consultant old age psychiatrists and medical team	6
Community mental health services for older people and memory service team members (nurses, assistants, psychologists managers)	33
Occupational therapists	6
District and community nurses	3
Voluntary organisations advice and carers support staff	15
Total	139

LA, local authority.

Collectively, they reported a wide repertoire of strategies but many offered only one or two strategies that reflected their type of service. A commonly reported strategy was to refer the patient to another service, in many cases the district nursing service. The small number of district nurse informants focused mainly on using continence pads as a containment strategy. Many informants considered that the local NHS provision of incontinence advice and absorbent products did not address the needs of people with dementia and their carers; in some instances these deficiencies were seen as contributing directly to decisions to move the person to a care home. Other system-level problems were identified, such as the lack of acknowledgement of toileting support in social care assessments.

Discussion and conclusion

To our knowledge there are no other published studies exploring multidisciplinary and multiagency perspectives on managing incontinence for people with dementia living at home, although there are some that have considered the issue from the perspective of care home staff.¹⁷² The study has limitations in that views offered by a small number of informants may not be representative of others throughout England. However, the intention was not to undertake a representative survey but to understand the breadth of issues and strategies. The findings suggest that many staff groups have relatively limited knowledge of the range of problems that can be experienced with a concomitant limited repertoire of responsive strategies. However, the cumulative responses also point to a mosaic of practical, psychological, behavioural, biomedical, environmental and supportive strategies that can be utilised. One question is whether knowledge alone of this mosaic of strategies can influence primary care professional practice in addressing these types of problems. The respondents also pointed to failures of publicly funded systems in addressing these problems, which raises the question of whether or not new commissioning processes and initiatives, such as personal budgets, will be better able to address them.

Experience, including impact and consequences, of people with dementia and their family carers over time

Dementia follows a course of progressive disablement over a number of years.¹⁷³ The experience, impact, cost and consequences over time are poorly described in relation to incontinence and TDs (defined as a range of problems associated with loss of independence in toileting or behavioural symptoms, sometimes resulting in soiled clothing or excreta uncontained in pads or voiding inappropriately). This study investigated the experiences, impacts, costs and consequences of incontinence in people with dementia and their family carers over a period of up to 3 years.

Method

This was a longitudinal mixed-methods¹⁷⁴ study investigating the experience of a purposive sample of people with dementia with continence problems living at home, and of their carers. Personal and general invitations to participate were distributed via community organisations, social care organisations, specialist community mental health services for older adults in five London boroughs, and GPs in eight PCT areas. Data collection was by serial qualitative interviews.¹⁷⁵ In addition, validated instruments were used to characterise the person with dementia who met the criteria of the ICD-10.⁸⁰ Their mental state and abilities were described by the MMSE,⁵² the NPI⁶² and the Disability Assessment for Dementia (DAD),¹⁷⁶ their TDs and incontinence by an adapted International Incontinence Modular Questionnaire [International Consultation on Incontinence Questionnaire (ICIQ)]¹⁷⁷ and their health-related quality of life using the DEMQOL.⁸⁶ Also recorded were the service use and cost consequences using the CSRI Parts 1 and 2,⁸⁸ as well as the carers' health-related quality of life [EuroQol: European Quality of Life-5 Dimensions (EQ-5D)],¹⁷⁸ and burden (ZBI⁸⁷ and NPI Caregiver Distress Scale¹⁷⁹). Analysis of the qualitative data was thematic,¹⁶⁵ through comparisons over time and between cases using the NVivo 8 software package and longitudinal charting. Statistical analyses of quantitative data were undertaken using SPSS version 20 and Stata version 13 software. Costs were derived from the PSSRU Unit Costs of Health and Social Care 2011⁸⁹ and estimates using the Office for National Statistics 2011 Annual Earnings Survey.¹⁸⁰

Ethics

Ethical considerations included those described above (see p. 84). The study was given a favourable review by the Camden and Islington NHS local REC 08/HO722/77 in 2008.

Results

Thirty-four people with dementia and 29 family carers were recruited over 2 years (1 December 2008 to 31 December 2010). During the period of the study, 10 people with dementia died, six moved to care homes and one withdrew. Because of the long recruitment period the remaining participants were in the study for different lengths of time (see *Figure 12*) but many family carers provided retrospective data on entering the study to describe their experiences over a longer period of time (*Table 41*). The characteristics of participants at the first interview are provided in *Table 42*.

The types of toileting and incontinence problems are described in *Table 43*.

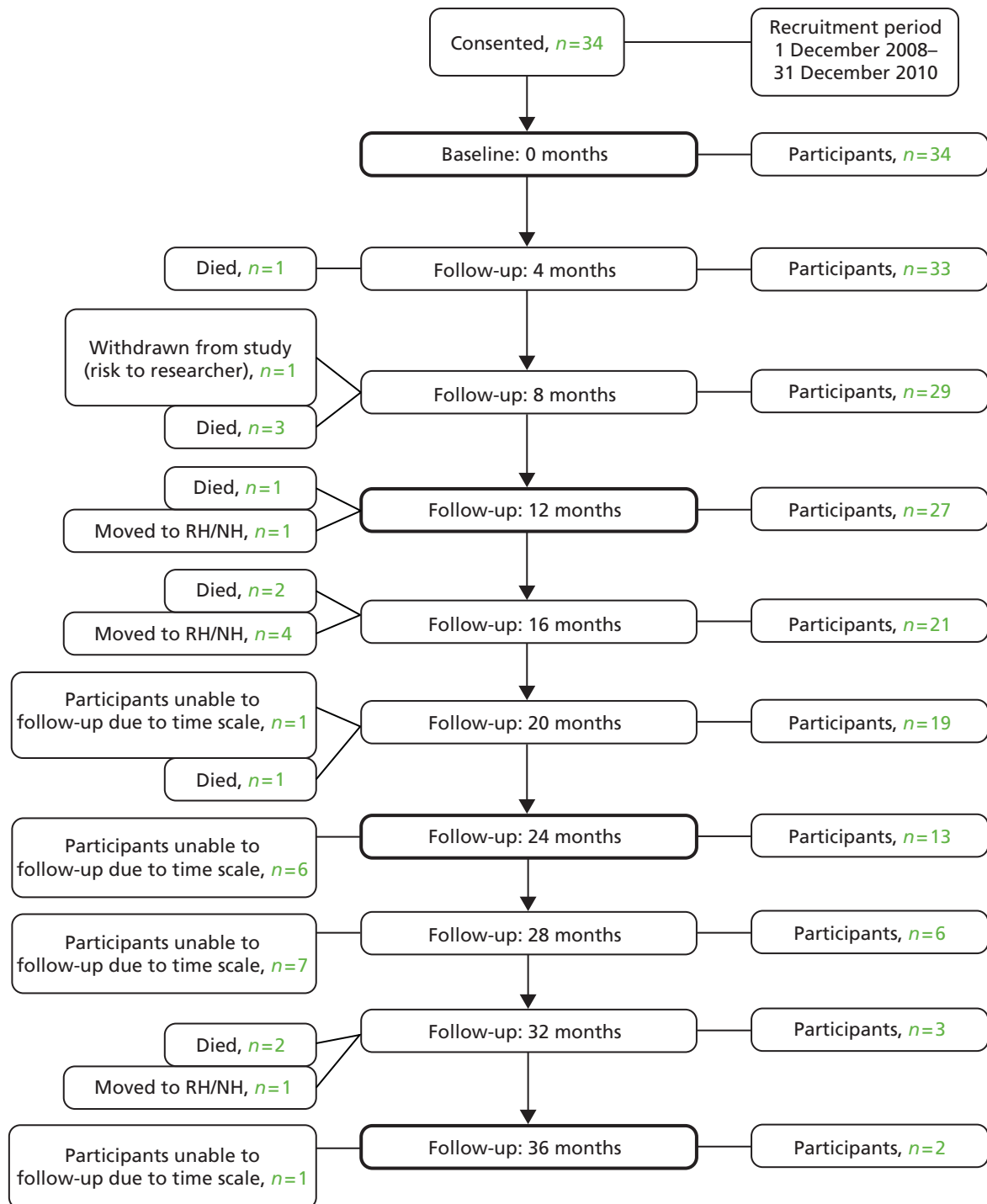


FIGURE 12 Flow diagram of participants over time.

TABLE 41 Length of time of reported data

Months of reported data	No. of participants
0–12	2
13–24	11
25–36	15
37+	6

TABLE 42 Characteristics of the person with dementia and their carer at first interview

Characteristics	Person with dementia (N = 34)	Carer (N = 29)
Male, <i>n</i> (%)	10 (29.4)	13 (44.8)
Female, <i>n</i> (%)	24 (70.6)	16 (55.2)
Age, years (mean/range)	81.9 (62–98)	68.1 (44–88)
Relationship to carer (N = 29), <i>n</i> (%)		
Spouse	17 (58.6)	–
Adult–child	11 (37.9)	–
Sibling	1 (3.5)	–
Ethnicity, <i>n</i> (%)		
White British	24 (70.6)	21 (72.4)
White other	4 (11.8)	1 (3.4)
White Irish	3 (8.8)	3 (10.3)
Black British	1 (2.9)	1 (3.4)
Black Caribbean	1 (2.9)	1 (3.4)
Black African	1 (2.9)	1 (3.4)
Chinese	0 (0)	1 (3.4)
English not first language	6 (17.6)	2 (6.9)
Person with dementia living alone	8 (23.5)	–
Person with dementia median measure scores (range)		
MMSE ⁵² (possible score 0–30) (<i>n</i> = 14)	18 (2–26)	–
DAD ¹⁷⁶ (possible score 0–100%) (<i>n</i> = 33)	15 (0–95)	–
DEMQL ⁸⁶ (possible score 28–116) (<i>n</i> = 8)	87 (52–101)	–
NPI ⁶² (possible score 0–120) (<i>n</i> = 24)	18 (0–69)	–
Carer measure scores (mean/range)		
EQ-5D ¹⁷⁸ (possible score 0–100) (<i>n</i> = 24)	–	75 (40–95)
NPI carer distress ¹⁷⁹ (possible score 0–50) (<i>n</i> = 24)	–	10 (0–32)
ZBI ⁸⁷ (possible score 0–88) (<i>n</i> = 27)	–	30 (11–60)

TABLE 43 Types of problems reported^a

Problem	Baseline	12 months	24 months	36 months
TDs	44.1% (15/34)	21% (4/19)	11% (1/9)	0% (0/2)
Urinary (UI)	29% (10/34)	31% (6/19)	11% (1/9)	0% (0/2)
Faecal (FI)	9% (3/34)	5% (1/19)	0% (0/9)	0% (0/2)
Double (UI plus FI)	56% (19/34)	53% (10/19)	89% (8/9)	100% (2/2)

a Individuals may have had TDs plus incontinence.

The progression of the dementia was evident in participants and was reflected in the DAD scores, which showed a significant reduction over time in ability from a median score of 15 to 10 ($p = 0.003$ by Wilcoxon signed-rank test). A series of basic regression models were fitted to the data. Inter-participant variability was allowed for by random-effect parameter, and bootstrap CIs were used to account for floor and ceiling effects in the outcomes. The effects on each of the carers' measures were adjusted for the person with dementia's NPI measure (*Table 44*). The carers' health-related quality of life scores were significantly negatively affected by the presence of FI (-5.3 , CI -10.4 to -0.1 , significant at the 5% level) but not by TDs or UI. The carers' distress scores (in response to BPSD) were significantly negatively affected in the presence of TDs (6.5 , CI 0.6 to 12.3 , significant at the 5% level) and UI (5.2 , CI 2.7 to 7.6 , significant at the 5% level) but not in the presence of FI.

A number of themes were identified: changes in problems over time; the processes of normalisation, both in managing toileting changes over time and also in managing excreta out of place; the iatrogenic effects of hospital inpatient stays and respite stays in care homes on both the PWD's toileting abilities and physical health (e.g. the development of pressure ulcers); the interplay of decreased mobility and incontinence; and the perceived positive impact of both paid help in personal care, which the carer controlled, and good excreta containment on reducing carer stress. *Figure 13* illustrates some of these themes through the changes and experiences over time of one person with dementia and their family carer. The presence of double incontinence (UI and FI) compared with one type of problem only (TD, UI or FI) was found to significantly increase the costs by 89% from a HSC perspective and by 69% from a societal perspective (*Table 45*). The HSC perspective includes costs both provided by the NHS or government and also privately purchased. Societal costs include costs of the time of the informal or family carers.

TABLE 44 Mean association of TDs with carer measures, with 95% CI

Carer measure	Presence of TDs (95% CI)	TDs adjusted for NPI (95% CI)	Presence of UI (95% CI)	UI adjusted for NPI (95% CI)	Presence of FI (95% CI)	FI adjusted for NPI (95% CI)
EQ-5D ¹⁷⁸	0.1 (-5.6 to 5.7)	3.6 (-4.0 to 11.2)	-0.8 (-12.0 to 10.5)	-2.8 (-18.0 to 12.4)	-5.3 ^a (-10.4 to -0.1)	-5.1 (-12.4 to 2.3)
Caregiver Distress Scale ¹⁷⁹	6.5 ^a (0.6 to 12.3)	N/A	5.2 ^a (2.7 to 7.6)	N/A	1.8 (-2.2 to 5.8)	N/A
ZBI ⁸⁷	4.9 (-0.7 to 10.4)	2.4 (-6.0 to 10.8)	0.1 (-11.3 to 11.5)	-4.1 (-19.6 to 11.4)	-0.1 (-4.8 to 4.6)	-2.9 (-9.0 to 3.3)

N/A, not applicable.

a Significant at the 5% level.

Participant 014: Female, aged 70 years, white British (T1)
Diagnosis: PPA, Pick's disease and frontal lobe dementia
Living circumstances: Living with husband in owned house
DAD score: 0% (T1), 0% (T2), 0% (T3)
NPI score: 02 (T1), 00 (T2), 08 (T3)
NPI distress score: 01 (T1), 00 (T2), 00 (T3)
Carer burden score: 13 (T1), 15 (T2), 16 (T3)
Carer QoL scores: 90 (T1), 70 (T2), 85 (T3)

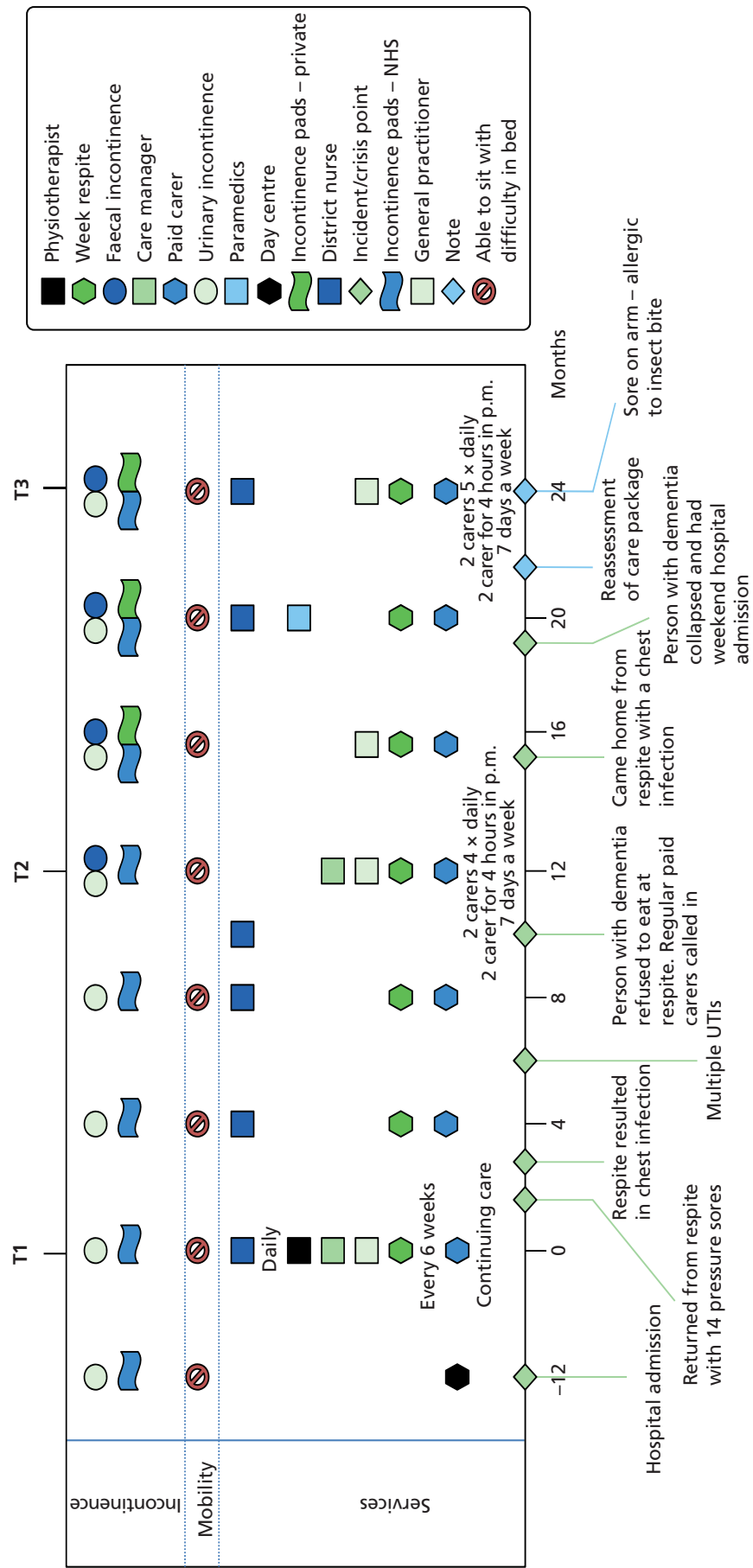


FIGURE 13 A longitudinal chart of one participant's experience. PPA, primary progressive aphasia.

TABLE 45 The 3-month mean costs by number of incontinence problems

Issue present, and significance	3-month mean costs in pounds sterling (SD): <i>n</i> = 34		
	HSC (SD)	Societal (SD)	<i>n</i>
One type only (TDs or UI or FI)	4200.9 (4110.8)	7464.6 (4885.1)	15
Double incontinence (UI and FI)	8207.5 (6722.2)	12431.3 (7163.7)	19
<i>p</i> -value (2 > 0 or 1)	0.03	0.01	

Discussion and conclusion

To our knowledge this is the first study reporting experiences of incontinence over time, and impacts upon this patient population and their carers. The small sample is a limitation but provides insights into the experience, types, costs and impact of incontinence that are not provided elsewhere. The results in full are discussed elsewhere.¹⁶⁹ The negative impact of the presence of FI on carer quality of life warrants further investigation. The perceived positive impact of assistance in personal care tasks, which are within the control of the carer, and effective containment of excreta require further investigation, in particular whether or not it influences or defers decisions about moving to a care home.

Phase 3: investigating the feasibility, effectiveness and acceptability of an identified strategy

Effective containment of excreta was identified as very important to family carers, both in discussing their experiences and also in its impact on factors such as reported burden (Phases 2 and 3). Carers within and outwith the advisory group prioritised the investigation of designs of incontinence pads to meet the needs of people with dementia and their carers. The one previous study of acceptability and effectiveness of different pad design did not include people with dementia living at home.¹⁸¹ The study aimed to investigate the feasibility of ascertaining acceptability, effectiveness and associated costs of different types of incontinence pad designs as used by people with dementia living at home and also to provide data to inform both future research design and also service providers.

Method

This was an observational study based on the methods of a previous clinical trial with cognitively intact adults¹⁸¹ and informed by the family carers in the advisory group. The study aimed to recruit a sample of 40 family carers, diverse in their, and the PWD's, characteristics, for example age, gender, stage of dementia. Family carers were recruited through voluntary organisations across Greater London, specialist mental health services for older people in North West London, and general practices and a community continence service in South West London. At time point 1, the family carers were instructed in observational and diary data collection. They were asked to complete the diary sheets for 1 week. Data characterising the person with dementia (DAD,¹⁷⁶ NPI⁶²) and the family carer burden¹⁷⁶ and the type of incontinence (ICIQ)¹⁷⁷ were also collected. At time point 2, the family carers were interviewed about the experience of data collection and their diaries retrieved. Analysis of quantitative data was undertaken using the SPSS version 20 software package. Analysis of the qualitative data was undertaken thematically.¹⁶⁵

Ethics

Ethical issues were as outlined previously (see p. 84). The study was given a favourable review by the NHS South East REC (10/H1102/34) in 2010.

Results

Twenty-five family carers of people with dementia living at home were recruited to the study over 18 months. There was diversity in the sample of family carers, the person they cared for and the toileting and incontinence problems (*Table 46*).

The range and funding source of aids and adaptations used are described in *Table 47*.

TABLE 46 Characteristics of participants

Characteristics	Family carer (N = 25)	Person with dementia (N = 25)
Female, n (%)	19 (76)	17 (68)
Male, n (%)	6 (24)	8 (32)
Age, years (median/range)	63 (32–89)	84 (64–90)
Relationship, n (%):		
Spouse	11 (44)	
Adult–child	11 (44)	
Sibling and other	3 (12)	
Ethnicity, n (%):		
White British	19 (76)	22 (88)
White other	4 (16)	2 (8)
White Irish	1 (4)	0 (0)
Black Caribbean	3 (12)	1 (4)
English not first language, n (%)	3 (12)	
ZBI ⁸⁷ possible score 0–88: median (range)	45 (8–60)	
DAD ¹⁷⁶ possible score 0–100%: median (range)		23 (0–83)
NPI ⁶² possible score 0–120: median (range)		21 (0–72)
TDs only		1 (4%)
UI only		4 (16%)
FI only		1(4%)
TDs + UI		3 (12%)
UI + FI		8 (32%)
TDs + UI + FI		8 (32%)

TABLE 47 The range of aids, equipment, adaptations and funding source

Items used	Provided by or funding source (n = 24)				
	Own	NHS	LA	NHS + own	LA + NHS + own
Incontinence pads	8 (33%)	10 (42%)	0 (0%)	5 (21%)	1 (4%)
Equipment (e.g. commodes)	5 (21%)	6 (25%)		0 (0%)	13 (54%)
Adaptation of home (17 had no adaptations)	6 (25%)		1 (4%)		

LA, local authority.

There was also diversity in the designs of incontinence pads used, which changed for some individuals when outside the home and between day and night-time (*Table 48*).

Those who were recruited demonstrated high levels of commitment to the study's aims. Twenty (80%) of the carers were able to complete some days of the diary sheets (mean number of days 8, range 2–16 days). Carers entered data about each change of pads; the number of times they entered data ranged from 4 to 56. One aspect was leakage of excreta outside the pad, for example onto clothes. The rate of leakage by pad design is reported in *Table 49*.

Analysis of data on the acceptability and effectiveness of different designs of incontinence pads revealed several important factors. Designs of pads were acceptable to the carer when they could safely and efficiently be changed by the carer (and others such as day centre staff). Safety factors related to designs that allowed the carer to change the pad and hold the person steady if necessary (i.e. to minimise risks of a fall). Efficiency factors related to speed in changing, to cause least disturbance to the person and with minimal effort on the part of the carer. Effectiveness related to the ability of the design to ensure containment of excreta.

It was evident that the required specifications of pads changed according to location (e.g. the use of public toilets or at home), the availability of the carer or others to change the pad and whether a pad was to be used in the day or at night. At night, 40% of the sample ($n = 10$) used either a more absorbent pad than in the day, a different design or two designs in combination. The results are described in full elsewhere.¹⁶⁹

TABLE 48 Types of design of incontinence pad used day and night

Time period	Design of incontinence pad used ($n = 27^a/n = 25$ night ^b) ^a					
	Large shaped inserts	Pull-ups	Small inserts	Nappy	T-shaped nappy	Combination of two types at once
Daytime ^c	10	10	4	1	0	2
Night-time	8	8	1	1	1	5

a Missing data from one person and two used two designs.

b One used no pad at night, and one alternated between two designs.

c Two participants changed when outside of the home to a higher level of absorbency ($n = 1$) and securing the pad to different type of underpants.

TABLE 49 Frequency of leakage events by design of incontinence pad

Design	No. of pad changes	No. of leakage events (%)
Large shaped insert pads	201	51 (24)
Pull-ups	218	41 (19)
Nappy	19	4 (21)
T-shaped nappy	8	2 (25)
Small insert pad	19	1 (0.05)

Discussion and conclusion

To our knowledge this is the first study exploring preferences and effectiveness of incontinence pad design when used by people with dementia living at home and their family carers. Considerable endeavour and resources went into the recruitment process, which was much slower than anticipated, and we were unable to recruit the planned numbers: future studies will need to take great care with recruitment strategies. There are limitations due to the sample size but the study provides data that will be used to inform the development of a clinical trial protocol. It also provides insights into the specifications in effectiveness and acceptability of different pad designs for people with dementia living at home not provided elsewhere.

Phase 4: developing and testing resources for practice

Drawing on the evidence of the earlier studies, a priority for the family carers in the advisory group was practical resources to assist primary care professionals to both recognise the range of problems faced by people with dementia and their carers and promote a variety of strategies that would be helpful.

This phase of the study therefore undertook the development and testing of a continence assessment tool for people with dementia, to be used by primary care professionals, primarily community nurses. It also undertook the development and testing of supporting educational materials.

Developing and testing a continence assessment tool and resources

The aim of this study was to develop and test a continence assessment tool and supporting resources for people with dementia, to be used by primary care professionals, primarily community nurses.

Methods

An adapted three-stage Delphi consultation study¹⁸² was used. Stage 1 brought together an expert group of carers, dementia specialist workers from the voluntary sector and health professionals. This group examined commonly used continence assessment tools, and discussions were facilitated to describe a broad range of principles and issues that would underpin an assessment tool designed to address the needs of people with dementia. At stage 2 a prototype dementia-focused continence assessment tool was developed using the data generated in stage 1, asking for agreement or disagreement to items plus suggestions for further items. This was used to consult, in writing, both the expert group in stage 1 and also a further group of carers and specialist continence professionals. The prototype was further adapted. At stage 3 a different, wider group of experts (carers and professionals) was consulted in writing. They were sent the draft dementia-focused assessment tool (*Figure 14*) together with a questionnaire to test its face and content validity. Recipients were asked (1) whether or not the tool would improve recognition of the problems (face validity) and (b) to rate each item for importance and identify missing or unnecessary items (content validity). It was emphasised that the tool's remit was a *supplement* to the continence assessment tools and guidance currently used, hence it was called an add-on tool. Participants were also sent supporting resource materials on which to comment (*Table 50*).

Ethics

The NHS research ethics service advised the researchers that the study did not require NHS research ethics review. The study adhered to university ethical conduct of research requirements.

<p>Dementia-focused CONTINENCE ASSESSMENT add-on tool</p>		Date	<p>Describe the impact of the problem for the client and the carer</p> <p>How bothersome does the client find the toileting difficulty? What is the impact on the client? (during the day/at night) How bothersome does the carer find the toileting difficulty? What is the impact on the carer? (during the day/at night)</p> <p>About the client</p> <p>Describe the client's cognitive abilities or degree of cognitive impairment (this may be a subjective view, or described using locally agreed assessment tools)</p> <p>What is the client's insight into their memory impairment? Does the client need help with intimate care? Is the client willing to accept help with intimate care?</p> <p>About the carer</p> <p>How are the client and carer related? Does the carer live with the client? Is the carer the sole carer? Is anyone else involved in providing informal care? Is the carer a full-time carer? Are they employed (full-time/part-time)? Have they had any training as a carer? Are there aspects of the carer's health that have an impact on them providing care? If the client needs help with intimate care, is the carer able, and willing, to undertake this aspect of care? Is it appropriate, and acceptable to the client, for the carer to assist with intimate care? Is the carer aware of statutory benefits that they, or the client, may be entitled to? For example, Attendance Allowance (client); Carer's Allowance and Disability Living Allowance (carer) Offer information about how to access the application forms What are the carer's expectations of this continence assessment and the continence service?</p>
		Place	
		Assessor	
Client details	Carer details	Referred by	
NHS number		Reason for referral	
Client aware of referral?	Carer aware of referral?		
<p>IF THE CLIENT LIVES ALONE, has a paid carer or family carer been consulted or provided information about the toileting difficulty/incontinence problem?</p>			
<p>Describe the problem and how it is being managed</p>			
<p>What is the toileting difficulty? Client's view: What is the toileting difficulty? Carer's view:</p>			
<p>When does it occur, and how frequently? (day/night-time; occasionally, once, or several times a day/night)</p>			
<p>Are there different toileting difficulties in different places? (when the client is at home, outside the home, at a day centre)</p>			
<p>How long has the client had this toileting difficulty?</p>			
<p>Is the toileting difficulty: improving/unchanged/worsening?</p>			
<p>How have the client and carer been managing? (particular strategies; aids such as pads, commode, mobile hoist; hygiene)</p>			
<p>THESE SECTIONS TO BE INCORPORATED AT THE END OF THE LOCAL CONTINENCE ASSESSMENT FORM</p>			
<p>Summary/next steps</p> <p>Immediate support needs identified: Is an urgent response required? Is a supply of temporary aids/incontinence pads needed?</p> <p>Information, advice and support provided for carer: Carer's expectations discussed: Other agencies/services involved? Permission obtained to share information?</p> <p>If the client lives alone: (1) Have others in the care network been contacted to help develop the care plan? (2) Does this person need referral to social services?</p> <p>Care/management plan: Is the plan framed in terms of dependent continence* OR contained incontinence* OR a combination?</p> <p>(N.B. this section may be unnecessary as it is likely to be a component of the local assessment form)</p> <p>*Dependent continence: dry, with toileting assistance, behavioral treatment, and/or medications *Contained incontinence: urine contained with pads or appliances Duteau C, et al. (2010) <i>Incontinence in the frail elderly. Report from the 4th International Consultation on Incontinence. Neurology and Urodynamic</i> 29, pp 165–178</p> <p>Review: Is another 'assessment' visit required? (to gather all relevant information, or to assess client in their home) Date of next review:</p>			

FIGURE 14 The EVIDEM-C add-on continence assessment tool.

TABLE 50 Resource material to accompany the EVIDEM-C add-on continence assessment tool

Toileting/continence issue	Examples of suggested actions/strategies		Further professional assessment or source of advice
	Techniques/knowledge/activities	Environmental/aids	
1 Recognising the need to void but unable to act on it in a timely way	Awareness of aspects of the person's behaviour that may signal the need to void, for example unexplained restlessness, tugging at clothes Map usual voiding patterns and plan support accordingly PV if acceptable		
2 Apathetic or not acting on the need to void	Map usual voiding patterns and plan support accordingly PV if acceptable		Consider assessment by another professional for other problems, such as depression, e.g. GP, CPN
3 Difficulty in locating the toilet in the home	Map usual voiding patterns and plan support accordingly PV if acceptable	Toilet signage	Occupational therapist <i>PromoCon</i>
4 Difficulty in recognising the toilet	Map usual voiding patterns and plan support accordingly PV if acceptable	Contrast and lighting, e.g. different coloured toilet set to toilet bowl Declutter the bathroom	Occupational therapist <i>PromoCon</i>
5 Unable to perform all difference of actions to void in the right place	Map usual voiding patterns and plan support accordingly Assist men to sit to urinate Family carer of opposite sex may need advice/explanation on how to assist in this	Consider ways in which the task could be simplified, e.g. pull-up trousers/jogging bottoms rather than zips	Occupational therapist <i>PromoCon</i>
6 Unable to perform all personal hygiene afterwards	Map usual voiding patterns and plan support accordingly Family carer of opposite sex may need advice/explanation on how to assist in this Consider wipes rather than toilet paper		Advice from: Continence specialist nurse Occupational therapist <i>PromoCon</i>
7 Physically unable to get to/use the toilet in a timely way and/or has dexterity problems which make it difficult to manage clothes and personal hygiene		Grab rails Raised toilet seats Commodes Urine bottles Extended wipes Easier clothing (Velcro® closures/elasticated waists)	Consider potential for assessment by other professional, e.g. GP and/or physiotherapist and/or occupational therapist <i>PromoCon</i> <i>Disabled Living Foundation</i>

continued

TABLE 50 Resource material to accompany the EVIDEM-C add-on continence assessment tool (continued)

Toileting/continence issue	Examples of suggested actions/strategies		Further professional assessment or source of advice
	Techniques/knowledge/activities	Environmental/aids	
8 Locks toilet door and is then unable to comprehend how to unlock it	Remove or disable the toilet door lock		Occupational therapist <i>PromoCon</i>
9 Uses inappropriate places or receptacles	Use behavioural management techniques, e.g. the ABC approach (Antecedents, Behaviour and Consequences) to then decide appropriate strategies: What happened, when? In what circumstances? With what consequences? Plan strategies based on this information	Consider strategies to make it easier to locate a toilet Place appropriate receptacle in the place used (if appropriate)	Advice from: CPN Occupational therapist <i>PromoCon</i> ^a
10 Aids not acceptable or not helpful		Consider different designs	Advice from: Occupational therapist <i>PromoCon</i> ^a <i>Disabled Living Foundation</i>
11 Resists assistance in toileting	Check awareness of good communication techniques for people with dementia to reduce anxiety/fear/embarrassment/reluctance Use behavioural management techniques to problem solve		Consider potential for assessment and advice by other professional, e.g. GP, CPN, clinical psychologist
12 Restlessness/does not remain on/at the toilet long enough to void	Check awareness of good communication techniques for people with dementia to reduce anxiety/fear/embarrassment/reluctance (Information Sheet 5) Use behavioural management techniques to problem solve		Consider other reasons for restlessness, e.g. pain Consider potential for assessment and advice by other professional, e.g. GP, CPN
13 Resists changing of body-worn pads	Check awareness of good communication techniques for people with dementia to reduce anxiety/fear/embarrassment/reluctance (Info. Sheet 5) Use behavioural management techniques to problem solve	Consider a different design of body-worn pads	Advice from: <i>Continence specialist nurse</i> <i>PromoCon</i> ^a <i>Disabled Living Foundation</i> Consider potential for assessment and advice by other professional, e.g. GP, CPN, clinical psychologist

TABLE 50 Resource material to accompany the EVIDEM-C add-on continence assessment tool (continued)

Toileting/continence issue	Examples of suggested actions/strategies		Further professional assessment or source of advice
	Techniques/knowledge/activities	Environmental/aids	
14 Removes all body-worn pads (dry and/or wet)	Use behavioural management techniques to problem solve (Information Sheet 4)	Consider a different design of body-worn pads, e.g. pull-up pant designs	Advice from: <i>Continence specialist nurse</i> <i>PromoCon</i> ^a
15 Leakage from body-worn pads	Ensure the product is being used correctly Ensure other issues are not interfering with the product's effectiveness, e.g. over-liberal use of barrier creams	Consider a different design or absorbency of body-worn pads (Information Sheet 6) Information about, and opportunities to test different designs of pads	Advice from: <i>Continence specialist nurse</i> <i>PromoCon</i> ^a
16 Problems voiding at night	Consider pattern of fluid intake, aiming for 1.5 l per day but reducing intake and type in the evening (cross reference to fluids and diet information in local assessment tools)	Night-time lights with motion sensors Consider commode/urine bottles for night-time use	Consider whether medications contributing to nocturia and refer for review as appropriate Consider potential for other professional to address any causes of nocturia, e.g. GP Advice from: <i>OT</i>
17 Problems in managing outside the home	Consider carrying a change of lower garments in case of 'accidents'	Provide information on RADAR ^b keys	
18 Concerns about 'smells'	Awareness of smell-neutralising products Consider removing items where accidental spills may not be noticed, e.g. toilet mats		Advice from: <i>Continence specialist nurse</i> <i>PromoCon</i> ^a
19 Problems in faecal matter in the wrong place (smearing, clearing up inappropriately and concealment of faeces)	Consider whether there are problems of constipation which can be addressed (local guidance applies) NB. The innate response of curiosity can mean people investigate (feel for) the 'problem' which often results in faeces on hands Use behavioural management techniques to problem solve	Toilet signage	Consider potential for assessment and advice by other professional, e.g. GP, CPN, clinical psychologist, continence specialist nurse <i>PromoCon</i> ^a
20 Problems in that the person takes multiple doses of laxatives, having forgotten taking them before, resulting in diarrhoea		Consider the use of medication aids such as dosette boxes Advise on medication storage	Consider potential for assessment and advice by other professional, e.g. GP

continued

TABLE 50 Resource material to accompany the EVIDEM-C add-on continence assessment tool (*continued*)

Toileting/continence issue	Examples of suggested actions/strategies		Further professional assessment or source of advice
	Techniques/knowledge/activities	Environmental/aids	
21 Problems of disposal of used body-worn pads	Awareness of principles of hygiene and waste disposal		
22 Problems of concealment of soiled clothing or pads	Use behavioural management techniques to problem solve		Consider potential for assessment and advice by other professional, e.g. GP, CPN, clinical psychologist

CPN, community psychiatric nurse.

a PromoCon provides a national service to improve the life for all people with bladder or bowel problems by offering product information, advice and practical solutions to both.

b RADAR is a National Key Scheme, which offers disabled people independent access to locked public toilets around the country.

Results

The three stages of the Delphi consultation involved 46 carers and professionals (*Figure 15*).

At stage 1, the key principle agreed by the group was that the typical NHS continence assessment tools should be turned 'upside down', and that the first question in the tool should be an enquiry about the problem and its impact as defined by the person (if able) and their carer. At stage 3, 26 experts, of the 50 invited, returned the questionnaire (*Table 51*).

The majority of respondents (87%) perceived the tool as being likely to improve primary care professionals' recognition of the toileting and incontinence problems experienced by people with dementia and their family carers. The GPs could see the value of the tool as an educational rather than a practice aid. All agreed that the first two questions, on the problem and the impact, were important. Most agreed on the importance of the items within the tool, although not all items were supported equally. For example, the carers did not rank the question regarding awareness of benefits as important. Caveats to the value of the tool on its own were added, such as the need for training. The results in full are described elsewhere.¹⁸³

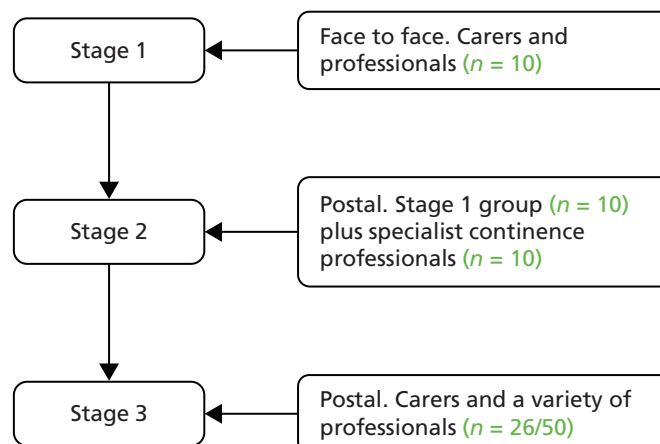
**FIGURE 15** The three-stage Delphi consultation and participants.

TABLE 51 Respondents to Delphi stage 3

Respondents' area of expertise	No. of responses
Carer	8
GP	2
Geriatrician/psychogeriatrician	1
Continence nurse specialist	3
District nurse/community nurse	7
OT	2
Other	3
Total	26

Discussion and conclusion

The face and content validity of the dementia-focused continence assessment tool were established. The study had limitations in the response rate from some groups but provides a breadth of opinion not provided elsewhere on such an assessment tool. The involvement of family carers (i.e. experts by experience) in the first two stages ensured that the perspective of service users was present. Continence services in the UK have been repeatedly criticised for the absence of service user involvement.¹⁵⁸ To our knowledge there have been no other studies developing continence assessment tools tailored to people with dementia. Using a three-stage adapted Delphi consultation technique we created a tool (see *Figure 14*) along with supporting resources (*Table 50*) that is person centred¹²⁰ rather than constructed from a biomedical perspective. The challenge, as pointed out by a number of participants, is how to ensure that those using the tool also adopt a person-centred approach and have a repertoire of strategies to address the problems identified.

Summary of the main findings

This study investigated ways in which toileting and incontinence problems could be addressed for people with dementia living in their own homes. The study design drew on the MRC framework for the development of complex interventions.¹⁰¹

The first phase was of one of review. Little evidence was found on prevalence, effective conservative interventions or local clinical guidance or provision of NHS-funded incontinence products tailored to the needs of this population. Our nested cohort study provides data on incidence of incontinence in this population for the first time.

The second phase explored the experiences and strategies of people with dementia, their family carers – including longitudinally – and of HSC professionals. People with dementia and their family carers experienced multiple impacts, including humiliation, distress, quality of life, and financial and iatrogenic consequences from some care services. The carer strategies emphasised preservation of dignity and effective containment of excreta. Decision-making balanced both the needs of the person with dementia and the family members. Some solutions had the potential to have unintended, negative consequences for the person with dementia. HSC professionals varied in the extent to which they recognised the range of problems and, consequently, in their repertoire of possible strategies.

The third phase explored the feasibility of investigating the effectiveness and acceptability of different designs of incontinence pads with people with dementia. Although there were significant problems in recruitment, those who volunteered were committed to the study. The study also revealed the types of

criteria family carers used in assessing designs of incontinence pads. This included safety and efficiency in changing pads as well as effective containment of excreta. These specifications changed in different settings, for example outside the home and at night-time.

In the fourth phase, a continence assessment tool (*Figure 14*) and supporting resource (see *Table 50*) were designed with an expert group and bench tested through a Delphi process. This used a person-centred approach and was tailored to the needs of people with dementia living at home. It was found to have good face and content validity, although it raised questions regarding whether or not it and the supporting materials alone could change professional practice. In addition, material from this and other phases were used to provide continuing professional development education materials for GPs,¹⁸⁴ community nurses¹⁸⁵ and social care staff.

Strengths and limitations

These have been described at each phase. In overview, the study strengths were the presentation of new knowledge not previously reported in each phase. The iterative processes between the phases allowed for greater reflexivity and responsiveness to both findings and the input from carers of people with dementia as well as professionals. The main weakness lies in the failure to always achieve the planned sample size, and the consequences of this for external validity. However, dementia and incontinence are both stigmatised conditions and the discussion of excreta, particularly faeces, is often a taboo subject in all societies.¹⁶⁷ This study was successful in engaging people with dementia and family carers in research on incontinence, and is a strength in both the research approaches and findings. The failure to always engage practitioners in studies indicates that this population and these types of problems are not necessarily perceived as a priority.

Interpretation of the findings

The study has addressed all of the research questions presented at the beginning of the chapter.

First, each phase of the study was able to add to the body of knowledge that primary care practitioners and commissioners can draw upon, because there is very little other evidence or guidance available tailored to this population.^{117,118} Toileting and incontinence problems are neglected among those who have been, until relatively recently, an overlooked population: people with dementia living at home.

Second, the depth and breadth of the description of the problem of incontinence and its impact, provided in this study, expand and illuminate accounts of people with dementia in care homes¹⁸⁶ and studies of older adults with incontinence but without cognitive impairment.^{166,170}

Third, a key message from this study for primary care professionals was to proactively enquire at each contact about toileting/bladder and bowel problems. The range of problems (from those amenable to medical treatment such as urinary tract infections through to voiding in inappropriate places) suggested a stepwise approach to identifying suitable and acceptable management strategies. The findings indicated that primary care professionals need a repertoire of strategies that draws on knowledge of cultural, psychological, behavioural, biomedical, technical and environmental aspects, as well as local systems, in order to help solve practical problems. This study has been able to develop resources for primary care practitioners that take cognisance of all factors (see *Figure 14* and *Table 50*). There is little other research detailing this mosaic of interlocking incontinence problems, although it is evident in the report of eight case studies in Australia.¹⁸⁷ Expert opinion tends to focus on physical practicalities¹¹⁷ or behavioural techniques¹⁸⁸ as solutions. It has highlighted for the first time that some strategies adopted by carers (family and paid care workers) may be unintentionally detrimental to the person and that health-care professionals need to be alert to this possibility.

Fourth, the study has developed and tested the first person-centred tool for continence assessment by primary care nurses, tailored to people with dementia living at home. This requires further field testing and evaluation.

Fifth, the study has demonstrated the high priority that family carers place on adequate containment of excreta, and its link with carer quality of life. The evidence of less-than-helpful responses from some NHS continence services supports other accounts from service users about variation in service quality and lack of professional help.¹⁴⁵ This study provides further evidence to support a continence paradigm shift from *cure and prevention* to *very good containment* as proposed by the International Continence Society expert group on UI in frail elders.¹¹⁷ A pilot study has been conducted that investigated the acceptability and effectiveness of different continence pad designs with people with dementia living at home and their carers. The results indicate that a clinical trial of designs of pads is feasible, although with caveats on recruitment, as discussed below.

Sixth, the study highlighted the difficulties in recruiting people with dementia and their family carers to observational studies that address issues of incontinence. This has also been reported in studies attempting investigations of interventions in the USA^{149,150} and Australia.¹⁸⁷ The influence of embarrassment and stigma on clinical practice and research for both dementia and incontinence is well documented.^{4,116}

Conclusions

Incontinence has been described as a 'geriatric giant',¹⁸⁹ a significant problem among older adults, and the evidence from this study suggests that it is yet to be 'tamed' for those with dementia living at home. The reasons are multifactorial and a mosaic of strategies is required to both reveal the problems and manage them in ways that are acceptable to the person with dementia and their family members. This study suggests that there are strategies and responses that primary care professionals and others can use to encourage greater openness that may reduce the taboo of incontinence within the stigma of dementia. It remains to be seen if these approaches, combined with more emphasis on effective containment of excreta, influence the point at which decisions are made for a person with dementia to move to a care home.

Impact

In addition to the impact through the presentations at events attended by HSC professionals, people with dementia and their family carers (see *Tables 70 and 71*), the study can point to two other types of impact. The first was the award to the study by the Royal College of General Practitioners for Research Paper of the Year 2011 in the category of dementias and neurodegenerative diseases.¹⁶⁹ The second relates to the invitations to provide materials on incontinence and dementia for the continuing professional development of:

- GPs by the *British Medical Journal* Quality group¹⁸⁴
- nurses by the Royal College of Nursing-published *Nursing Standard*¹⁸⁵
- adult care staff by the South East England DH and the Social Care & Local Partnerships Programme.

Building research capacity

Laura Cole, research associate, has undertaken part-time doctoral study registered at St George's University of London.

Changes to protocol

Owing to recruitment problems, the continence element of the programme did not undertake a longitudinal cohort study. Instead, a longitudinal qualitative study was agreed and undertaken. (Agreed by the Programme Director, December 2010.)

List of appendices

Protocols^a

Appendix 17 Chapter 3: Overall EVIDEM-C protocol 2007.

Appendix 18 Chapter 3: Protocol – Exploring issues and solutions in promoting continence and managing incontinence with people with memory problems living at home and their carers, 2008.

Appendix 19 Chapter 3: Protocol – Professional views of current issues and solutions in promoting continence and managing incontinence with people with memory and cognition problems living at home.

Appendix 20 Chapter 3: Protocol – Investigating the experience of managing continence problems over time, version 2, 2010.

Appendix 21 Chapter 3: Protocol – Incidence and management of incontinence in general practice patients with dementia; an analysis of THIN data, 2011.

Appendix 22 Chapter 3: Protocol – Investigating the acceptability, effectiveness and associated costs of different types of absorbent products used for incontinence by people with memory problems living at home, 2010.

Appendix 23 Chapter 3: Protocol – a modified Delphi consultation to develop a dementia-focused continence assessment tool for use with people with dementia living at home, 2010.

Appendix 24 Chapter 3: Adoption by research networks and research permissions.

Appendix 25 Chapter 3: EVIDEM-CL1 March 2011 – briefing for Local Authority Adult Services managers and social workers.

Research instruments and tools

Appendix 26 Chapter 3: Aide-memoire for guided conversations with the person with dementia.

Appendix 27 Chapter 3: Aide-memoire in the qualitative interview study with family carers.

Appendix 28 Chapter 3: Interview tools to characterise the person with dementia and the carer in the longitudinal study and absorbent pads study.

Appendix 29 Chapter 3: Validated tools used in the longitudinal study and the absorbent pads study.

Appendix 30 Chapter 3: Toileting difficulties and incontinence questions used in addition to the ICIQ-UI and ICIQ-N, for the longitudinal study and the absorbent pads study.

Appendix 31 Chapter 3: Further incontinence questions about pad usage for the longitudinal study.

Appendix 32 Chapter 3: Additional table in the Client Service Receipt Inventory (part 1) longitudinal and absorbent pads study.

Appendix 33 Chapter 3: Data collection tools for examining feasibility and acceptability in the absorbent pads study.

Appendix 34 Chapter 3: Additional Table in the Client Service Receipt Inventory (part 1) for the absorbent pads study.

a This includes the overall EVIDEM-C protocol as written in 2007, plus the subsequent protocols written for individual elements. Study tools and instruments are in *Appendices 26–34*. *Appendix 24* lists the applications made for study adoption, research governance permissions and NHS service support costs for research. Details of research ethics review are given with each study in the main report.

Chapter 4 EVIDEM-EoL: quality of care at the end of life

Abstract

Timely and appropriate agreements between visiting health-care professionals and care home staff regarding end-of-life care for older people with dementia (OPWD) are difficult to reach. This study tracked care received by 133 OPWD over 18 months in six residential care homes, including medication review and economic evaluation. Interviews with residents, care home and visiting NHS staff focused on their views of end-of-life care for OPWD and ways of working. Just over 20% of the resident cohort died. There were no significant differences between those who died and those still alive in terms of sex, age, care home, duration of prior residence or a formal diagnosis of dementia. Sedative load was not significant but inappropriate prescribing was. Providing end-of-life care to OPWD was characterised by three types of uncertainty: treatment uncertainty related to difficulties in prognostication and how to interpret and manage key events and symptoms; relational uncertainty related to roles, responsibilities and relationships among those involved; and service uncertainty related to service capability.

Phase 2 used a co-design approach [Appreciative Inquiry (AI)] with three of the six care homes that built on existing relationships and expertise and, when appropriate, end-of-life care tools. The intervention was evaluated in terms of its ability to address the different types of uncertainty. AI did not increase resource use and there was a reduction in hospital costs. The intervention supported a shift in care home culture that could mitigate uncertainties inherent to end-of-life care of OPWD and different ways of working between NHS and care home staff.

Introduction

Background: the need for this study

People with dementia have a limited life expectancy and the type of end-of-life care that they need has been widely discussed.^{190–193} These discussions focus particularly on the place of care and on the adaptation of existing end-of-life care pathways, but people with dementia experience different trajectories of functional decline and have different needs.^{194,195}

Communication problems, confusion, functional loss, nutritional deficiencies and complications, such as infections and incontinence, can compound the distress of a person who is dying, challenge clinicians' knowledge and expertise,¹⁹⁶ and result in inappropriate medical interventions and referral to hospital.^{197–199}

There are significant methodological challenges in researching end-of-life care for people with dementia.^{200,201} Most research in this area tends to rely on proxy or retrospective accounts of particular symptoms and events. Fewer studies have addressed the environment and organisation of care, or decisions by different practitioners on individual patient outcomes.

In the UK, the quality of care of people with dementia in care homes is variable.^{202–204} The cognitive ability and dependency of residents vary between care homes, and there is a considerable overlap in residents' needs between homes with on-site nursing and those without.²⁰⁵ Many factors influence how care homes work with primary health-care services. These include ownership, staff turnover, the qualifications of the care home manager, access to specialist palliative care, financial incentives offered to GPs, and the history of innovation within the home.^{206–210} There is little evidence that care home residents, relatives and staff are involved in identifying priorities for end-of-life care for people with dementia, or in developing models

of care that go beyond the individual patient-focused encounter. There is a need to develop and test dementia-specific approaches to end-of-life care for this often marginalised population.^{211,212}

The NHS End of Life Care Programme for care homes²⁰⁹ seeks to ensure that when residents are dying they can avoid emergency hospital admissions and be supported by care home and NHS staff who are skilled in providing end-of-life care. Care homes are being encouraged to use end-of-life care support tools, such as the Gold Standards Framework (GSF),²¹³ Preferred Priorities for Care,²¹⁴ and the Liverpool Care Pathway (LCP).²¹⁵ These interventions increase staff confidence and knowledge, reduce unplanned hospital admissions, and allow more people to die in their preferred place of care.^{216,217}

Research questions

This study had two phases. In the first phase the research question was, what are the pathways to death of OPWD living in a care home? In the second phase the research question was, can an intervention be developed to promote integrated working between primary care and care home providers, to improve end-of-life care for OPWD?

Methods

The methodology used in Phases 1 and 2 of the study is detailed in the study protocols shown in *Appendices 35 and 36*.

Phase 1 objectives

Phase 1 objectives were to:

- characterise OPWD living in care homes and describe their respective pathways to death, including a survival analysis to identify indicators of the end of life
- describe the care and support needs of this population, and of their carers
- establish how care home staff and NHS primary care practitioners define, assess and provide end-of-life care for this population
- describe how different contexts and models of care in care home environments influence experiences of end-of-life care
- identify the treatments and interventions received (including medication and potentially inappropriate prescribing), and services and resources used, leading up to death.

Study design

Phase 1 used a prospective, mixed-methods design including case notes analysis, interviews, mapping of service use and economic evaluation. Data from residents' care notes were extracted at three time points (*Table 52*). Care notes of residents who had either died or left the home before the end of the data collection period were reviewed to the date of death or leaving the home.

TABLE 52 Phase 1 care notes review periods

Time point	Dates
Baseline	March 2009 to July 2009
Time point 2	July 2009 to November 2009
Time point 3	December 2009 to April 2010

Unstructured conversational interviews were undertaken with a purposively selected sample of older care home residents with dementia. The manager and, where possible, deputy manager, as well as two NHS professionals (e.g. GP and district nurse) with ongoing involvement with each home were interviewed. Emergency care practitioners and paramedics were also interviewed to establish how they interpreted their responsibilities when called to an older person with dementia in a care home. Care home notes of older people who died during Phase 1 were reviewed to document services received prior to death, the place of death and the care provided. These reviews were complemented by interviews with care home staff. Interview schedules and data extraction forms are shown in *Appendices 37–46*. Interview information sheets are shown in *Appendices 49–51*.

Inclusion and exclusion criteria

Inclusion and exclusion criteria for care homes and OPWD are detailed in *Appendix 35*. Inclusion criteria for care home residents were age ≥ 65 years, and a documented diagnosis of dementia or an assessment by the senior care worker that their level of cognitive impairment and behaviour were consistent with a diagnosis of dementia. Exclusion criteria were people with dementia who did not speak English, those whom the care home manager thought it inappropriate to approach (e.g. people in the terminal stage of the disease) and individuals who lacked capacity to consent and for whom a consultee could not be identified.

Information sources

Care home characteristics were collected using Annual Quality Assurance Assessment (AQAA) forms completed for the study by the care home managers (*Table 53*). Missing data were obtained through Care Quality Commission (CQC) listings and care home managers' interviews.

Sample

Details of the recruitment process used for both the care homes and the OPWD are reported elsewhere²¹⁰ (see also *Appendix 35*). A total of 214 residents were eligible for participation in the study across the six care homes. Care homes were identified using the CQC (previously known as the Commission for Social Care Inspection) directory of care homes. Inclusion criteria were that the care home was for older people, provided personal care and specialist support in dementia care, had a minimum of 20 beds and there was no onsite nursing provision. To optimise the opportunities for participation, a further inclusion criterion was that the last CQC inspection report was favourable and that care home staff considered that they have a good working relationship with their local primary care services. Of the 10 care homes approached, six agreed to participate. The six care homes had a mix of ownership and geographical location.

A staged approach to the recruitment of OPWD was adopted, involving separate meetings with staff, residents and relatives. Individual consent was secured with residents with dementia who could consent in the moment and for those without capacity, through letters and follow-up contact with consultees.

Minimum data set

Areas of data collection are detailed in *Appendix 35*. Participants' health and care needs over time were documented, as well as service utilisation (using an adapted version of the CSRI).⁸⁸ Additional data on residents were obtained using the DAD,¹⁷⁶ the Barthel ADL Index,²¹⁸ the Cohen–Mansfield Agitation Inventory (CMAI),²¹⁹ and the Cornell Scale for Depression in Dementia,²²⁰ completed by home managers and senior carers.

TABLE 53 Annual Quality Assurance Assessments dates

Care home					
CH1	CH2	CH3	CH4	CH5	CH6
April 2007	July 2008	March 2009	June 2008	March 2009	March 2009

Analytic methods

Case notes review and interviews

Data extracted from residents' care notes were analysed using SPSS version 20. Interviews were digitally recorded, anonymised and analysed thematically using NVivo version 8. Two researchers undertook the analysis and discussion of key themes and issues.

Review of resident deaths

Health events and care received in the month preceding death were extracted from care notes and through interviews with care home managers and/or senior care workers. Data were summarised in timelines depicting deceased residents' end-of-life trajectories, using Microsoft Visio™ software version 2010 (Microsoft Corporation, Redmond, WA, USA). Two researchers were involved in defining dying trajectories, using an inductive approach to classification of Visio timelines.

Medication review

Residents' medical administration records were reviewed to (1) determine the sedative load and use of sedative and psychotropic medications and (2) estimate the prevalence of potentially inappropriate prescribing (PIP) among OPWD in care homes. To determine the sedative load and use of sedative and psychotropic medications, regular medications were classified using the Anatomical Therapeutic Chemical classification system and individual sedative loads were calculated using a model to quantify the cumulative effect of taking multiple drugs with sedative properties (see Parsons *et al.*²²¹ for further detail). The prevalence of PIP was determined using 31 of the 65 Screening Tool of Older Persons' potentially inappropriate Prescriptions (STOPP) criteria (see Parsons *et al.*²²¹ for further detail).²²²

Characteristics of older people who died compared with those alive

Examination of characteristics of older people who died compared with those alive using Kaplan–Meier methods (significance values where quoted are for the log-rank test) was undertaken to examine if there were indicators that residents were reaching end of life. The analysis was restricted to residents who met the following criteria: (1) residents who were alive and resident in the care home at the date of the baseline data collection and (2) residents who had a valid date at which their survival time was censored (at date of either death or transfer, or recorded alive at date of last data collection).

Costing analysis

Objectives

- To compare the resource utilisation patterns between residents who were alive and dead by the end of Phase 1.
- To establish the estimated costs for supporting end-of-life care for OPWD in care homes.

Descriptive statistics derived using SPSS version 20 were used to report estimated service use and costs. The Wilcoxon rank-sum test (two independent samples test) was used to detect differences in service utilisation and costs between residents who were alive and who had died by the end of Phase 1. HSC unit costs estimates were taken from the Unit Costs of Health and Social Care 2010.²²³ Medication costs were estimated using information from the *British National Formulary*.²²⁴ The monthly accommodation cost per resident was based on the average of the accommodation costs between the two time points. For those residents with missing records, the overall average accommodation cost was used.

Ethical considerations

The protocol of Phase 1 of the EVIDEM-EoL study entitled 'Changing practice in dementia care in care homes: developing and testing evidence-based interventions at the end of life' (REC reference: 08/H0502/74) received a favourable ethical opinion from the Southampton & South West Hampshire REC (A) on 14 July 2008.

Public involvement

Two members of the Public Involvement in Research Group (PIRG) based at the University of Hertfordshire provided support to the study. Both were recruited because of their particular expertise and experience of dementia and mental health services. One member of PIRG was a member of the project advisory group, attended coffee mornings at the care homes to explain the study to residents, was involved in some of the qualitative analysis, including the interviews with residents, and commented on the final report. Both members commented on various study materials throughout the project, including care home newsletters. The steering group was chaired by a member of the PIRG who had been a carer of someone with dementia and three other members of the group were PPI representatives, all of whom had been carers of people with dementia who had died in a care home.

Phase 2: Intervention objectives

The intervention phase objectives were to:

- identify interventions/ways of working to support integrated working between care home staff and primary health-care services
- test ways that primary health-care services and care home staff can work together to reflect the priorities, experiences and concerns of OPWD living in care homes at the end of life
- consider how available end-of-life care frameworks help primary care and care home staff to manage uncertainty at the end of life
- identify facilitators and barriers to sustaining effective end-of-life care for people with dementia living in care homes.

Study design

Phase 2 used a co-design approach (AI)^{225,226} to bring together care home and visiting NHS staff to identify what worked well in end-of-life care for people with dementia, and to use that as a basis to plan and implement change. The exploration and enhancement of what is working well in an organisation is often framed as a '4-D cycle' (Box 5). The cycle is often conceptualised as discrete steps, although the process is non-linear, iterative and ongoing.

The 4-D cycle was implemented over three facilitated hour-long AI sessions over 6 months. The AI method and session design are detailed in *Appendix 47* (for further detail regarding the design of the intervention, see Nicholson *et al.*²²⁷). Phase 2 tracked the events and care experienced by OPWD living in the care homes who participated in the intervention phase. Data were extracted from residents' care notes at two time points, staggered over 7 months of data collection that ran from January to July 2011.

Baseline data extraction coincided with the start of the intervention (*Table 54*). Researchers reviewed participating residents' care notes over the 3 months prior to the start of the intervention or closely thereafter and again in July 2011 after the third and final round of intervention sessions in the care homes. Baseline data were collected in this way for 90% of the study sample. Baseline data for the remaining residents ($n = 8$) were collected between mid-March and mid-April 2011 owing to delays in obtaining consent.

BOX 5 Appreciative Inquiry '4-D cycle'

Discovery phase

Appreciating the best of what is Conversations between participants (within the chosen topic area) reveal stories of people working at their best. In the EVIDEM-EoL study the topic was the best experience of collaborative working in caring for a resident dying with dementia in a care home.

Dream

Envisaging what might be The stories are collectively discussed in order to generate new ideas, understanding and agreeing a shared future image of the future. This shared future is often summed up in a statement of intent. For example, in the EVIDEM-EoL study, one care home created the future ideal: 'All residents who wish to can live and die here, their home'.

Design

Together, create innovative ways to make it happen Participants choose and prioritise what needs to change to enable participants to move towards the agreed future and identify resources to enable these changes to occur. Within the EVIDEM-EoL study the design phase focused on one context-specific innovation per site.

Destiny

Sustaining the change Together, participants think about how to involve the wider organisation and systems necessary to ensure changes are sustained and spread.

TABLE 54 Phase 2 intervention: AI session dates

Session	Care home		
	CH1	CH5	CH6
1	25 January 2011	3 February 2011	19 January 2011
2	15 March 2011	24 March 2011	14 March 2011
3	28 June 2011	29 June 2011	20 June 2011

Impact of the Appreciative Inquiry intervention

The impact of the AI intervention on integrated working in end-of-life care was evaluated through analysis of resident deaths following the intervention and resource use before and after the intervention.

Resident deaths were examined through care note reviews, complemented by interviews with care home staff, for changes in services received prior to death, place of death and care provided following the intervention.

Resource use was examined among residents who participated in both phases of the study (see *Costing Analysis*, below, for further details).

Finally, postintervention interviews with all participants following the third and final AI session (see *Appendix 47*, interview schedule) were undertaken to examine perceived changes in working practices.

Minimum data set

A minimum data set of information was generated, as in Phase 1. Additional data on residents were obtained using the Clinical Dementia Rating Scale,²²⁸ completed by care home managers and senior carers.

Sample

Care home and resident samples

The six care homes that participated in Phase 1 received feedback and summaries of the Phase 1 findings, and all care homes were then invited to participate in Phase 2. Three of the six homes agreed to join the intervention phase, with a total of 154 residents eligible for participation.

Intervention sample

The GP practices and district nurses approached in Phase 2 were the same as those recommended to researchers in Phase 1. In two of the practices [attached to care homes 5 and 6 (CH5, CH6)] the GPs who had participated in Phase 1 both suggested other GPs at the practice to interview. Only the district nurse associated to CH6 participated in both phases of the study.

Care homes involved staff as they were able, with interviews being completed with all of the managers. The manager of CH5 attended two sessions before leaving her post. This manager had not yet been replaced by the third AI session, which was held with the GP and deputy manager only.

Relatives sample

A significant amendment was made to the Phase 2 protocol in 2011 following a recommendation from the study's advisory group to include relatives of care home residents both living and deceased. Relatives were recruited via study information leaflets left in the care homes, and through care home managers. Researchers also approached potential participants at relative group meetings normally held in the care home. Five participants were recruited in this way, including one relative living at the care home with his/her partner.

Analytic methods

Interviews and care note data were analysed as in Phase 1. The facilitated meetings were digitally recorded, anonymised and analysed thematically using NVivo version 8 to organise and manage the analysis. Two researchers were involved in the analysis and discussion of key themes and issues.

Costing analysis

Objectives

- To establish the estimated costs for supporting end-of-life care for OPWD in care homes for Phase 2.
- To compare the resource utilisation patterns between the same residents who were in both phases.

Patterns of service utilisation and estimation of costs were carried out as in Phase 1.

Ethical considerations

The intervention phase of the EVIDEM-EoL study entitled 'EVIDEM-End of Life: Changing practice in dementia care in care homes: developing and testing evidence-based interventions at the end of life – Phase 2' (REC reference: 10/H0502/55) received a favourable ethical opinion from the Southampton & South West Hampshire REC (A) on 10 August 2010.

Results from Phase 1

Care home characteristics

Care homes were a mix of provider type, size, location, building structure and religious affiliation (Table 55).

Resident funding status and care home fees, as well as staff numbers, working patterns and qualifications are shown in Tables 56–58.

TABLE 55 Care home size, environment and affiliation^a

Characteristic	Care home					
	CH1	CH2	CH3	CH4	CH5	CH6
Provider type	Private not for profit	Private not for profit	Private not for profit	Voluntary	Private	Private
No. of places	46	62	60 ^b	66	67	57
No. of dementia places	46	61	60	66	67	57
Location	Suburban	Urban	Suburban	Urban	Rural	Rural
Building	Former LA	Purpose built	Purpose built	Purpose built	Conversion	Purpose built
Religious affiliation	No	No	No	Yes	No	No

LA, local authority.
 a Source: CQC listings.
 b One place for learning disability.

TABLE 56 Care home provider type and resident funding status^a

Characteristic	Care home						Total N (%)
	CH1 (n = 44)	CH2 (n = 58)	CH3 (n = 57)	CH4 (n = 62)	CH5 (n = 66)	CH6 (n = 54)	
Provider type	Private not for profit	Private not for profit	Private not for profit	Voluntary	Private	Private	
Privately funded	7 (15.9%)	0 (0%)	32 (56.1%)	47 (75.8%)	17 (25.8%)	27 (50.0%)	130 (38.1%)
Publicly funded	37 (84.1%)	58 (100%)	25 (43.9%)	15 (24.2%)	49 (74.2%)	27 (50.0%)	211 (61.9%)

a Source: AQAA data.

TABLE 57 Care home fees (2009–10)^a

Characteristic	Care home						Average
	CH1	CH2	CH3	CH4	CH5	CH6	
Min. cost per week (£)	Unavailable	495	595	525	500	420	507
Max. cost per week (£)	Unavailable	580	695	640	660	600	635
Cost range (£)	Unavailable	85	100	115	160	180	128

a Source: CQC listings.

TABLE 58 Care home staff numbers, working patterns and qualifications^a

Characteristic	Care home					
	CH1	CH2	CH3	CH4	CH5	CH6
Total no. of caring staff	41	52	43	42 ^a	40	41
Full time, <i>n</i> (%)	5 (12.2)	14 (26.9)	20 (46.5)	23 (54.8) ^a	(59) ^c	26 (63.4)
Part time, <i>n</i> (%)	36 (87.8)	38 (73.1)	23 (53.5)	19 (45.2) ^a	(41) ^c	15 (36.6)
Agency (temporary) care staff	0	– ^b	– ^b	1 ^a	– ^b	– ^b
Full-time direct care workers to residents	0.89	0.9	0.75	0.68	0.61	0.76
Non-caring staff members	21	11	32	– ^b	11	22
Direct care workers holding NVQ at Level 2 or above, <i>n</i> (%)	14 (34.1)	31 (59.6)	19 (44.2)	19 (47.5)	26% (exact number unavailable)	29 (70.7)
Direct care workers turnover in past 12 months	13 (1FT; 12 PT)	25 (FT/PT not specified)	5 (FT/PT not specified)	4 in past 6 months ^a	6 (FT/PT not specified)	8 (FT/PT not specified)
Manager's time in post, years	4.5	2	3	3	3	6
Manager dementia training ^a	Yes	Yes	Yes	Yes	Yes	Yes
Manager end-of-life training ^a	Yes	No	No	Yes	Yes	Yes
Volunteers ^a	Yes	No	Yes	Yes	No	No

FT, full time; PT, part time.

^a Source: care home manager interviews.

^b AQAA data collection procedure modification (information no longer extracted).

^c Source: Care Homes' Minimum data set.

Organisation of care

All of the care homes operated a key worker system with a named care worker. Most operated teams headed by a senior care worker/team leader and tried to keep the same teams for continuity of care. Only one care home had permanent night staff. Training in most care homes was ongoing and in-house (see *Appendix 55, Table 106*). Frameworks for structured end-of-life care, such as the LCP²¹⁵ or GSF²¹³ for Care Homes, appeared rarely, if ever used (see *Appendix 55, Table 107*).

Resident needs

Resident needs are shown in *Appendix 56, Table 108*. Overall, care home 1 is characterised by the highest concentration of dependent older people with advanced dementia. Residents at care homes 3 and 4 had similar levels of dependency but less of dementia-related dysfunction. Residents in care homes 5 and 6 were more heterogeneous, evidenced by wider ranges of cognitive and functional ability.

Reported number and location of resident deaths in the year prior to the study are shown in *Table 59*. Between 30% and 50% of residents who had died in the year prior to the study died in hospital or in a hospice.

Access to primary and specialist palliative care

General practitioners

Care homes arrangements with GPs differed considerably (see *Appendix 57, Table 109*). For example, some GPs had set days to visit (but would also visit at other times if necessary), whereas others visited on request only.

TABLE 59 Deaths in year prior to study^a

No. of deaths in year prior to study	Care home					
	CH1: 12	CH2: 12	CH3: 16	CH4: 14	CH5: 10	CH6: 3
At home, <i>n</i> (%)	7 (58.3)	7 (58.3)	11 (68.8)	7 (50.0)	7 (70.0)	2 (66.6)
At hospital or hospice, <i>n</i> (%)	5 (41.6)	5 (41.6)	5 (31.3)	7 (50.0)	3 (30.0)	1 (33.3)
Short-term/temporary residents in last 12 months before completion of AQAA	51	63	73	1	12	3

^a Source: AQAA data.

District nurses

All the care homes had frequent visits from district nurses. These nurses also provided diabetes care, wound and continence care, as well as ordering equipment from medical loans or equipment services, for example pressure-relieving mattresses. Their involvement in end-of-life care was variable and in one care home the district nursing team had no history of such involvement.

Out-of-hours general practitioners and emergency ambulance services

Care homes frequently called on the services of out-of-hours (OOH) GPs. The decision to call the emergency services for distressing symptoms was often linked to staff confidence in managing end-of-life care.

Specialist care

None of the care homes had Admiral Nurse support or used night-sitter services. Counsellor services for staff were available on request via GP referral for only two of the six care homes. Only three of the care homes received any kind of regular support from a Community Mental Health Team. Three out of the six care homes reported never receiving support from palliative care specialists. The care homes that had access to specialist services reported variable patterns of contact, and in one home the service was restricted to residents with cancer.

Phase 1 resident baseline characteristics (n = 133)

Recruitment and retention

One hundred and thirty-three OPWD were recruited, representing 62% of the population (see *Appendix 58, Table 110*).

Resident age, length of stay, admission route into the home

Appendix 58 (Tables 111 and 112) shows resident characteristics, including age, length of stay and admission route into the home. Median age at admission ranged from 82.7 years in CH5 to 87.5 years in CH3. Length of residency ranged from 0.2 years in CH6 to 3.4 years in CH2. A total of 43% of residents were admitted to the care home from their own home; 6% were admitted from a relative's home; 29% from hospital; 11% from another care home; and 11% from sheltered/warden-controlled housing.

Cognitive function, activities of daily living, behavioural status, distressing behaviour

Over one-quarter 26.3% (*n* = 35) of the sample did not have a formal diagnosis of dementia recorded (see *Appendix 58, Table 113*) but were identified by care home staff as having memory problems and/or behaviours consistent with a diagnosis of dementia (e.g. memory lapses, disorientation to time and place, lack of ability to problem solve, needing help/prompts for personal care). Of those who had a formal diagnosis of dementia, 70% did not have the source of their dementia diagnosis recorded.

Resident needs in relation to ADL were documented in the areas of continence, personal care, maintaining a safe environment, and eating and drinking, and are shown (see *Appendix 58, Tables 114 and 115*).

Assessment of all residents using validated tools including the DAD scale,¹⁷⁶ CMAI²¹⁹ and Cornell Scale for Depression in Dementia²²⁰ confirmed the presence of symptoms that were consistent with a diagnosis of dementia (*Tables 60 and 61*). Care home 1 was characterised by a high concentration of dementia-related disability, as evidenced as by DAD scores ranging from 0% to 20% (see *Table 61*). Care homes 5 and 6 are characterised by wide ranges of disability levels as evidenced by DAD scores ranging from 2.5% (i.e. more dysfunction) to 100% (no disability).

Around 15% of the overall sample displayed aggressive behaviour and around 50% of the sample displayed both physically non-aggressive and verbally agitated behaviour. Only 12% of the overall sample was assessed on the Cornell Scale for Depression in Dementia scale as exhibiting symptoms of depression (see *Table 61*).

TABLE 60 Resident function within care homes (DAD; $N = 101^a$)

DAD	Care home						Total
	CH1	CH2	CH3	CH4	CH5	CH6	
<i>n</i>	18	– ^b	15	22	32	14	101
Median	11.25	– ^b	12.5	10	29.14	40	17.5
Mean (SD)	10.42 (6.26)	– ^b	17.50 (15.50)	16.88 (16.90)	32.88 (25.54)	35.50 (24.77)	23.47 (21.83)
Range	0–20.00	– ^b	0–42.50	0–48.72	2.50–100.00	2.50–100.00	0–100.00

a Source: DAD¹⁷⁶ completed by care home managers and/or senior care workers. Total score out of 100. Higher scores represent less disability in ADL, whereas lower scores indicate more dysfunction.

b Care home staff unable to administer assessments because of time constraints.

TABLE 61 Distressing or challenging behaviour in care homes reported by staff^a ($N = 133$)

Characteristic	Care home						% of total $N = 102$
	CH1 ($n = 19$)	CH2	CH3 ($n = 15$)	CH4 ($n = 22$)	CH5 ($n = 32$)	CH6 ($n = 14$)	
CMAI²¹⁹ ($n = 102$)							
Aggressive behaviour, n (%)	3 (15.8)	– ^b	2 (13.3)	4 (18.2)	6 (18.8)	1 (7.1)	16 (15.7)
Physically non-aggressive behaviour, n (%)	8 (42.1)	– ^b	6 (40.0)	12 (54.5)	15 (46.9)	11 (78.6)	52 (51.0)
Verbally agitated behaviour, n (%)	11 (57.9)	– ^b	9 (60.0)	11 (50.0)	14 (43.8)	7 (50.0)	52 (51.0)
Cornell Scale for Depression in Dementia²²⁰ ($n = 101$)							
Indicating probable depression (i.e. score of ≥ 12), n (%)	5 (27.8)	– ^b	0 (0)	0 (0)	5 (15.6)	2 (14.3)	12 (11.9)

a Source: CMAI and Cornell Scale for Depression in Dementia completed by care home managers and/or senior care workers.

b Care home staff unable to administer assessments because of time constraints.

Average number of comorbidities and prescribed medications

Residents had a wide range of documented conditions and symptoms, with just under half experiencing three or more comorbidities (Table 62). Residents were prescribed a median of seven medications, with a range of 0–17 (Table 63).

Sedative load of medications

Analysis of sedative load and use of sedative and psychotropic medications among participating residents showed that approximately one-third of residents were not taking any medications with sedative properties at each time point, whereas a significant proportion of residents had a low sedative load score of 1 or 2 (54.8%, 59.0% and 57.1% at baseline and time points 2 and 3, respectively). Sedative load scores were similar throughout the study period for residents with dementia in each of the care homes, and lower than previously reported in studies conducted in long-term care (for further details, see Parsons *et al.*²²²).

Evaluation of potentially inappropriate prescribing

Analysis of the prevalence of PIP using STOPP criteria shows that 46.2% and 40.9% of the sample were prescribed at least one potentially inappropriate medication (PIM) at time points 2 and 3, respectively. Long-term (i.e. > 1 month) use of neuroleptic drugs, non-steroidal anti-inflammatory drug use for > 3 months and proton pump inhibitors use at maximum therapeutic dosage for > 8 weeks were the most prevalent PIMs in this study population (for further details, see Parsons *et al.*²²²).

Health events

Range of health events

Health-related events recorded in care notes were reviewed in order to capture possible signs of physical decline (see Appendix 58, Table 116). The proportion of residents for whom an event was recorded at each time point over the course of Phase 1 is shown in Appendix 58, Table 117. Problems relating to eating, drinking and falls were among the most frequent events, whereas pain, distress and decreased mobility were documented relatively less often. The number of falls across care homes per time point is shown in Appendix 58, Table 118. Across homes, 22%, 31% and 30% of residents had sustained a fall in the 3 months preceding data extraction at baseline, time point 2 and time point 3, respectively.

TABLE 62 Comorbidities per care home^a

Comorbidities	Care home						Total
	CH1	CH2	CH3	CH4	CH5	CH6	
≥3, n (%)	9 (45)	13 (52)	3 (18.8)	7 (30.4)	22 (64.7)	4 (26.7)	58 (43.6)

^a Source: care notes.

TABLE 63 Prescribed medication^a

Characteristic	Care home						Total
	CH1	CH2	CH3	CH4	CH5	CH6	
Mean no. medications (SD)	7.60 (3.35)	7.70 (4.19)	7.07 (4.73)	6.87 (2.88)	7.91 (2.87)	6.67 (4.13)	7.40 (3.56)
Median no. medications	6.5	7	6	7	8	6	7
Range	3.0–15.0	2.0–17.0	0.0–17.0	1.0–13.0	2.0–14.0	2.0–15.0	0.0–17.0

^a Source: Medical Administration Record sheets.

Advance Care Planning

Documented involvement in end-of-life discussions is shown in *Appendix 58* (see *Table 119*). Forty per cent of residents had no evidence of end-of-life discussions recorded in their care notes. It is worth noting that end-of-life discussions as recorded in the care notes pertained for the most part to decisions regarding faith-based and post-death arrangements (e.g. religion and funeral arrangements) rather than care-related preferences (i.e. resuscitation status; significant carers, family members whom the resident would want to be present at the end of life) (*Table 64*).

Deaths over the course of Phase 1

Just over 20% ($n=27$) of the sample died over the course of Phase 1, including 15 residents in the care homes and 12 in, or on their way to, hospital (see *Appendix 58, Table 120*). A further six residents ($n=5$) were discharged from the care home into a care home with nursing over the course of the study.

Health events and service utilisation in the month leading up to death

The most widely reported symptoms among residents in the month preceding death were problems with eating and drinking (18 of the 22 residents for whom data were available), perceived general deterioration (14 out of 22), breathing problems (13 out of 22), infection (9 out of 22) and increased sleepiness (9 out of 22). These mirror events and symptoms as they were recorded in the care notes across the sample (i.e. residents both alive and dead at the end of Phase 1) and over the 12-month period (see *Appendix 58, Tables 114 and 115*), and suggest that care home staff do not perceive any significant differences in symptoms between residents who are close to death and those who are not, nor any sudden changes in symptoms in the month preceding death. Only 3 out of 22 deaths reportedly involved any pain management. Examination of service utilisation in the month preceding death reveals that only 2 out of the 22 resident deaths, for which data was available, reportedly had received specialist services support (i.e. hospice nurse and Twilight Nurse). Both cases involved a resident with a cancer diagnosis.

Characteristics of older people who died compared with those still alive

The typical illness trajectory of OPWD is one of progressive functional decline over a prolonged period. Among the 127 residents with available data there were 17 deaths. Six residents had moved from the care home and 104 residents were alive at end of the study. There were no evident differences in survival comparing 80- to 89-year-olds with those aged ≥ 90 years. Survival rates appeared slightly lower for males but this difference was not significant ($p=0.096$). The absence or presence of a formal diagnosis of dementia ($p=0.67$) was not a relevant indicator for impending death. The mortality rate was highest in care home 6, but the 98% CIs indicate the relative imprecision of these estimates, given the small number of deaths per care home. Our results suggest that for care home staff and visiting health-care practitioners, it is difficult to predict how long this period will last or to differentiate even in hindsight between residents who are dying and those who are not.

TABLE 64 Evidence of discussion regarding resuscitation status^a

No evidence of resuscitation discussions, n (%)	56 (42.11)
Evidence of resuscitation discussions, n (%)	22 (16.54)
No evidence of discussions on end-of-life wishes, n (%)	53 (39.85)
Unavailable, n (%)	2 (1.50)

^a Source: care notes.

Dying trajectories

Residents' trajectories to death were examined in depth, and summarised from care home notes and staff accounts in the form of Visio timelines. Classification of Visio summary timelines resulted in three distinct end-of-life trajectories: anticipated, unexpected and uncertain dying.

Trajectory A, anticipated dying Anticipated death with planned end-of-life care in the care home. These residents were recognised to be approaching death and decisions were made about providing for end-of-life care in the care home (*Figure 16*). In all cases, care continued in the home up to death; none were transferred to hospital or hospice. Twelve cases fitted into this model – the majority of the deaths.

Trajectory B, unexpected dying Acute illness or sudden event leading to death in the care home or emergency admission to hospital where the resident subsequently died. Only two deaths were classified as 'unexpected'. In both cases, residents had been stable in the care home and then suffered an unexpected acute event (i.e. pulmonary embolus and breathing difficulties), which led to unexpected death in the care home or emergency admission to hospital (*Figure 17*).

Trajectory C, uncertain dying Diagnostic uncertainty or disagreement as to the best course of action that led to hospital admission and death in hospital. For these residents the period before death appeared to be a time of diagnostic uncertainty. They were unwell but it was not evident to the care home staff that they were close to the end of life. Resident deaths that fit into this category were further classified into treatment uncertainty ($n = 5$) and service uncertainty ($n = 3$).

Treatment uncertainty These residents died in hospital following admittance for reasons such as treatment of infection, not responding to oral antibiotics or for further investigation of an illness for which the cause was not clear (*Figure 18*). Equally, there were residents who were still alive at the end of data collection, whose experience of episodes of ill health did not signal their impending death within the next 6 months (*Figure 19*).

Service uncertainty Three deaths occurred in the midst of disagreement as to where the resident should be cared for and by whom, leading to prolonged stays in hospital awaiting placement in a care home with nursing, and in one case to discharge from the hospital back to the care home just 1 day before death (*Figure 20*). Finally, in four of the cases it was not possible to categorise the death because of limited information.

Living and working with uncertainty

This section synthesises the qualitative data from Phase 1 interviews with OPWD ($n = 18$), care home staff ($n = 33$), GPs ($n = 5$), district nurses ($n = 5$) and emergency ambulance services staff ($n = 3$), which focused on the experience of providing and receiving care. Interviews illustrated the issues and decisions that led up to the events observed in the resident dying trajectories outlined above, and made explicit how the experience of dying with dementia is shaped by multiple factors and not just symptom-related issues.

Interview data indicate that care home staff members were more likely than NHS staff to have undertaken dementia training (see *Appendix 60, Tables 124 and 125*). Only two GPs (out of five) and two district nurses (also out of five) reported having received some form of training in dementia care. All but one member of care home managerial staff had received dementia training. None of the GPs had undergone any further specialist training in geriatric or end-of-life care.

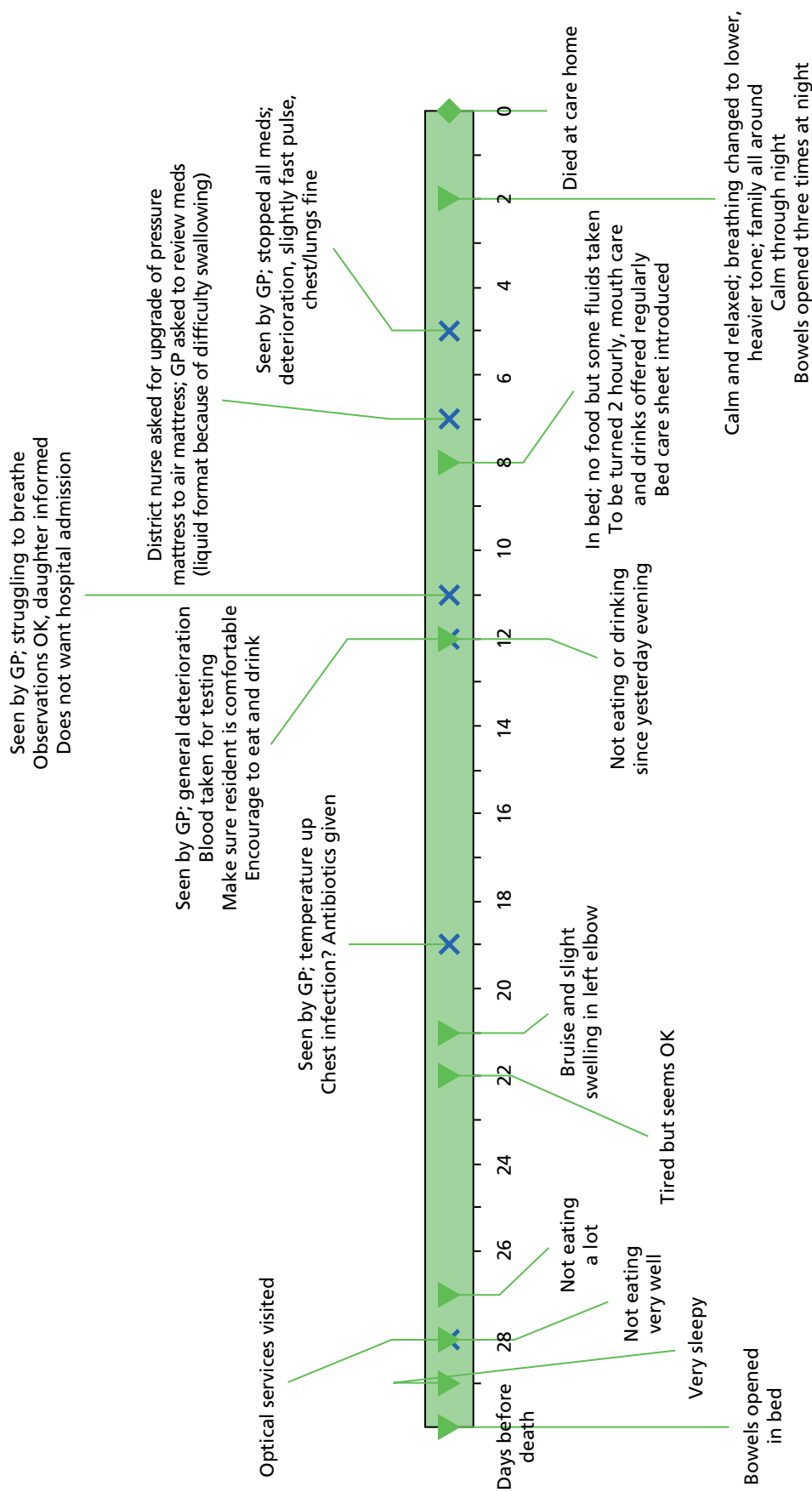


FIGURE 16 Anticipated dying: an illustration.

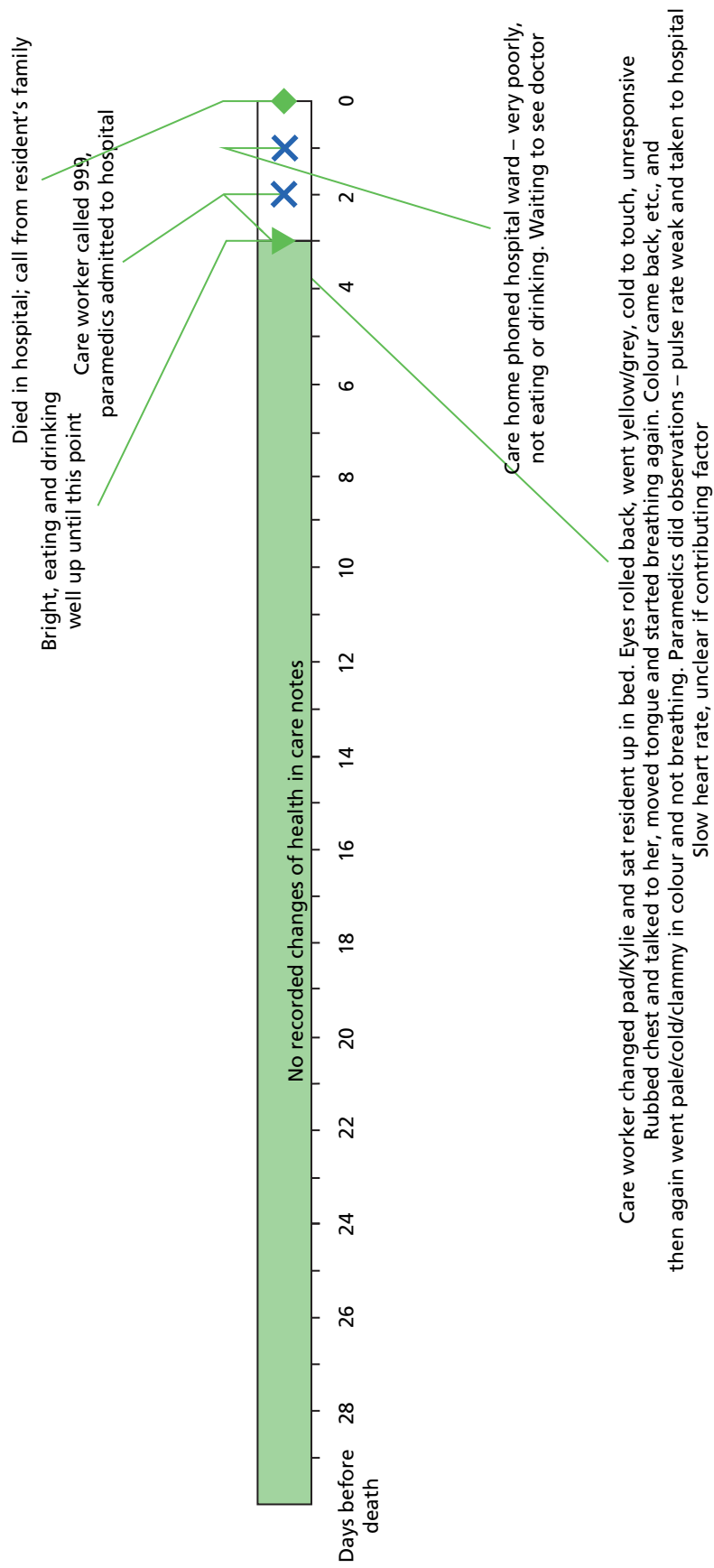


FIGURE 17 Unexpected dying: an illustration.

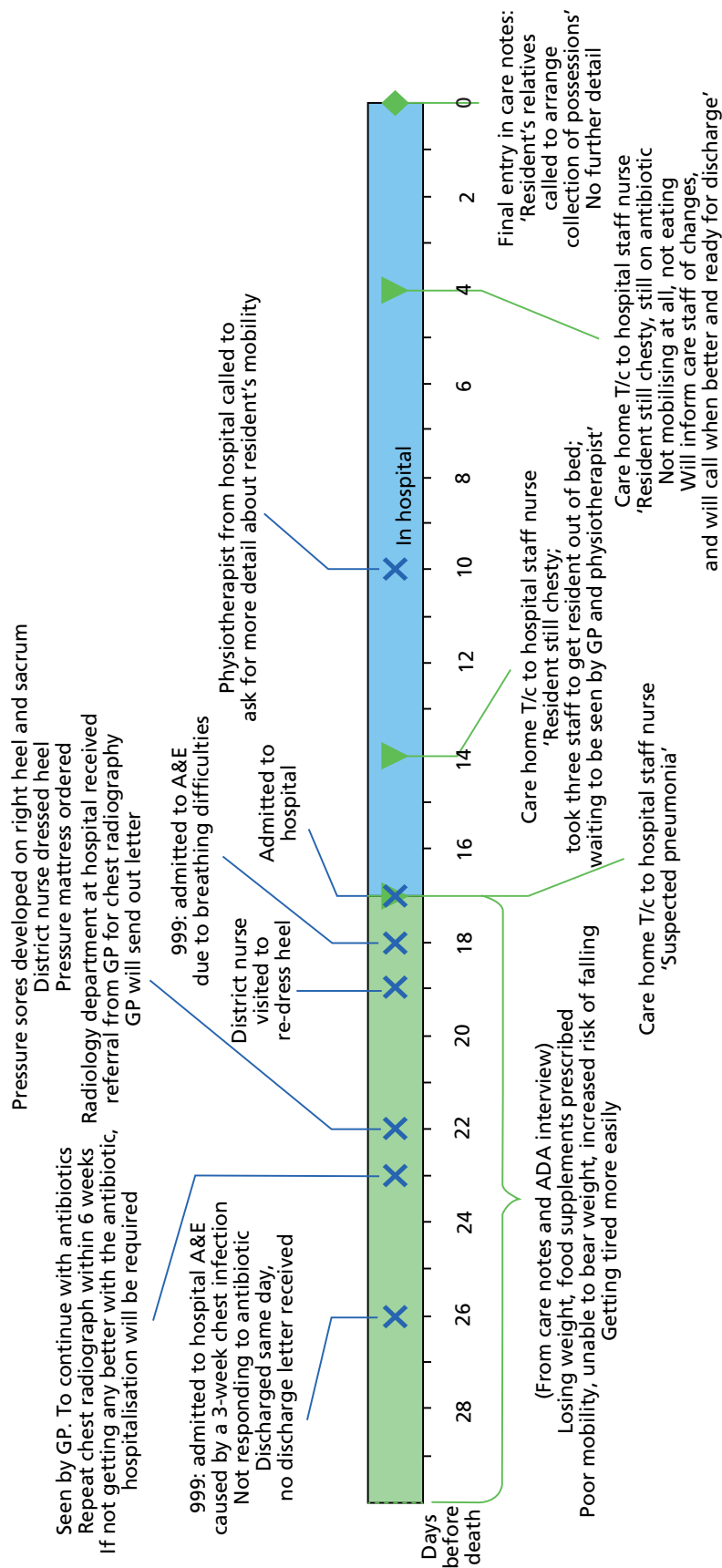


FIGURE 18 Treatment uncertainty of a deceased resident: an illustration. A&E, accident and emergency; ADA, after death analysis; T/c, telephone call.

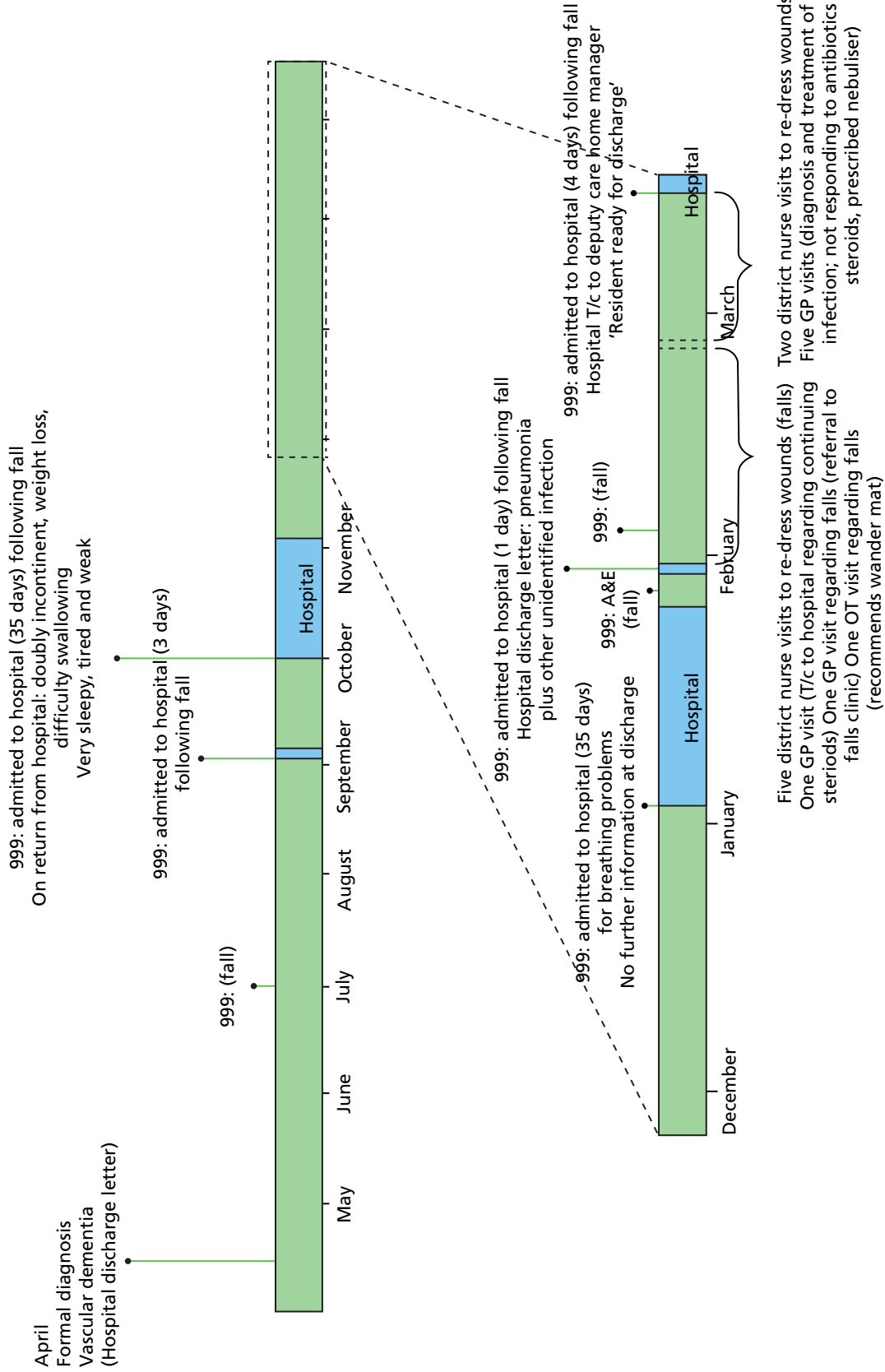


FIGURE 19 Treatment uncertainty of a living resident: an illustration. A&E, accident and emergency; OT, occupational therapist; T/c, telephone call.

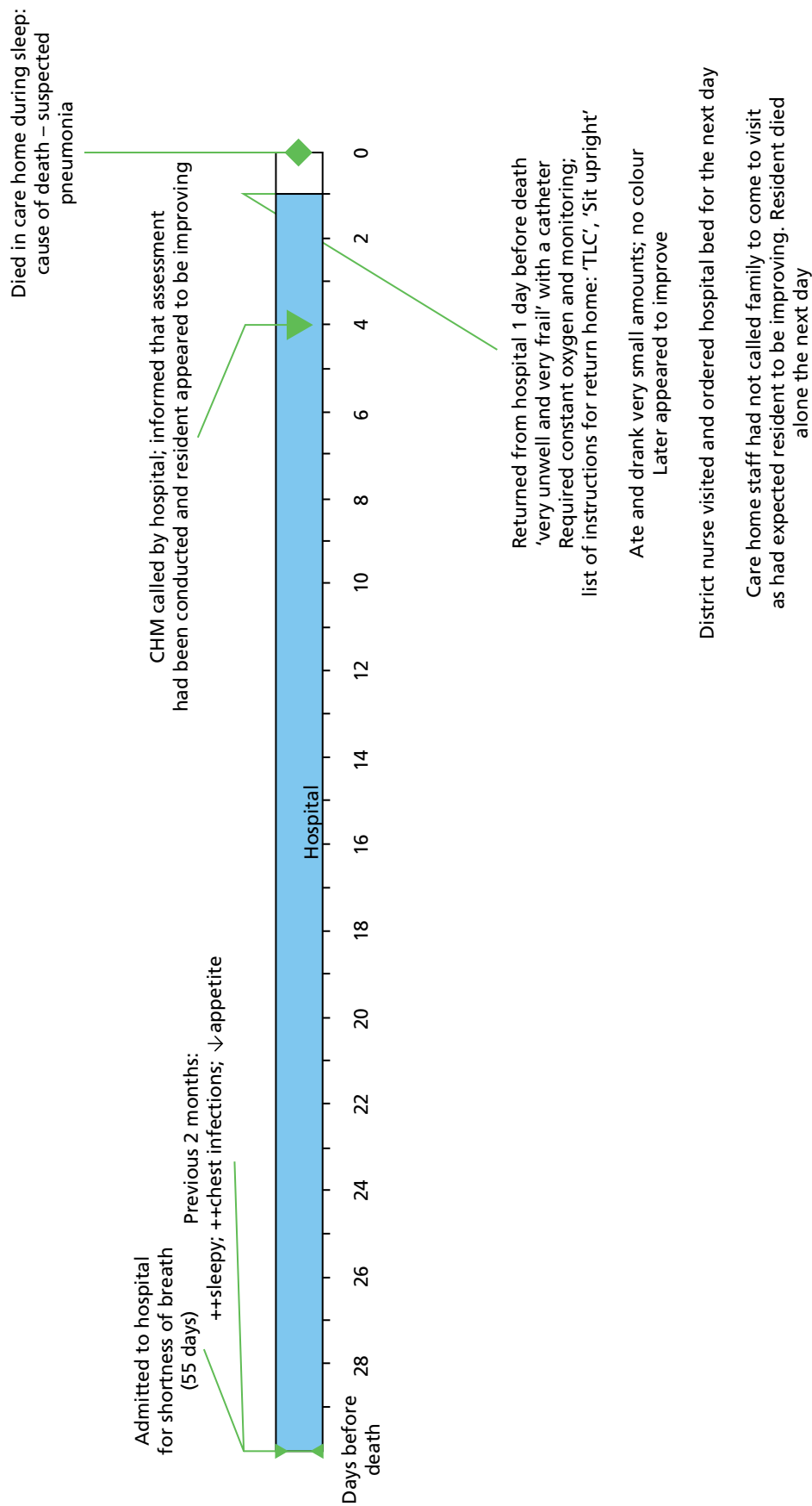


FIGURE 20 Service uncertainty: an illustration. CHM, care home manager; TLC, tender loving care.

Residents' interviews

When discussing end-of-life priorities and needs, the recurrent and overarching theme was one of uncertainty about their future and how they would be involved in decision-making. Among older people, important themes were uncertainty about the progression of their disease, how they understood living in a care home and who they identified as the person(s) who understood them. Place of death was not necessarily a meaningful measure of effective end-of-life care. Preferences and expectations about end-of-life care were blurred with the everyday experiences of care. Findings demonstrated the importance of ongoing review and discussion with people whose dementia might wrongly be seen as precluding meaningful discussion. Residents' uncertainty about the future and being in the care homes is discussed in detail by Goodman *et al.*²²⁹

Care home and NHS staff interviews

Uncertainty was also a dominant theme in the staff interviews. It was expressed in terms of diagnostic uncertainty and clinical decision-making at different time points, and staff uncertainty about roles and responsibilities within care homes and NHS services, including questions about workforce capacity and uncertainty when accessing primary and community care services.

Uncertainty in the resident trajectory

Knowing *when* someone with dementia was actively dying was very difficult. Although care home and NHS staff knew signs of deterioration such as weight loss, reduced function, chest infections and increased apathy were significant indicators, these were often not documented, were diffuse, and could either be present for long periods of time, or, with treatment, might resolve. This variable path to death was recognisable after death but not always in the moment. Treatment uncertainty affected decision-making about withdrawal of treatments and referral to hospital, and how information about the person with dementia was communicated to family members and within/across organisations.

Clinical decision-making in care homes was not seen as the work of one person and had to take multiple perspectives into account. For care home staff, decision-making about quality of life related to the responsiveness of the resident, their ability to still interact and take an interest in their surroundings. For clinical staff it was whether the treatment was unduly prolonging a life that was naturally coming to an end (and one that they themselves would not want to live). When the dying period was protracted it was difficult to maintain both communication – between clinicians, care home staff and family members – and responsiveness in times of crisis.

Examples of when staff had worked together well suggested that there had been time to discuss symptoms and involve relatives, and that the pathway to death had been clear. NHS staff seem to have had very little input to the care of some residents who died, and it was unclear if this was because it was not required or because their needs were not obvious and they had been overlooked.

Uncertainty in roles, relationships and responsibilities

At the outset of the study, NHS and care home staff believed that they had good working relationships but communication and responsibility for decision-making were often unclear. To provide end-of-life care NHS staff relied on care home staff to describe what was normal for the older person, and to inform decisions to visit, treat, liaise with family and involve other services. Interviews highlighted persistent themes of uncertainty in how these roles and relationships were negotiated. When it was clear that someone was terminally ill, and in the last days of life, some (but not all) care home staff wanted something, such as the LCP,²¹⁵ to give them permission to talk about dying, liaise with NHS staff and help structure their activities. However, two managers commented that the LCP meant that primary care staff 'took over' end-of-life care, which 'medicalised' dying, excluded the involvement of staff and complicated communication between them.

Paramedics interviewed in this phase reported that they were sometimes used as a 'go-between', and the 'easy option' when a GP was unavailable to attend or when an inexperienced care worker was unsure what to do. This was an area that was also raised during post-death analysis interviews by some care home managers. It suggested a sense that these two participant groups lacked the authority and opportunity to discuss and debate the choices and decisions that staff make in emergency situations.²³⁰

Uncertainty about access to, and capacity of, services

There was uncertainty within and across groups about the value of focusing on end of life, and whether or not care homes were the best place to die. Only GPs were convinced that end of life for people with dementia should be in the care homes. District nurses and care home managers, for different reasons, were unsure.

For care home managers, it was because their focus was on the living; consequently, talking about dying was often felt to be inappropriate. District nurses, regular visitors to care homes and some paramedics were concerned that neither they nor the care home staff had the capacity to care for people at the end of life. This view was supported by examples of care home staff working unpaid overtime when a resident was dying because there was limited cover at night. GPs also hinted at the possibility that some OPWD were overlooked because reviewing their care would generate more work for their already full caseloads.

Uncertainty about access to, and capacity of, services to provide end-of-life care was related to the limited responsiveness of primary care services and the eligibility of residents for specialist palliative care services and equipment (even if they could be provided in time). Similarly, there was evidence of people dying in hospital while waiting for a placement to a care home with nursing because the hospital staff were uncertain if the care home could provide end-of-life care.

Service utilisation and associated costs

Distribution of service use per month

All care homes residents are entitled to the full range of NHS primary, community and hospital-based care support but were found to access only a limited number of services on a regular basis. Three main categories of service were defined:

- Hospital services were limited to emergency (ambulance), accident and emergency (A&E), inpatient and outpatient services.
- Community health services included district nursing as well as OOH GP services.
- GP services.

Use of these services was examined among all residents for whom data were available. There were no significant differences between residents who were alive at the end of the study period and those who had died, in terms of age on admission, gender, reason for admission, admission route and number of long-term conditions (*Table 65*).

Service use for the whole sample is shown in *Appendix 59, Table 121*, and for those alive at the end of 12 months plus those who had died. In accordance with other research that has found that costs are usually highest for people 1 year before death,²³¹ service use was significantly greater among those individuals who had died in all three categories of service.

TABLE 65 Distribution of baseline characteristics

Characteristic	Overall (n = 133)	Alive (n = 116)	Dead (n = 17)	p-value ^a
Age on admission (years): mean (SD)	84.0 (6.7)	84.0 (6.9)	84.4 (5.5)	0.984
Gender: % female	77.4	79.3	64.7	0.178
Reason for admission (%)				0.513
Isolation	5.7	6.8	0.0	
Not coping	44.3	43.2	50.0	
Bad health	18.2	16.2	28.6	
Needs not being met	25.0	25.7	21.4	
Other (note: missing for 45 individuals)	6.8	8.1	0.0	
Admitted from (%)				0.0728
Own home	43.3	42.9	46.7	
Relative's home	5.8	6.7	0.0	
Hospital	29.2	29.5	26.7	
Other care home	10.8	10.5	13.3	
Sheltered housing/warden controlled	10.8	10.5	13.3	
No. of long-term conditions: mean (SD)	2.4 (1.5)	2.4 (1.5)	2.4 (1.5)	0.844

^a Based on Wilcoxon rank-sum test for continuous variables and chi-squared test for categorical variables.

Distribution of costs

The distribution of health-care costs for the overall sample is shown in *Appendix 59* (see *Table 122*), and for those alive at 12 months compared with those individuals who died. Generally, each care home resident in Phase 1 incurred about £2549 per month in terms of accommodation, health service use and medication consumption. Given the significant differences in service use, it was not surprising to observe that primary care, hospital and community health-care costs were significantly greater for those individuals who died than those alive at the end of 12 months. Including the costs of accommodation and medicines did not alter this finding, despite accommodation costs being much greater than all of the other health-care cost components.

Multivariate analysis of total costs

Table 66 presents the results of a multivariate analysis of total costs (including accommodation and medication costs). A generalised linear model was used to estimate the relative effects of individual characteristics on total costs. Death significantly increased total costs. The marginal effect of death on total costs was a £379 increase (other characteristics at their average values). Results also suggest that individuals admitted from a relative's home or from another care home incurred significantly lower total costs than those admitted from their own home. Further investigation regarding route of admission of older people into care homes may be warranted.

TABLE 66 Multivariate analysis of total costs: generalised linear model ($n = 113$) – marginal effects, 95% CI of marginal effects and p -values

Characteristic	Marginal effect	95% CI	p -value
Age at admission, years	-56.2	-111.1 to -1.3	0.05
Gender: male	-478.6	-1336.4 to 379.3	0.27
Admitted from:			
Relative's home	-1527.3	-2333.5 to -721.3	0.00
Hospital	-330.4	-1037.4 to 376.7	0.36
Other care home	-377.7	-1154.0 to 398.5	0.34
Other/sheltered housing/warden controlled . . .	-346.4	-1145.9 to 453.0	0.40
No. of long-term conditions	90.5	-138.2 to 319.3	0.44
Died	2592.7	432.1 to 4753.2	0.02

Notes $R^2 = 0.31$.

Kurtosis = 3.12.

Marginal effect of death on total cost (£) (95% CI) = 379 (57 to 702).

Results from Phase 2

Phase 1 identified uncertainty at all levels as a potential barrier to the delivery of effective end-of-life care for OPWD in residential care homes. This analysis led us to design an intervention that could address these different but overlapping levels of uncertainty by building on existing relationships, strengths and achievements and, when appropriate, end-of-life care resources. This section considers how AI (and the tools that emerged in the process of implementing it) was effective in addressing the different types of uncertainty experienced by care home and NHS staff. The findings from Phase 2 are organised and discussed under three headings.

How AI addressed uncertainty:

- in interpersonal and interprofessional relationships (*Relational uncertainty*)
- in identification and management of end-of-life care for people with dementia and resource use (*Treatment uncertainty*)
- around the knowledge and skills required to provide end-of-life care for people with dementia and the capacity of NHS and care home staff and services to provide this (*Service uncertainty*).

Relational uncertainty

Creating communicative space

Appreciative Inquiry sessions were protected, non-hierarchical meetings and were held in the care home. The starting point was discussion of the participants' strengths in end-of-life care; it was a space in which care home staff heard first hand (and in most cases for the first time), from visiting NHS staff, that their experience in dementia care and knowledge of the resident was valued and 'fundamental' to end-of-life care.

A persistent theme in Phase 1 was concerns about the accountability of care home staff to the regulator (CQC), and, for NHS staff, their personal liability. The AI processes meant that practitioners were able to admit their own fears and concerns, and acknowledge their co-dependency. At the end of the intervention, one GP commented to the care home manager that he used to dread coming to the care home but this was no longer the case.

Participants perceived the most important outcome as appreciating colleagues' roles in end-of-life care. The GP linked to care home 1 recognised that post AI there was a greater shared understanding of what they were trying to achieve.

It's (. . .) important to share that we actually have the same goals, that we think the same things are important, it enables easier conversations on a daily basis, because we know where we are all coming from

GP-CH1

Out-of-hours checklist

These discussions demonstrated how important it was for NHS staff to value the knowledge that care home staff had about their residents and dementia. It highlighted why this valuing was less evident when contacting OOH services. Care home staff did not know what information the OOH GP needed. OOH GPs would tell care home staff to call an ambulance when the information received seemed insufficient to make an assessment of the urgency of the problem. It was through 'appreciating' the challenges of their respective roles that the development of the OOH checklist arose. The checklist provided sufficient information for the GP and it could be left by the phone ready for OOH call-back. It was a tool developed together that addressed a shared frustration.

Do Not Attempt Cardiopulmonary Resuscitation audit

The AI intervention gave care home staff the confidence to share information and initiate conversations with the primary health-care staff. In care home 5, the GP carried out an audit of Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) forms in April 2011, which revealed only one out of 53 residents (i.e. the total number of residents in the care home, including those not consented to the study) or others on their behalf had completed such a form, but by July 2011 there were seven, and, by March 2012, 25 out of 55 residents (45.5%) had a DNACPR form. Residents identified as nearing the end of life were more likely to be included on the practice palliative care register and have their situation discussed with family members. The process of the DNACPR audit, and the involvement of the GP, triggered conversations across the care home about anticipating end of life, and normalised talking about dying. All three senior care workers interviewed in this care home following the intervention described how they initiated discussions with the GP regarding possible signs of deterioration and transitions to end-of-life care. Indeed, the proportion of care home staff involved in discussions around of life care of residents was observed to have doubled after the intervention (see *Appendix 61, Table 126*). The GP interviewed after the intervention recognised this change:

The communication (. . .) is no longer doctor-carer, 'you do this, I'll do that' (. . .) there's an improved confidence with the staff to be able to say, 'doctor, we're concerned that this patient is deteriorating, what do you think we should do?' (. . .) or 'his family are here', and then I say, 'OK, fine, I think we should all come together'.

GP-CH5

Prompt sheet

The explicit focus on end-of-life care started a discussion about care homes as places for living and dying. In care home 1 participants worked together to develop a prompt sheet that could help staff initiate a conversation about preferences and priorities for end-of-life care with residents, using a range of resources including information from the Dying Matters coalition.²³² The AI sessions had sharpened the organisation's focus on providing end-of-life care:

We do talk about [end of life] (. . .) [but] I think the meetings really helped us to focus a bit more on that (. . .) helps to focus on what we are doing. People are coming here [and] we know that they will eventually pass away (. . .) that is what we should be planning for.

Deputy Care Home Manager-CH1

There was evidence this had made her more receptive to the subject of end-of-life wishes when carrying out care reviews with residents, thus allowing residents to raise and discuss end-of-life topics.

Treatment uncertainty

Symptom management

Uncertainty about symptom management, such as breathlessness, repeated falls and difficulty eating and drinking had been documented in Phase 1, as triggers for admission to hospital or calls to emergency services. During the final AI session, one care home manager expressed concern over 'eating and drinking' issues at end of life and personal liability, suggesting that AI was an intervention that could accommodate and address underlying concerns about responsibility alongside clinical decisions. Post intervention there was evidence of consultation with specialist palliative care services and improved understanding about situations when supplementary and enteral nutrition would not be appropriate.

Post-death analysis and use of Visios

Phase 1 made it explicit that NHS staff lacked confidence in their knowledge about dementia, and care home staff their lack of clinical knowledge. The use of Visios in Phase 2 enabled an exploration of what 'normal' looks like for the resident with dementia and what symptoms were significant (see *Appendix 51*). AI balanced a focus on an unplanned hospital admission and death with a discussion of what had been achieved leading up to the resident's death. It encouraged reflexivity and review, and enabled participants to 'hold' situations when it was unclear what the best decision would be, for example when a resident was well in between increasing episodes of ill health. It enabled them to identify and reinforce what had worked well, how to improve care but also accept that in some of the deaths it was only with hindsight that the situations were clear, which led to discussion on how to negotiate uncertainty across organisations and between practitioners.

Documentation change

Finally, the AI intervention addressed treatment uncertainty by making the challenges participants encountered explicit, and by the co-development of documentation that helped bridge the gap between social and medical views of care. This included care plans that used language and instructions that made clear to care staff the medical decisions that had been reached with the GP. End-of-life care tools were being appropriated by care home staff to make explicit the impact that medical decisions had on end-of-life care practices, especially in times of crisis and exacerbation:

Yeah basically he (family member) doesn't want his mum to go to hospital so it's not so much a 'Do Not Resuscitate' [as a] 'Don't Call Paramedics – call GP'

Deputy Care Home Manager-CH6

Service uncertainty

Appreciative Inquiry focused on the capacity and assets of the workforce and the evidence for what was achievable and appreciated. Among care home staff there was evidence of increased confidence that primary health-care services would respond when needed:

That is something that we are really promoting here [with the doctors]. Instead of going to hospital . . . lately quite a few deaths that we had, they passed away in the home. [T]hrough this research, I think we have [discovered] what we can [provide] here in the home with the help of the doctors, rather than have to send someone to hospital for treatment (. . .) now, having the GP involved and everything we know that they can stay here, they can be looked after and cared for here.

Deputy Care Home Manager-CH5

Increased district nurse involvement

Finally, a change brought about through the AI intervention in care home 6 included 'coffee mornings' between care home staff and the wider district nursing team to introduce incoming members of staff and discuss any issues (an innovation that was still in place 18 months after the end of data collection). Family members interviewed after a relative's deaths in this care home also noticed how district nurse involvement had been instrumental in enabling their mother to die in the care home:

They knew my mother didn't want to go into hospital, they knew what the situation was, um and they ... the home felt ... When she spoke to me about, when [Deputy Manager] spoke to me about mother going to hospital, I said can you care for her in the home? Have you got enough you know ... and she said yes, we have, with the District Nurses coming in

Family member-CH6

Overall, the numbers of primary health-care staff involved in the resident deaths increased. For example the district nurses working with care home 1 who had not been involved in end-of-life care in Phase 1 were consulted for advice, nursing support and reassurance in Phase 2 (Figure 21).

Costing analysis

Comparison of resource utilisation and associated costs was undertaken between the overall sample in Phases 1 and 2. Table 67 shows the costs incurred per resident per month for each category of costs.

As the sample size of this study is relatively small, only median values are presented. Each care home resident in Phase 2 incurred about £2633 per month in terms of accommodation, health service use and medication consumption compared with £2549 in Phase 1. Accommodation costs (including care home staff and food and so on) accounted for around 90% of the total costs per month. There was a decrease in community health costs (-83%) and hospital costs (-52%). Medication costs however nearly doubled. Overall, total service costs incurred dropped by 15% from Phase 1 to Phase 2.

One of the most commonly used quantitative means for measuring end-of-life care has been place of death.²³³ This study saw similar proportions of residents dying in hospital (55%) and in the care home (45%) in Phase 1 (15 out of 27 deaths in care homes) and Phase 2 (five out of nine deaths in care homes). However, we observed a decrease in the length of inpatient stays and emergency ambulance use specifically, which was found to significantly reduce hospital costs overall.

Costs before and after the intervention were further examined among residents who had participated in both phases of the study. Results are similar to those derived from comparisons between the wider samples and were subject to significance testing. Among residents who participated in both phases of the study ($n = 28$), hospital and community care costs were significantly lower in Phase 2 than in Phase 1 ($p = 0.0456$ and $p = 0.0001$, respectively). However, there was no significant difference between primary care costs between the two phases ($p = 0.8376$).²³⁴

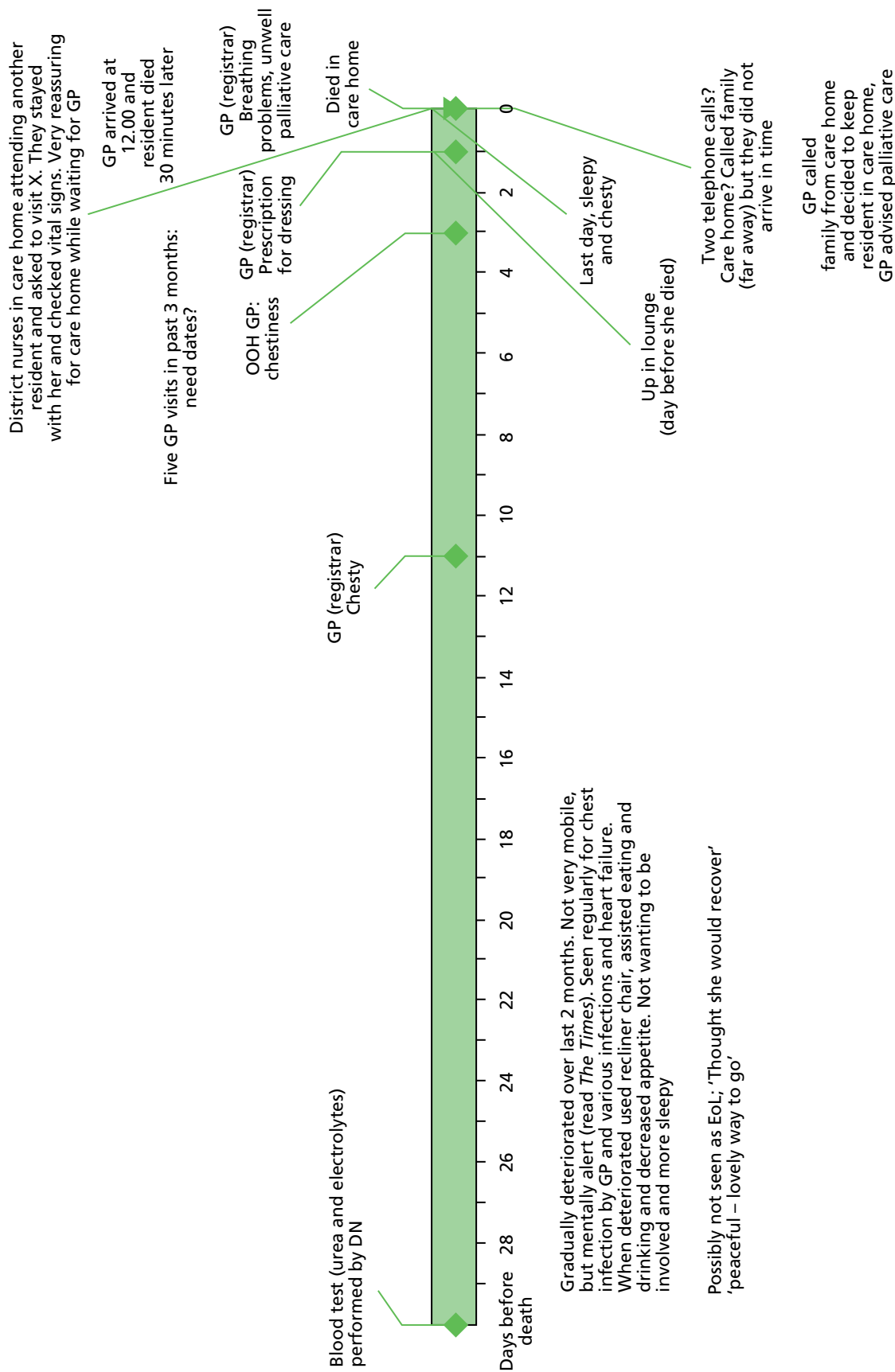


FIGURE 21 District nurse involvement: an illustration. DN, district nurse; EoL, end of life.

TABLE 67 Estimated costs: Phase 1 vs. Phase 2

Costs (£) per resident per month	Median		Percentage change in terms of median costs
	Phase 1	Phase 2	
Accommodation	2243.35	2380.49	6
Medication	56.54	81.17	44
Primary care	76.31	83.90	10
Hospital	38.98	18.52	-52
Community health	45.46	7.82	-83
Total service	193.98	164.52	-15
Total service and accommodation	2488.17	2539.47	2
Total (service, accommodation, medication)	2548.53	2632.61	3

Discussion

Summary and discussion of Phase 1 findings

Prognostication is difficult for people with dementia.^{200,201} Key symptoms and events among OPWD can sometimes be indicative of a transition from living to dying.²³⁵

There were no significant differences between residents who were alive at the end of the study period and those who had died, in terms of age on admission, formal dementia diagnosis, gender, reason for admission, admission route and number of long-term conditions.

There was considerable heterogeneity, however, in the resident population across care homes in terms of length of stay, function, residents with a dementia diagnosis, and individual resident's use of resources. Future research on end-of-life care for people with dementia needs to consider how the diversity of the care home population affects the experience and knowledge of care home staff about end-of-life care.

Phase 1 showed that in care homes with no on-site nursing there were different pathways to death. Not all residents had advanced dementia and dementia was not always the cause of death. However, dementia did complicate decision-making. There was evidence of attempts to use Advance Care Planning but there was considerable variation in how this was documented, who was involved in the decision-making and whether or not this information was used. Interviews with residents demonstrated that residents' accounts of care preferences and identification of key care staff had the potential to inform future decision-making and augment the completion of an Advance Care Plan.

In the care home environment, dying with a dementia could be a 'contested' process,²³⁶ complicated by uncertainty at the individual, service and organisational levels of care. Different participants had considerable discretion about how they engaged in providing end-of-life care for people with dementia, both in the care home and between services. Patterns of working could either foster discussion of residents' needs or limit opportunities for it.

Access to services was inextricably linked to uncertainty about roles, responsibilities, capacity and knowledge of the workforce, and whether the person with dementia was approaching the end of life. From an organisational perspective, however, there was an additional lack of clarity. This was uncertainty about the appropriateness of service requests, the capacity of the primary care workforce to provide ongoing support, entitlement to specialist services and whether hospital and emergency services believed that care homes were able to provide end-of-life care.

The co-dependency between NHS and care home staff and the examples of when collaborative working mitigated some of the challenges described suggested an intervention that would require the engagement of all those involved, incorporate the residents' views and preferences and build on relationships that were already in place. It had the potential to address and 'hold' the uncertainty experienced when staff are reliant on input from (multiple) external services, as well as answerable for decision-making to family members and the regulator.

Summary and discussion of Phase 2 findings

Although 'clear care pathways' for people with dementia at the end of life were desirable, they were often unattainable. AI sought solutions from among those already involved in providing care. As a context-sensitive intervention it addressed the participants' interests and concerns, and created a process of working that, using Fisher and Ridley's terms,²³⁷ could foster 'practical certainty' in situations when uncertainty was an intrinsic and enduring feature. AI's effectiveness is judged by its ability to create an environment in which participants were able to safely acknowledge their co-dependency and appreciate each other's role in end-of-life care (i.e. Discovery Phase), imagine the best end-of-life care for people with dementia within the home (i.e. the Dream Phase) and work together to design end-of-life care tools that would help them to attain their ideal (i.e. Design Phase).

The relocation of a person with dementia to a care home can signal a reduction in, or even the end of, the involvement and responsibility of NHS professionals. This study demonstrated the value of an intervention that sustained ongoing negotiated involvement of NHS staff.

Appreciative Inquiry focused on the practical delivery and expectation of care by taking into account the assets of the organisations involved and the capacity of the participants to build on previous achievements. It complemented approaches to dementia care that emphasise what a person retains and has capacity to do. A deficit model of care that starts with failure (e.g. breakdown in communication, knowledge deficits, inappropriate admission and uncontrolled symptoms) can identify service shortcomings, but is less likely to engage with the complex uncertainties that NHS and care home staff encounter, which Phase 1 findings demonstrated. AI did not preclude the use and refinement of existing Advance Care Plans, end-of-life care frameworks and extra training in end-of-life care, all of which aim to address the same issues.²³⁸⁻²⁴⁰ AI led to their increased use (DNACPR, palliative care register, LCP²¹⁵). However, its context-specific, non-hierarchical approach to co-design was arguably more flexible and better suited to working across organisations and between public and independent providers. Implementation of AI in Phase 2 helped reduce the use of health services and corresponding costs, and these results were corroborated by the qualitative findings. The total costs incurred by residents were lower in Phase 2 than in Phase 1.

Appreciative Inquiry was an intervention that could accommodate and address underlying concerns about responsibility and liability alongside clinical decisions. The difference between using AI and introducing an established end-of-life tool such as the GSF²¹³ was that AI led to the use and development of end-of-life resources that arose from a change in working relationships. A decision to use a particular tool did not change how care was organised, but rather was itself a result of a change in care practices and working relationships initiated by the AI intervention.

Relative interviews in conjunction with care home notes demonstrated the importance of involving relatives in end-of-life discussions and medical decisions concerning residents and keeping relatives informed of any changes and/or deterioration. The reasons why some relatives wanted more rather than less medical intervention and encouraged hospital admission needs further investigation. One relative interview highlighted the importance of viewing a resident's death within the context of their life before admission to the care home.

Finally, findings related to medication use in Phase 1 were not explored or challenged in Phase 2, but suggest that sedative load was not as significant as anticipated. Inappropriate prescribing does appear, however, to be an issue among older people both living and dying with dementia, which may warrant further research.

Limitations

The EVIDEM-EoL study is an exploratory study. The results are tentative. AI appears to improve and change working relationships with promising outcomes. It is an approach that fits with others that emphasise relational approaches to care.^{241,242} Nevertheless, more research is needed to test these findings further and with more robust controls.

The small sample of care homes and care home residents is a limitation affecting generalisability, although the resident characteristics and size of care homes were consistent with other studies in care homes without on-site nursing.²⁴³⁻²⁴⁵ Care home notes from which resident baseline characteristics were extracted could be inconsistent across time points. Residents' long-term conditions are likely to be under-reported as a result. Phase 2 was shorter, which might lead to an underestimate of the impact of the interventions introduced in Phase 2 on resource utilisation. There could also be potential underestimation of the costs of resources to support the care home residents. Outcome measures for end-of-life care were captured in the study but were limited to place of death and evidence of documentation. This made it more difficult to assess the association between resource utilisation (i.e. costs) and the quality of life of the residents in this study.

Conclusion

Dying with, or from, dementia is invariably 'protracted, unglamorous and ordinary'.²¹¹ The everyday realities of living in a care home, the impact of dementia and other health problems, and the physical and practical isolation from NHS services further complicated that process. Appreciative Inquiry addressed these context-specific challenges, emphasised the capacity and assets of the organisations and services involved, provided a basis from which to co-design new tools and use existing end-of-life care resources.

An important output of this study is the development of a framework that defines the different manifestations or levels of uncertainty, and that can be used to test the comprehensiveness and strengths of future interventions designed to improve end-of-life care for people with dementia in care homes.

As Seymour *et al.*²⁴⁶ have observed, for the vast majority of those who die, the promise of hospice and palliative care has never been fulfilled. The rapidly changing demography of ageing and dying requires solutions that are grounded in a reality that can carry the vision of hospice and palliative care into settings with limited access to specialist palliative care. Kellehear and Young²⁴⁷ have argued for a 'public health of dying' in as much as care homes are small communities of care, reliant on unqualified staff, family members and a varying range of support services; this study provides a model of relational working that arguably reflects some of those goals and realities. From an economic perspective, the findings have highlighted that there is greater scope for more efficient use of resources. However, further and continuing research on the costing and economic analysis of different end-of-life care models for OPWD in care homes is needed.

Changes to protocol

Phase 1

Phase 1 of the EVIDEM-EoL study entitled 'Changing practice in dementia care in care homes: developing and testing evidence-based interventions at the end of life' (REC reference: 08/H0502/74) received a favourable ethical opinion from the Southampton & South West Hampshire REC (A) on 14 July 2008. The Phase 1 protocol was subject to three significant amendments.

- *Amendment 1* sought to offer anonymous resident data to the EVIDEM registry study (see *Chapter 6*) (approved 30 June 2008). Amendment 1 (REC reference: 08/H0502/74) was approved by the Southampton & South West Hampshire REC (A) on 5 March 2009.
- *Amendment 2* sought to refine the process of consultee engagement. Amendment 2 (REC reference: 08/H0502/74) was approved by the Southampton & South West Hampshire REC (A) on 5 March 2009.
- *Amendment 3* sought to include ambulance staff from the London Ambulance and Paramedic Service and the Bedfordshire and Hertfordshire Paramedic Service in the research study. Amendment 3 (REC reference: 08/H0502/74) was approved by the Southampton & South West Hampshire REC (A) on 11 August 2009.

Phase 2: Intervention phase

Phase 2 of the EVIDEM-EoL study entitled 'EVIDEM-End of Life: Changing practice in dementia care in care homes: developing and testing evidence-based interventions at the end of life – Phase 2' (REC reference: 10/H0502/55) received a favourable ethical opinion from the Southampton & South West Hampshire REC (A) on 10 August 2010. Phase 2 of the study was subject to one amendment that sought to include relatives of residents living in participating care homes in the study. *Amendment 1* (REC reference: 10/H0502/55) was approved by NRES Committee South Central – Southampton (A) on 27 May 2011.

List of appendices

Appendix 35 Chapter 4: Phase 1 protocol.

Appendix 36 Chapter 4: Phase 2 protocol.

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Appendix 39 Chapter 4: NHS and social services staff topic guide.

Appendix 40 Chapter 4: Emergency services carer topic guide.

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Appendix 42 Chapter 4: Care home manager/senior carer topic guide.

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Appendix 47 Chapter 4: Intervention design, Phase 2.

Appendix 48 Chapter 4: Intervention information – general.

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Appendix 54 Chapter 4: EVIDEM-EoL Advisory Group members.

Appendix 55 Chapter 4: Care home characteristics.

Appendix 56 Chapter 4: Care home resident needs and deaths in year prior to study.

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Appendix 58 Chapter 4: Resident baseline characteristics.

Appendix 59 Chapter 4: Service utilisation and associated costs.

Appendix 60 Chapter 4: Sample information – interviews.

Appendix 61 Chapter 4: Phase 2 – documentation changes.

Chapter 5 EVIDEM-MCA: implementing the Mental Capacity Act 2005

Abstract

The MCA 2005¹⁷ safeguards the rights of people with dementia and carers, enshrining principles of capacity, decision-making and best interests. Our study, designed in four phases (pre diagnosis, immediately after diagnosis, living with dementia, end of life), explored the MCA's implementation and impact.

We interviewed practitioners from agencies working with people with dementia ($n = 272$), 'well' older people about approaches to long-term planning ($n = 37$), OPWD ($n = 16$) and carers ($n = 15$) about views and experiences of using the MCA to make plans and everyday decisions, and many of these were followed up 9–12 months later. Framework methods were used to analyse and categorise themes.

Baseline interviews indicated limited awareness, knowledge and understanding of the MCA but by follow-up these had grown. The need for training to be a continuous process informed by supervision, rather than one-off events was identified. An 'information merry-go-round' for people seeking advice and information was found. Some 'well' older people had made financial plans but appeared reluctant to think about HSC preferences and choices. Principles of the MCA, such as 'best interests' decision-making, were useful for carers to apply when deciding for their relatives. Few professionals are aware of offences under the MCA and lack confidence in distinguishing criminal acts (ill treatment and wilful neglect) from poor care.

Practitioners working with people with dementia may be uniquely placed to address decision-making and longer-term planning. Specific information and advice can empower people with dementia and carers and minimise risks of abuse and neglect. Implementation of major legal changes, such as the MCA, needs to be managed in all settings and needs long-term commitment.

Introduction

This study investigated one of the major changes affecting day-to-day practice in dementia care in England, a change that also fundamentally enhanced the rights of people with dementia and their carers. The MCA 2005¹⁷ in England and Wales, implemented in 2007, enshrines much of the practice already established under case law.^{248,249} It safeguards people who lack ability to make specific decisions, enhances personal autonomy and enables people to make advance decisions about their care and finances and to refuse treatment. It introduced new proxy decision-making roles to address health, welfare and financial matters, and specialist advocacy when major health and welfare decisions are being considered for people who do not have family or friends. The implications of the MCA for HSC practitioners were initially unclear.^{250,251}

It had been estimated that over two million people in England and Wales were likely to be personally affected by the provisions of the new MCA.²⁵² These were expected to include many people with dementia and their carers, their representatives or service providers.²⁵³ The MCA now provides a statutory framework to empower and protect people, notably those who fear cognitive impairment, those who have newly received a diagnosis of dementia, or those who have advancing symptoms who may not be able to make specific decisions at specific times (www.dca.gov.uk).²⁵⁴ It clarifies who can make decisions, in which situations, and the steps that should be taken when considering these decisions (see Mental Health Foundation, 2012 for a review on the topic).²⁵⁵ It also enables people to plan ahead in the event of loss of their capacity to make particular decisions.²⁵⁶

The ability to make choices about future care and treatment decisions led to predictions that the MCA would have great potential to enhance practice and thus contribute to better outcomes for people with dementia and their carers.²⁵⁷ People with dementia may require specialist advice sensitive to their particular values and circumstances to formulate and communicate their wishes and preferences about care and treatment. However, there are likely to be key transitions or times when advice and assistance may be most pertinent.²⁵⁸ These include professional encounters, such as the communication of a diagnosis of dementia, transitional periods when planning and setting up care packages, or when facing the end of life. It was predicted that professionals would need to devote time to assisting people with dementia and their carers to benefit from the MCA, and to make sure that they were ready to explain and debate its implications within teams and across agencies.²⁵⁹ Although savings of professional time were envisaged, there were concerns that practitioners might feel compromised by work pressures or be unable to provide the necessary expertise and support.²⁶⁰ Furthermore, proactive promotion of the MCA by service managers and professionals may be required if people with dementia are able to maximise their opportunities for planning their care and making their wishes known.

Essentially, the MCA offered people with dementia a crucial opportunity to influence professional decision-making. It confirmed that professionals should presume capacity to make decisions unless proven otherwise and that best interests should be the basis for action if a person is not able to make a specific decision. It has the potential to enhance the confidence of people with dementia and their carers that they are able to shape their current and future care and treatment. Lastly, the new criminal offences of ill treatment and wilful neglect defined by the MCA were designed to strengthen adult protection systems, to the benefit of people with dementia and others who may have particular difficulty in reporting abuse and providing evidence. The full implementation of the MCA in late 2007 provided a unique opportunity to explore the early, then ongoing implementation and impact of the MCA with a focus on its incorporation into practice and service cultures.

Methods

Aims and objectives

Two overarching aims of the study informed the initial study design (see *Appendix 62* for the study protocol). These aims were to:

1. identify the implementation issues arising from the introduction of the MCA in the services working with people with dementia and their carers over a 5-year period, in community settings (including care homes)
2. explore and make recommendations about continued professional development programmes about the MCA, and their links to adult safeguarding training and practice.

Study design

The study was designed as four phases to reflect the trajectory of the dementia syndrome: (1) pre diagnosis; (2) post diagnosis; (3) living with dementia after diagnosis; and (4) towards the end of life. Distinct research questions were developed for each phase, incorporating the overarching aims of the study. Participants for each phase were recruited accordingly. The phases, research questions and participants are summarised in *Table 68* and details can be found in *Appendix 63*.

To capture the element of change over time in the implementation of the MCA, we incorporated a longitudinal element in our study by interviewing most practitioners at two time points: time 1 and time 2 (and some groups at time 3). As our intention was to investigate how the MCA was becoming embedded in practice settings, the study was designed in order to elicit practitioners' own experiences over time as a way of capturing changes in their understanding and experiences.

TABLE 68 Phase classification of research questions and participant groups

Phase	Pre diagnosis	Immediately post diagnosis	Living with dementia after diagnosis	End of life
Characteristics of phase	Before diagnosis Possibly before contact with specialist HSC services	Early planning Capacity not likely to be greatly impaired	Capacity may be impaired Safeguarding against abuse is priority	Attitudes towards Advance Care Plans Proxy decision-making may be needed
Research questions	RQ1: How do 'well' older people conceptualise and consider future care needs? RQ2: What support is there for older people and how is it conceptualised by staff? RQ3: What are the knowledge, views, experiences and expectations of the MCA among staff supporting 'well' older people living in the community, who may wish to consider planning for their possible futures?	RQ4: What are the knowledge, views, experiences and expectations of the MCA among staff supporting people in the early stages of dementia? How does this change over time? RQ5: What advice, information and support are available to those keen to plan soon after receiving a diagnosis? RQ6: What framework does the MCA provide for people with dementia and carers living in their own homes when making everyday decisions?	RQ7: What are the knowledge, views, experiences and expectations of the MCA among staff supporting people in the later stages of dementia, when capacity may be impaired? How does this change over time? RQ8: What advice, information and support are available to those whose relatives with dementia lack capacity? RQ9: What frameworks can be put in place so that people with dementia – with and without capacity – are safeguarded against abuse? Does the MCA help?	RQ10: What are the knowledge, views, experiences and expectations of the MCA among staff who work with people with dementia at the end of their lives and their carers regarding Advance Care Plans? RQ11: How does the MCA help them make proxy decisions?
Research participants	Older people interviews Age Concern (now Age UK) Safeguarding Adult Coordinators	Alzheimer's Society Carers' Centres Safeguarding Adult Coordinators People with dementia plus carers	Social workers Admiral Nurses People with dementia plus carers Safeguarding Adult Coordinators Alzheimer's Society staff survey	Care home staff and managers Care home staff and managers

RQ, research question.

Settings

Participants were interviewed at their convenience. For the majority of practitioners, interviews took place in work hours in a private office or staff room at their place of work, although a small minority opted for telephone interviews. 'Well' older people, people with dementia and their carers all preferred interviews to be conducted in their own homes. Three participants offered to be interviewed in the researchers' office, as they were in the area and their offices were unsuitable (e.g. open plan).

Inclusion and exclusion criteria

No exclusion criteria applied to staff interviews as we sought responses from staff in each service, at all grades and undertaking a range of work with people with dementia. Because of time constraints and work pressures, some staff declined the opportunity to participate. As participation was voluntary, no further invitations were extended.

Inclusion criteria for interviews with 'well' older people were that participants had to be aged > 50 years (to explore how people possibly plan ahead as they approach later life) and the ability to participate in an interview in English. No other exclusion criteria were applied.

For interviews with dyads of people with dementia and their carers, the inclusion criteria were the presence of a formal diagnosis of dementia, and the presence of a carer whom they either lived with or saw for more than half the week. An ability to speak English was also necessary. No other exclusion criteria were applied.

Sources

In order to access the wide range of participants needed, different community-based groups were asked to publicise this study as a recruitment strategy. These included advocacy groups, social clubs and social groups, lunch clubs, support groups, Carers' Centres, Alzheimer's Society groups, Age Concern (now Age UK), Greater London Forum for Older People, University of the Third Age, local authority (LA) social services/adult services departments, and a selection of care homes in the private and not-for-profit sectors. We were keen to access as diverse a range of participants as possible, and hence recruited from different areas in and around London along with agencies that worked with diverse client groups. As Robson¹²⁵ suggests, we adopted flexibility in our sampling framework, for instance, although we started with a quota sampling frame, that is, aiming to speak to people with varying job roles and experiences, we also adopted a 'snowballing' approach – the practice of asking interview participants for suggestions of other potential participants.

Recruitment and sampling strategy

For all phases of the study, a quota sampling strategy¹²⁵ was designed to recruit participants who would be willing to share their views with the research team. An invitation letter and details of the study were provided for those who expressed interest. In some cases, contact was initiated by a presentation by a member of the research team on a related topic, at the end of which recruitment was discussed and participants were invited to participate. This proved an effective way to make contact, as it engaged the group or agency from the start and fostered a relationship based on mutual trust. Once permission from senior management had been obtained, invitation letters were cascaded to all staff via e-mails or in hard copy. Voluntary participation, confidentiality and anonymity of responses were emphasised. As noted above, 'snowballing' was a further means to recruitment.

Data collection

All who expressed interest were approached, the study was described to them, implications of taking part were explained, assurances of confidentiality were made and consent was obtained. For the analytical method chosen (see *Analytic methods*, below), SSIs within a structured format are considered most appropriate. For this reason, structured questioning was seen as too restrictive for participants to talk in detail about individual experiences, and open-ended questioning was seen as too broad and reflexive, which could have diluted the focus of this study. SSIs were conducted using topic guides developed in light of the study aims and emerging knowledge about the MCA in practice. Most interviews lasted 30–45 minutes.

To achieve maximum consistency, a similar methodology was applied to interviews with 'well' older people, people with dementia and carers. However, the researcher (KS) conducting the interviews adopted a more exploratory approach to the interview when talking with people with dementia and probed where relevant. Her experience in other phenomenological research studies was helpful in engagement and conducting interviews on sensitive subjects.

For the subsample of Alzheimer's Society staff, the Society had chosen an electronic survey as being the most efficient way to collect information from busy staff, and questions were developed accordingly. This contained as many questions from other interview topic guides as relevant and feasible.

In view of the potential sensitivity and personal nature of the interviews, participants were reassured that their anonymity would be maintained and, therefore, all identifying personal details have been changed or replaced with ellipses and 'their' has been used to replace his/her. Participants who requested

information about the MCA following the interview were provided with sources of information and specific material that was relevant to their role or interest. Following some interviews, the research team provided training on the MCA to care home staff or information to older people's groups.

Interview topic guides

Tailored, semi-structured topic guides were developed to explore the research questions at each phase. Topic guides were piloted and discussed with members of the study advisory group. For practitioners this was tailored to activities of the specific agency or professional group being interviewed. The topics covered included:

- *Training* The model and effectiveness of training received (if any), the nature of the training, the effectiveness of training in developing expertise and confidence.
- *Roles and activities* Any impact of the MCA on specific roles and activities, matters raised by people with dementia and/or carers.
- *Looking ahead* Predictions about use and uptake of the MCA and its impact.
- *Personal perspectives* Any documents that participants had drawn up for themselves or others, exploring the reasons why/why not.

A longitudinal element was captured in two ways. First, participants were asked to reflect on changes in their practice, and how these may have affected their knowledge and experiences when using and abiding by the MCA. Second, questions were specifically framed to ask participants to describe 'new' or 'recent' procedures, frameworks, structures and processes encountered following the first interview. Although time 1 and time 2 interviews were not always directly compared, an understanding of findings from time 1 interviews informed the development of the time 2 topic guide, thus further capturing the longitudinal element of this study.

The topic guides for 'well' older people in Phase 1, and people with dementia and carers in Phases 2 and 3, incorporated questions around planning (financial, HSC – referred to as 'welfare' in the MCA), everyday decision-making, proxy decision-making and sources of support they would consider or had used, or were unknown or unavailable. *Appendix 64* includes all topic guides used in the study.

Sample size

Because we used a qualitative methodology, no sample size was determined in advance. Instead, members of staff in participating organisations were approached and the importance of the study explained to them. For qualitative interviews with 'well' older people, recruiting and data collection ceased when thematic saturation was achieved, that is, when no new themes appeared to be emerging from the data. The same principles of thematic saturation were followed for interviews with dyads of people with dementia and carers. For this group we anticipated recruiting 12 dyads, allowing for around two dyads to drop out over the course of the longitudinal element of the study.

Analytic methods

All interviews were digitally recorded and transcribed verbatim by an experienced transcriber. All transcripts were checked for clarity, verified by the interviewer for consistencies and subjected to framework analysis.^{261,262} Framework analysis is appropriate for this type of evidence-based practice study, as it enables the delineation of themes in relation to prespecified research questions. This enables a priori questions to be answered through the use of qualitative research and is particularly useful in HSC services research.²⁶² More details of the five main stages in framework analysis can be found in *Appendix 65*.

Ethical permissions

Ethical requirements were maintained across all phases. Appropriate permissions from senior managers were obtained for interviews with their staff. Local government bodies' requirements for research governance approvals were met. All participants were approached through staff e-mails or written invitations but voluntary participation was emphasised and confidentiality was assured. We were keen to assure participants that the interview was not a test of them or their service, but simply an exploration of their views.

All data collected were stored in password-protected computers, accessible to only the research team. When reporting findings, any identifying data were removed and only the interviewer who collected the data was able to identify a participant. For interviews with ‘well’ older people, ethical approval was obtained from King’s College London REC (REP(GGS)/08/09–29). For interviews with dyads of people with dementia and carers, ethical approval was obtained from the Social Care REC (09/IEC08/17). For the survey of Alzheimer’s Society staff, relevant data sharing agreements were exchanged and signed.

Results

In order to obtain a multidimensional perspective on the implementation of the MCA, the study data were analysed as a complete data set. Principles of framework analysis enabled the identification of themes in relation to questions from the interview topic guides. Significant cross-cutting themes were delineated from transcripts rather than from each phase. Although the phases helped with designing the study and data collection, we judged this would be a more holistic means of presenting the findings, understanding the data and addressing the overall aims of the study.

Sample characteristics

Overall, semi-structured interviews conducted included: 272 interviews with practitioners over all time points; 37 interviews with ‘well’ older people; 16 interviews with people with dementia; and 15 interviews with carers of people with dementia. We further conducted analyses of 84 responses to a survey of carers undertaken by the EVIDEM-ED team and of 86 survey responses by staff working for the Alzheimer’s Society. See *Table 69* for description of the interviews.

TABLE 69 Participant interviews along the phases of EVIDEM-MCA

Phase	Pre diagnosis	Post diagnosis (just received)	Post diagnosis (later in trajectory)	Towards end-of-life care
Characteristics of phase	Before diagnosis	Early planning	Capacity may be impaired	Attitudes towards Advance Care Planning
	Possibly before contact with HSC services	Capacity still likely to not be impaired too much	Safeguarding against abuse is priority	Proxy decision-making may need to be made
Research participants	Older adult interviews = 37	Alzheimer’s Society = 10	Social services staff (time 1) = 10	Care home staff (time 1) = 43
	Age Concern (now Age UK) = 10	Staff from voluntary associations and Carers’ Centres = 15	Admiral Nurses (time 1) = 15	Care home staff (time 2) = 28
	Safeguarding Adult Coordinators (time 1) = 13	Safeguarding Adult Coordinators (time 2) = 12	Admiral Nurses (time 2) = 15	
		People with dementia and carers = 12	Safeguarding Adult Coordinators = 15	
		EVIDEM-ED questionnaire survey of carers = 84	Alzheimer’s Society staff survey = 86	
Total	272 interviews with practitioners over all time points			
	37 interviews with ‘well’ older people			
	16 interviews with people with dementia			
	15 interviews with carers of people with dementia plus 84 responses to questionnaire			
	86 survey responses (Alzheimer’s Society)			

Detailed breakdowns of sample characteristics are presented in each of the published papers. In summary, these comprised 10 staff from Age Concern (now Age UK) groups;²⁵⁸ 15 staff from Carers' Centres and other voluntary associations and nine staff from Alzheimer's Society branches;²⁶³ 13 Safeguarding Adult Coordinators (SACs) at time 1,²⁶⁴ 12 at time 2,²⁶⁵ and 15 at time 3;^{266,267} 28 care home managers and senior care staff and 15 care workers in care homes at time 1,²⁶⁸ and 28 care home staff at time 2 (*in preparation*); 15 specialist dementia community nurses (Admiral Nurses) at time 1,²⁶⁹ and 15 again at time 2;²⁷⁰ 10 social services' staff at time 1 (*in preparation*). We also analysed the views of 86 Alzheimer's Society staff who contributed to a survey about responding to financial abuse of people with dementia and carers.²⁷¹

Additionally, 37 'well' older people were interviewed for Phase 1;²⁷² a survey captured responses from 84 carers for Phase 2; and 15 dyads were interviewed comprising a person with dementia and their carer for Phases 2 and 3.

Thematic findings: overall

A number of themes were derived from transcripts. For the purposes of this report, overarching themes are presented (for an overview see *Table 70*) and between-group differences are highlighted.

Detailed findings are reported in the study's publications. Please refer to *Appendix 66* for a narrative description of each theme.

TABLE 70 Overall thematic findings from all transcripts

3.2.1. Universal appeal of MCA	3.2.2. Training	3.2.3. Implementation	3.2.4. Everyday decision-making	3.2.5. Long-term planning	3.2.6. Safeguarding
3.2.1.1. Beneficial	3.2.2.1. Frequency and format of training offered	3.2.3.1. Quickly and easily adapted into adult safeguarding practices and procedures	3.2.4.1. Negotiated on regular basis between person with dementia and carer	3.2.5.1. Planning influenced by personal factors	3.2.6.1. Inherent safeguarding value of MCA
3.2.1.2. Dignity and rights protected	3.2.2.2. Challenge of translating training into practice	3.2.3.2. Confidence and expertise	3.2.4.2. Past preferences and best interests principal key to making proxy decisions	3.2.5.2. Financial plans and funeral plans common, less so HSC plans	3.2.6.2. Financial management and safeguarding against financial abuse is a significant area of concern as capacity deteriorates
3.2.1.3. Familiarity with details not widespread but growing		3.2.3.3. Risk of information 'merry-go-round'	3.2.4.3. Challenges remain in understanding how best interests can be weighed up – i.e. whose best interest if the well-being of one depends on well-being of the other?	3.2.5.3. Most patients and carers did not know where to turn – conceptualising debilitating conditions is a good way to start these discussions	3.2.6.3. Warning signs of financial abuse need to be publicised more to raise awareness among practitioners, community support networks, financial bodies and society in general
		3.2.3.4. MCA expertise at all levels unlikely, but central expertise required	3.2.4.4. Inequalities in information access remained, in terms of those who had access to family solicitors and knowledgeable family members compared with those who did not		3.2.6.4. Role of banks and other community support networks

Universal appeal of the Mental Capacity Act

One of the most important themes to emerge from the study was the wide appeal of the values and principles of the MCA to practitioners working in HSC services, to 'well' older people, and to people with dementia and carers. Most of those who knew about it or had experience of using it were strongly positive about the MCA. This wide appeal contained the following three subthemes.

1. Beneficial to range of health, social care and voluntary sector practitioners.
2. Dignity and rights protected of people with dementia and carers.

The second of these two subthemes was illustrated in one of our early interviews with a participant working for a local Age UK group (see below). Although Age UK is not a specialist dementia-focused organisation, its branches and national organisation play a substantial part in advice-giving to older people. This illustrates the value of taking a broad system perspective to dementia care and support. It also highlighted the dimension to the MCA of enhancing the rights of people with dementia rather than seeing it as a professional burden.

I think it would be that it maybe just allowed people to have more rights, be supported in terms of making their decisions, and so I think that is the key thing, and that people are able to retain rights more than they have been able to, and I think the Act is around the best interest of the individual more and something about it being less restrictive in terms of the intervention on behalf of people, so I think it is really about broadening people's rights.

Age Concern (now Age UK) staff member, CO 02

3. Awareness not widespread but growing.

This third subtheme is illustrated by a short extract from a specialist community nurse working with people with dementia (an Admiral Nurse). This practitioner had yet to call on specialist support but, in practice, her decision-making appeared to rest comfortably on principles of thinking about decisions on the basis of what was in the person's best interests.

I think the only way really that it has been useful in terms of practising is that it's at the back of my mind now. When I come into contact with people and decisions have to be made, I am thinking 'is that something that is in that person's best interests or is this case where somebody else should be called in?' So I am more aware but in actual fact there hasn't been any actual incident where I felt that I have actually put it into practice.

Admiral Nurse 03

Training

We systematically asked all practitioner groups about the training they had received in order to explore the sources of their understanding and knowledge. The frequency and format of training and the challenge of translating training into practice were two subthemes that emerged. The first exposed professionals' variable introductions to the MCA and ways in which didactic training was not always seen as useful. Those who had missed initial training were not often offered opportunities to remedy this. In services with very high turnover this is a particular problem, as there is little opportunity for peer education. Some participants spoke of the problem of translating training into practice and we found few reports of the MCA being used in supervision. Staff within local authorities with responsibilities for safeguarding, and for the MCA Deprivation of Liberty Safeguards, emerged as valued sources of local knowledge and support.

Implementation

At the level of implementation, most practitioner groups found the MCA easy to apply in everyday practice. Principles of the MCA were universally accepted, and seen as reflecting the values of the Human Rights Act.²⁷³ Most practitioners felt that the MCA generally clarified their thinking around matters such as capacity and making best-interests decisions. Recording decision-making processes was proving relatively straightforward. The following four subthemes emerged.

Quick and easy incorporation into safeguarding practices and procedures

There was strong evidence from interviews that the MCA had made a difference to the safeguarding of people with dementia from abuse and neglect. Prior to the MCA this had been seen as difficult as intervention powers were unclear and individuals' refusal of support seemed hard to override. Those working in safeguarding services were unanimous that people with dementia were better safeguarded, as the extract below from one interview shows.

I think it gives a framework for evidence decision-making on behalf of someone. I think it also gives us a framework to discuss with families their responsibilities under the MCA framework. It gives people who don't have capacity a level of protection – capacity has to be made in a particular systematic way and it gives us protection as to why that decision has been made in their best interests.

Safeguarding Adult Coordinator 04

Confidence and expertise

We asked all practitioners to report on their own levels of confidence and expertise in the MCA. Our analysis is reported by professional group. Generally, those working in adult safeguarding scored highest, whereas care home staff were less confident but recognised their own limited expertise, as the quotation below illustrates. This finding has major implications for the wider system of support for people with dementia as lack of familiarity with legal powers and safeguards in one setting may mean that communication between different practitioners is not based on similar understandings. For example, we found that advance statements in a care home might be known to a manager but not other staff and the decision-making authority of a person who had been granted LPA might not be understood by care home staff. These findings chime with some of the findings of EVIDEM-EoL.

My knowledge on a standard basis would be around 2 (out of a possible 5), but if I were to do research for my clients then I would delve into it and on that specific issue, then I would be confident in getting the information. We just offer general advice and up to a level of 2 I would know general advice, and we could research if we don't know, that is more than adequate [for] my post.

Care home worker 01

Risk of information 'merry-go-round'

Taking a system-wide approach, this study also found that people with dementia and their carers remain poorly served by some agencies and professionals. The advice and information they seek may not be easily accessible and they run the risk of being passed from agency to agency. Advice to find information online seems particularly inappropriate for many people with dementia: 'Frustration that people are referred to numerous sources of information which are not able to give them advice or address their specific concerns'.

Mental Capacity Act expertise at all levels is unlikely, but central expertise is required

We noted above that local sources of expertise were emerging but did not always have explicit roles in being the main source of local knowledge. Our linked study, which audited MCA knowledge and practice in an acute hospital,²⁷⁴ also observed the limits of MCA expertise within the hospital and in its own policies and procedures. We do not suspect that this hospital is unique.

Everyday decision-making

The MCA contains principles that support everyday decision-making. However, there was limited evidence of their formal application and operation with respect to people with dementia living in their own homes and their carers. Our interviews with these individuals revealed a number of subthemes that throw light on how decisions are made within such close relationships: negotiated decisions, past preferences, weighing best interests and inequities in access to knowledge. This area had not been investigated previously. Our interviews were with people with early dementia and these themes may not necessarily apply to people whose symptoms are more severe. Four subthemes were identified, the first three of which are illustrated by a quotation from a participant.

Everyday negotiation

I like retirement. I like being at home. We [wife and myself] have breakfast together and decide what we're going to do all day. Mostly we're together but if she has one of her Ramblers' outings, I don't stop her. I'm not that kind of husband! But mostly we do things together.

Man with dementia

Past preferences being key to making proxy decisions

Oh I don't ask her what she wants any more. I know what she'll say anyway – 'anything you like, you decide'. So I just do what's best for us both. She has never had sugar in her tea. Never! And lately, she seems to like it! So I let her be, let her have it if that's what makes her happy. When the sugar runs out, I'll get some more but I'm not going to break my back getting the sugar for her because she's never had it before, you know?

Spouse carer of woman with dementia

Weighing best interest decisions

I need to make sure that my health does not suffer. I know I should be doing anything that's good for him, and I would. But I get so tired these days and I worry . . . if I go what will happen to him? So sometimes I need to force myself to rest . . . for his benefit, if you see what I mean?

Spouse carer of man with dementia

Inequalities in access to information

This subtheme arose in these interviews as well as in those with professional participants. In particular, there appear to be inequalities of access to information among those who do not have close family members or friends, and those who are not familiar with making financial plans and arrangements. Such people may never have consulted a solicitor and may regard themselves as being able to rely on continuity of care – for example, presuming that they will be able to retain their 'family' GP if they move to a care home.

Long-term planning

We asked a diverse group of people with dementia, their carers and 'well' older people to discuss their thoughts about long-term care needs and planning. They described personal perspectives and circumstances, talked of different types of plans, and some acknowledged not knowing where to turn. Three main subthemes were identified which are illustrated in the quotations below:

Planning influenced by personal perspectives and circumstances

I live for today, tomorrow you die. It has been successful for me so far, I am 79 . . . I enjoy good health and I go away every year and everything.

OA 021, male, age 79 years, black Caribbean

I don't care if I am dying tomorrow, I said to people 'look, if it is my turn that God said I should come and join Him', I said 'I am prepared, what is the use of worrying?'

OA 035, female, age 65 years, black Caribbean

What the Government have to realise is as I get older my friends get older, so at the moment I am waiting to find out if one friend is going to be buried, another friend has Alzheimer's and so it goes on and on and on and on, no way can I ask a friend my age. Younger friends lead very busy lives and they have got family problems of their own.

OA 012, female, age 84 years, white British

Financial and funeral plans common, less so health and social care plans

Participant: I am hoping that I won't be looked after [in a care home], but yes I will wait until I cross that bridge, I think.

Interviewer: Is there a reason you have avoided thinking about it now?

Participant: No, I have not thought about it, perhaps I need to think about it, I was just interested in getting the money sorted, but you are right, I do need to think about it, haven't heard about it before. (OA 016, female, age 59, British Indian)

Participant: Hopefully I will probably die [in own home] because I don't want to go into a home, unless I have to, or into an old people's bed-sit with a warden.

Interviewer: Have you made any written formal plans to ensure this?

Participant: No, I think that automatically would happen with the council.

Interviewer: Have you made any provisions to prevent being moved into a home?

Participant: No, I don't know how I can.

OA 023, female, age 68 years, white British

Limited support with knowing where to turn

No (not sure where to seek help around care), I have a financial adviser so he keeps up to date with everything, and, you know, he is very good – like certain policies that I used to have that he felt that I should cash them in, you know, because I have become ill, he said it is no use carrying on with them, so he has advised me to keep a certain life[style], car, and things like that – but certain policies I was paying in monthly and that and he said it is not worth it at the moment so that is very good.

OA 037, female, age 53 years, British Indian

If I made plans in the future, well I could think of an event immediately that would save me the trouble, if my doctor tells me I have only six months to live, something like that. But I think if a doctor told me that I had dementia, then yes, I would be making plans in that case, but I cannot think of anything else which would precipitate that. Well it is all I can think of at the moment, there may well be others you know, or if I have a sudden debilitating illness I suppose, like muscular dystrophy.

OA 010, male, age 70 years, white British

Safeguarding

As noted above, a significant element of the MCA is the safeguards it provides for vulnerable people such as those with dementia. Almost all practitioners noted this in their accounts of everyday practice. Alongside this central tenet, three subthemes emerged, which are illustrated in the quotations below:

Inherent safeguarding ethos

I think it has shifted the relationship between the people who receive services and those who provide services if it's being implemented properly. And it can be challenged in law. It keeps us in our place. We provide support and expertise but in the end it's their decision. And in our care management procedures it's about positive risk taking. Life is about risk and adventure. When I first came into safeguarding it was about protection. If they are being empowered and feeling in control the chances of them being victimised are less.

Safeguarding Adult Coordinator 08

Need for help with financial management and safeguarding

Financial abuse is one of the second biggest abuse (types) that occurs in (area), it's the second biggest of our alerts. There are a substantial amount of people with memory impairment which leads people to believe that they can get away with it.

Safeguarding Adult Coordinator 07

Warning signs of financial abuse should be publicised

We've done one (referral to the Police concerning a person who had gained) Power of Attorney. He befriended a couple when they had capacity. The husband died and the wife gave him Power of Attorney. He moved into the property and he moved her into a small room. The (person granted) Power of Attorney was not willing to spend money on her – for nightdresses and things when these were asked for. We've gone to the Court – the Office of Public Guardian has asked for bank statements. We've moved the lady to a place of safety; he doesn't know where she is, while investigations are going on.

Safeguarding Adult Coordinator 019

Role of banks and community support networks in risk reduction

Many of those who had encountered people with dementia (whom they thought were at risk of financial abuse) thought that more could be done to reduce these risks if banks and other financial bodies were more engaged with safeguarding services so that they could draw attention to emerging concerns about a customer's vulnerability. Our investigation of this subject was extended by a partnership with the national Alzheimer's Society in which we offered support in the devolvement of their national staff survey and shared data from our interviews with Adult Safeguarding Coordinators. This partnership established the extent of carers' concerns about financial exploitation of their relative with dementia and, for the first time, highlighted the growing risks of internet and telephone scams.

Discussion

Strengths of the study

There are two main strengths of this study: (1) the range of practitioner groups that shared their views of understanding and using the MCA in their work and permitted us to see this from a systems perspective and (2) the longitudinal nature of the study that enabled us to explore change in perceptions among the same groups of practitioners, their successors, and among people with dementia and their carers. Together, these contributed to a form of triangulation of data that provided us with a holistic perspective on how the MCA is being implemented and incorporated into practice and everyday decision-making.

We gained insight into a breadth of experience, as well as depth over time. Our familiarity with the emerging literature on the MCA led to an invitation to produce an integrative review of the MCA evidence for dementia practitioners.^{275,276}

An additional strength of this study is its predominant use of qualitative methods, which gave participants the opportunity to discuss their experiences in greater depth than might have been possible from any other method, such as a survey. Qualitative interviews further enabled us to probe appropriately according to the responses given. We also drew on survey methodology when we wanted to obtain a greater number of responses and a broader (rather than deeper) perspective, as in the survey of Alzheimer's Society practitioners' views of managing money, and by conducting secondary analysis of the EVIDEM-ED survey of carers' satisfaction with legal and financial advice, planning and referrals. We drew on national and local media for examples of criminal prosecutions under the MCA (as these are not collected nationally). We also mined our research unit's unique collection of Serious Case Reviews to investigate their coverage of MCA practice.

Methodologically, the rigour or trustworthiness of the study can be established by three criteria: credibility or validity of study findings, confirmability or dependability of study findings, and transferability or generalisability of the interpretations:

- (a) *Credibility or validity* was sought through obtaining a wide range of perspective, over time, on the issue, ensuring that a broad holistic view of the research question was obtained in our data. A commitment to iterative collection and analysis also supported this.
- (b) *Confirmability or dependability* of interpretations was established through clear description of analytical methods, peer analysis of data, rigorous paper trails and reflexive thinking on the parts of the researchers.
- (c) *Generalisability or transferability* to other settings was sought through detailed discussion with research peers, through the multidisciplinary advisory groups of the MCA study and the research programme as a whole, who offered insights in the transferable elements of our study in various settings.

Limitations of the study

Our study is limited in that participants were not always the same between time 1 and time 2 due to staff changes and differences in availability. We were unable to observe practice and everyday decision-making and relied on participants' accounts. Our interviews with people with dementia and their carers were undertaken with a group in which dementia symptoms were not severe. Planning and decision-making may change as severity and disability increase.

Interpretation of the study findings in light of previous research

Interviews conducted during time 1 revealed interesting trends related to early implementation and expectations of using the MCA. The value of the MCA in supporting carers was a development first identified in this study during early interviews with Alzheimer's Society staff.²⁶³ These staff reported that the framework of the MCA was very useful to carers, particularly around long-term care planning and the 'best interests' principle. Challenges in proxy decision-making have been recorded²⁷⁷ and, based on this understanding, we investigated how proxy decision-making by carers was developing and changing over time. Although a person with dementia and their carer may require separate advice,²⁷⁸ we found that many of our dyads presented themselves as a unit and talked of the importance of getting advice together so they could discuss the implications with each other 'there and then'. We found that, if approached sensitively, some dyads welcomed the opportunity to discuss long-term care planning. However, some did not and in many cases, it falls to a skilful practitioner to gauge individuals' needs and wishes. We also have drawn attention to the potential to think about advance planning and arrangements among people who do not have family or friends who are willing and able to take on such roles.

Safeguarding Adult Coordinators appeared to find the MCA easy to incorporate into their systems of work.²⁶⁴ Most were well informed about it and acted as sources of expertise locally. Prior to the MCA, many SACs considered there had been a legal vacuum around decision-making.²⁷⁹ We cautioned at time 1 if this concentration on MCA work could mean that safeguarding work was in danger of being sidelined, further contributing to demands on SACs' time and resources. By time 2, most SACs continued to be well informed and had greater experience in using the MCA.²⁶⁵

There is a need, however, for continuous training to be sustained over time, given the high rate of staff turnover in social care settings,²⁸⁰ and even among SACs as our participant groups showed. The extensive investment by the DH in developing training and publicity at the time the MCA was implemented in 2007²⁸¹ will not be repeated. Having the confidence to use and refer to the MCA also grew, alongside knowledge and experience with using the MCA, but it is unclear how case law and other developments are being fed into practice. At the time of writing (April 2014) Parliament has been debating the new Care Act 2014, as proposed by the White Paper *Caring for our Future: Reforming Care and Support*,²⁸² and the experiences of the MCA implementation have lessons for how new law can be incorporated into professional transfer training. We have discussed these lessons with stakeholders in Ireland where a new Mental Capacity Bill, similar to the MCA, is shortly to be published and with dementia researchers and gerontologists in Australia, including policy-makers in the state of South Australia.

Our study also highlighted how voluntary sector organisations often served as valuable sources of support and advice to people living in the community but their knowledge varied. Staff from Age Concern (now Age UK) and carers' organisations were not always specifically trained about the MCA, and tended to rely on signposting to other organisations that they felt would be more knowledgeable about legal matters.²⁵⁸ Signposting is an important part of any local information strategy and the need for it may be greatest among people lacking confidence, having mixed experiences with 'officialdom' and those who are on their own in later life. Age UK at the local level was a major resource for some older people who were keen to discuss and consider long-term care planning.²⁷² However, our interviews with 'well' older people revealed that attitudes to planning could also be based on personal inclinations and long-term habits, as well as preferences. Approaching GPs or primary care services was not generally considered appropriate unless there were health concerns. Professionals working with people with dementia and their carers may need to offer time and a listening ear in order to support people who are feeling that matters are slipping out of their control at many levels.

By time 2, community nurses' and adult safeguarding staff's understanding of the MCA was generally more sophisticated. However, specifics of the MCA remained blurred among some and memories of training were dim. Some community nurses, initially themselves often lacking confidence, expressed concern about a lack of understanding of the MCA among other professionals.²⁷⁰ One exception to this was that many participants at time 2 were aware of the importance of financial planning and that they could promote understanding of this among their clients or service users.²⁶⁵⁻²⁶⁷ This confidence was obvious about end-of-life care planning, except among care home managers who described undertaking such discussion with residents on moving into the home, but largely without reference to the MCA.

This study has highlighted that many professionals have experience of family members with dementia, an observation that has not previously been evidenced. At a personal level, some reported finding family decision-making and planning potentially easier under the MCA, but loss of decision-making capacity or family disputes were sources of tension. We note the value of building upon the personal experience of practitioners to promote empathy with family carers in the provision of timely information and advice.^{263,268} There have been surprisingly few investigations of the overlap of professional and personal experiences of dementia caring and so this study has added to the literature.

The offences of ill treatment and neglect created by the MCA were poorly understood and their implications have not been reported widely in professional or research-based literature.³⁹ Understanding among practitioner groups was minimal, as reported in our papers.^{269,270} Accounts given appeared to be based on 'common sense' rather than legal definitions and thus potentially erroneously downgrading the offence of ill treatment and wilful neglect as poor practice. We therefore investigated this subject more thoroughly through the use of a consensus group. This group recognised the importance of highlighting that poor practice could be addressed by legal sanctions but were unsure how to access emerging case law and to promote learning from it. In conjunction with our understanding that some MCA training has been reported to be didactic and piecemeal, or needs to better reflect practice dilemmas and uncertainties, we have developed resources on this facet of the MCA reflecting the findings of our interviews. These include overviews for dementia practitioners²⁸³ and for the care home sector.²⁸⁴

Conclusions and implications

There are three main lessons to be drawn from this study. For HSC practitioners it is evident that this legislation met a need in practice and that the legislation has largely been easy to work with, that professional values are in accordance with the values and principles of the MCA, and that it has promoted interdisciplinary and interagency working. This is possibly a result of the consensus that shaped the legislation: the involvement of practitioners in the implementation of the MCA and the devising of its Code of Practice. Engagement with practitioners and with stakeholders from patient/user and carer groups may be a valuable consideration for other change processes.

Second, this study has gleaned information about training transfer, the process by which professionals and non-qualified staff (the majority of practitioners working in dementia care) are provided with training while in post and change their practice. One advantage of a longitudinal study is that we were able to discuss training at various intervals, to talk to practitioners about what seemed to work well and whether or not they were able to refresh their knowledge and skills. We found that training was not always welcome or seen as relevant if it was didactic in nature, that there seem to be gaps among hospital-based staff in particular, and that few employers are explicitly checking that their new staff are familiar with the MCA. There was surprisingly little use of the MCA in supervision among professionals. Many practitioners were reliant on local expertise but this ran the risks of overloading certain sources. In light of the high levels of concern about financial abuse of people with dementia expressed by many participants, there may be scope to highlight this among all practitioners – especially to alert them to the targeting of people with dementia by strangers and by electronic or telephone contacts.

The third lesson lies in the potential inequalities of information. Providing information online may be acceptable to professionals but it is not welcomed by many older people or carers. Those with knowledgeable family members or those who have legal advisers are better off in this regard. Information was also not always shared among services, with one particular gap in social care – where some care home staff are not familiar with the implications of the MCA and the legal documents that their residents may have drawn up but which the residents are no longer able to bring to staff's attention. The key professional here is the person's GP but the sharing of MCA details with the GP and consequent passing to new care providers was not commonly encountered. We further noted the potential of an 'information merry-go-round' locally, as not all voluntary sector staff offering information and advice were confident in their knowledge of the MCA and potentially re-referred people making enquiries. A similar lack of expertise and confidence was also found among some professionals, such as some community nurses, who were otherwise likely to be seen as highly informed about dementia.

We do not suggest that everyone needs to have legal expertise in dementia services. The implication of this study is that it should be available and that information, advice and assistance are not the same. Commissioners may wish to ensure that these three areas are covered. Although memory services,

for example, may give early information, some people with dementia and carers do not wish to take this up at the time of diagnosis but when these issues do arise they may not have contact with staff from a memory service. Advice to look 'online' may not be adequate or person centred.

Conclusion

This study broke new ground in investigating legislation that has fundamentally altered dementia practice and the experiences of many people with dementia and their carers. Although many people with dementia and carers will not encounter the MCA directly, it has great salience for them and its principles are widely supported by practitioners. Our research has outlined how new law is transferred to services and professionals. It has learned about changes in experience and confidence over time. It has focused on day-to-day decisions, as these are at the heart of human relationships. We are most grateful to all those who have allowed us to hear directly of their practice, plans, decisions and experiences.

Impacts

- The research team has engaged with members of staff working with CNWL NHS Foundation Trust at events such as the annual summer schools across the study period, providing updates and workshops on aspects of the MCA (see *Acknowledgements, EVIDEM-MCA publications and presentations*). Discussions have been held with different professional groups and feedback provided to the Trust on MCA staff training.
- A Dementia E-Learning Package (2012) was commissioned by King's College School of Nursing and Midwifery and has subsequently been delivered to staff across the NHS South West. This educational package comprises the following modules: Introduction to Legal, Ethical and Cultural Issues in Dementia Care; Developing Competence in Social, Legal and Cultural Context; and Advanced Competence in Social, Legal and Ethical Context of Dementia. These are continuing professional development courses that a range of staff can undertake.
- The research team was invited to undertake a literature review for the Joseph Rowntree Foundation on improving practice in communication with older people living in housing with care schemes, which made use of the EVIDEM-MCA study's findings. This was published by the Joseph Rowntree Foundation²⁸⁵ and revised for a peer-reviewed publication.²⁸⁶
- The research team worked with Dr Mareeni Raymond on the development of a toolbox for GPs on dementia for BMJ Quality during 2011 to 2012.
- This study team provided assistance to staff of the Mental Health Foundation as members of its advisory groups on the Mental Capacity Advocates study and Proxy Decision-Making (INDIPS study). The study is represented on the Advisory Group of the NIHR School for Social Care Research (SSCR)-funded study of the MCA Deprivation of Liberty Safeguards.
- Membership of the Dementia Action Alliance (DAA) was awarded to the Social Care Workforce Research Unit. The DAA is a national consortium of over 100 organisations committed to transforming the quality of life of people living with dementia in the UK and people who care for them. Our application drew attention to work on the EVIDEM programme and other studies. In our application we drew up an action plan to outline how we remain actively committed to involving people with dementia and carers in current and future research (www.dementiaaction.org.uk/info/2/action_plans/117/social_care_workforce_research_unit_kings_college_london).
- The study contributed to the Alzheimer's Society's policy and communications work on safeguarding people with dementia from financial abuse²⁸⁷ (http://alzheimers.org.uk/site/scripts/documents_info.php?documentID=1770). The research team provided expert review of three of the Society's fact sheets on Financial Abuse and Making Decisions, which are available to members of the public.
- The research team has informed student and professional development studies in several UK universities by discussing study proposals and details (e.g. at University of Bedfordshire).
- The MCA lead at the DH has requested all outputs from this study and pre-publication copies have been sent to her.

Building on research capacity

Nested within the EVIDEM-MCA study was a further NIHR Service Delivery and Organisation-funded research study, 'The transition from cognitive impairment to dementia: older people's experiences'.²⁸⁸ This study complemented the EVIDEM-MCA study by providing the opportunity to investigate the dementia diagnosis transition from the perspective of people receiving this diagnosis and their carers. It highlighted the nuances of providing 'information' and the need to think about what information is wanted, understood and retained. The literature review confirmed the professional focus on care and treatment at the end of life (Advance Care Planning), and less so on day-to-day decision-making in dementia.²⁸⁹ Implications for commissioners and primary care teams were published in the *British Journal of General Practice* in 2013.²⁹⁰

A second study was also nested in the EVIDEM-MCA study. Although the EVIDEM-MCA study protocol explained that the focus on the research would be community based, the opportunity arose to work on the findings of an audit covering policy and practice about the MCA in one teaching hospital. This audit provided valuable insight into the implementation of the MCA in this setting, where reasonability appeared to have been diluted and procedural documents were incomplete and overlapping, and where training had been partial and not reflective of the needs of adult learners.²⁷⁴

Research capacity was further built by the involvement of new and junior staff in the study. This included assistance with interviewing, when senior staff mentored researchers who were new to dementia research, and help with study outputs (from Nigel Charles, now of University of Plymouth, and Jess Harris of King's College London). The EVIDEM-MCA study has also provided illustrative case examples of approaches to research with care homes as published in the ENRICH Research in Care Homes resources (www.DeNDRoN.nihr.ac.uk/enrich/#.UEcmZcEiaHc).

Changes to protocol

The original protocol aimed to recruit a range of staff from HSC services. This included IMCAs and medical staff using the MCA. We subsequently learned that the DH and others had commissioned studies with IMCAs^{291,292} and in the field of health care, with patients²⁹³ and with health-care practitioners.^{254,294,295} There was a clear evidence gap in the views, experiences and expectations of social care staff when using the MCA. Social care practitioners were also those who were most likely to come into contact with people with dementia and carers living in the community. Following guidance from our advisory group, we focused on this particular and diverse group of practitioners, as this was, and remains, the under-researched population and sector.

List of appendices

Appendix 62 Chapter 5: EVIDEM-MCA protocol.

Appendix 63 Chapter 5: Details of the four phases of study design.

Appendix 64 Chapter 5: Semi-structured interview schedules.

Appendix 65 Chapter 5: Five main stages in framework analysis.

Appendix 66 Chapter 5: Narrative account of findings.

Chapter 6 EVIDEM: from cohort to research register

Abstract

The EVIDEM programme aimed to develop a cohort of up to 2000 people with dementia and their carers in order to recruit along the dementia disease trajectory, from diagnosis to end of life. The EVIDEM programme's position in an NHS Trust allowed the research team to work closely with the North Thames DeNDRoN to create a register for people with dementia and their carers who wanted to become involved in research. The register contributed participants to EVIDEM studies, facilitated other dementia studies in the North Thames DeNDRoN area and provided a model for register development more widely.

A technology development methodology was used to develop the register. The construction and population of a dementia research register was feasible but its initial phase of development was complex because of ethical and organisational difficulties. Recruitment from primary care was particularly costly in staff time and identified only a small number of people with dementia who were not already known to specialist services. Recruiting people with dementia through secondary care was more effective but was also a resource intensive process.

In 21 months of operation across four NHS trusts, clinical researchers invited 1400 people with dementia or their carers to enrol in the register, gained consent from just over 800 and recruited around 230 to studies. To achieve the upper target of 2000, cohort members would take, we estimate, about 4–5 years of consistent recruitment through the existing register.

Background

UK government policy is to maintain people with dementia syndromes in their own homes for as long as possible.¹⁸ However, the needs of people with dementia and their carers are inadequately addressed at all key points in the illness trajectory, from diagnosis through to end-of-life care.²⁹⁶ Further research is required to understand the barriers to the timely recognition of dementia syndromes in primary care,⁷ the support needed by people with dementia and their families after diagnosis, the factors predicting relocation of people with dementia syndromes to care homes, the best methods of managing incontinence and challenging symptoms²⁹⁷ and the therapeutic options available to clinicians, which are currently sparse and insufficiently evaluated.²⁹⁸

Some treatments for people with Alzheimer's disease have been shown in trials to be modestly effective in modifying symptoms²⁹⁹ and emerging therapies – both pharmacological and psychosocial – will need rigorous evaluation in large-scale trials. The design of these trials will raise many questions, including which populations should be studied, for how long and with which principal and secondary end points?³⁰⁰

These questions may be difficult to answer. Difficulties in ensuring that samples are representative have meant that people with dementia who are recruited to clinical research have been younger than the general population of people with dementia, whereas women, the oldest old and ethnic minorities have been under-represented in study populations. Such under-representation may not always affect the external validity of relative effect estimates, but measures of absolute effectiveness, absolute harm and cost-effectiveness are associated with underlying risk levels in different sociodemographic groups and under-representation of subgroups will bias absolute effect estimates.³⁰¹ Research on dementia could gain much from the study of patient populations that more appropriately reflect the population at risk.³⁰²

Age is particularly important given the potential for delays in dementia diagnosis, the inexorable progression of dementia and the diminishing capacity of people with dementia to give informed consent to participate in research.

In theory, primary care-based studies could address these problems of representativeness because of the heterogeneity of the community-dwelling population but, in practice, we know from recent trials that recruitment to studies on dementia through general practice is problematic.^{303,304}

Promoting dementia research

One of the barriers to recruiting people with dementia to clinical trials is the lack of a suitable tool that would facilitate identification of potential participants with the desired baseline characteristics. Registers for patients with motor neurone disease and Huntington's disease have been long established but to date there is no equivalent register in the UK for those with dementia syndrome. This situation prompted North Thames DeNDRoN to test the concept of a research register of people with dementia who would express an interest in participating in dementia and cognitive impairment research in general, rather than specific studies. North Thames DeNDRoN was one of the seven regional DeNDRoN networks and was a collaboration between three universities [Imperial College London (ICL), Queen Mary's University of London (QMUL) and University College London (UCL)] and 36 NHS trusts covering all North London boroughs plus areas of Essex, Hertfordshire and Bedfordshire (26 acute trusts, 10 mental health trusts). It is hosted by one NHS trust.

The EVIDEM programme needed to recruit to five specific studies but also had an interest in creating a cohort of people with dementia to allow studies to take place along the entire trajectory of dementia, from diagnosis to end of life. A joint approach to creating a register and deriving a cohort was a logical way to combine researcher expertise with the research facilitation objectives of DeNDRoN. A full description of the early stages of this project is reported elsewhere,¹⁰⁰ and this chapter is based substantially on that account.

Research registers

There is now considerable experience of developing research registers, particularly in North America. Many registers have been developed to facilitate epidemiological studies³⁰⁵ but can also offer an organised and systematic way to maintain contact with participants from previous research and recruit an even more diverse pool of subjects interested in participating in future studies.³⁰⁶

Research registers have been used in dementia research to study the clinical expression of Alzheimer's disease³⁰⁷ and to improve the flow of information in order to increase research participation.³⁰⁸ The US Consortium to Establish a Registry for Alzheimer's Disease (CERAD)³⁰⁹ has functioned as a vehicle for a wide range of studies and as a mechanism for developing and testing dementia-specific instruments. In 2008, the Leon Thal Symposium proposed the development of a US National Registry and Database to meet the multiple needs of the research field, including the development of a research programme on prevention.³¹⁰ Similarly, the European Alzheimer's Disease Consortium, in 2010, proposed the construction of international research registries for studies of familial Alzheimer's disease and for therapeutic trials.³¹¹

However, there are difficulties in developing research registries. Although registries based on routinely collected data can offer opportunities for research, they pose problems of data organisation and accuracy for researchers.³¹² Prospective collection of additional data requires organised outreach from the registry to patients, providers and staff, integration of the register into pre-existing clinical routines and addition of reminder systems to clinical workstations.³¹³ Unique challenges in recruiting and retaining participants with neurological disorders for research studies include the cognitive deficits of the participants and the complex ways in which many neurological conditions present.³¹⁴

The perceived advantages of a research register were that it could allow prescreening of research-ready populations for different types of study, allow more accurate assessments of study feasibility (because the potential research population would be known), and create the basis for longitudinal studies.

Construction and contents

The research and development questions we asked in the joint EVIDEM and North Thames DeNDRoN project were:

1. Is it feasible to develop and sustain a research register for people with dementia?
2. What are the actions and resources required to develop and implement a dementia research register?
3. What are the clinical requirements for a dementia register for the purpose of clinical trials recruitment?
4. What are the likely recruitment rates to a dementia research register?

Register design

The development of the register was based on a standard technology development methodology, originally derived from the construction of decision support systems.³⁸ This involves phases of modelling and prototype creation, 'bench testing' and refining of the prototype with experts, and then 'field testing' of the refined prototype register in exemplar sites. We have used this methodology elsewhere in the EVIDEM programme (see *Chapter 1*).

A co-design approach was taken,³⁷ bringing together researchers (in the EVIDEM programme), research network developers (in DeNDRoN) and people with dementia and carers, through the PPI arm of DeNDRoN. Expert advisors from the Centre for Health Informatics at University College London were recruited to the design team to develop the electronic database for the register.

The design team met on six occasions during 2008–9 and held monthly teleconferences to review progress. The design team consisted of five members from the EVIDEM programme (Iliffe, Lowery, Rait, Walters, Kharicha) and two from North Thames DeNDRoN, bringing together academic, clinical and research network expertise. The design team developed a prototype register, 'bench tested' it with other experts in the field, and then initiated recruitment to it, initially in one specialist pilot site but also in selected general practices.

The proposals for the register were discussed with DeNDRoN's PPI working group (made up of DeNDRoN regional workers and members of third-sector organisations) and its PPI forum (made up of people with neurodegenerative diseases and their carers).

Modelling, 'bench testing' and prototype development

The objectives agreed by the joint design team were to:

- (a) identify people with dementia and their carers through primary and secondary health care, social care, community care and voluntary sector organisations in the North Thames DeNDRoN region
- (b) invite patients to join a research register
- (c) gain consent for a minimum data set of information about patients to be held on the research register
- (d) enable clinical research staff and registered research staff to search for patients relevant to a set of user-defined parameters, and then use that retrieval set as the basis for making contact (through the patients' clinicians)
- (e) enable the register staff to maintain a list of studies to which the patient has been invited, is deciding about, has consented to or is participating in
- (f) enable appropriate matching of register members to research projects and further anonymised analyses
- (g) manage all such data securely, using role-based access and maintaining an audit log.

Recruitment to the registry would occur in the geographical area covered by the North Thames DeNDRoN (North London, and parts of Essex, Buckinghamshire and Hertfordshire). Recruitment would be tested in primary care, secondary care, and if possible in social care (e.g. care homes), community health care (e.g. community nursing services, Admiral Nurses) and third-sector (voluntary) organisations (e.g. Alzheimer's Society).

The target population was defined as people of any age, with any form of dementia, residing in the community or residential care within the defined geographical area.

The inclusion criteria chosen were people with either a formal specialist (imaging/neuropsychological) or informal generalist diagnosis of dementia, as well as participants with cognitive impairment presumed secondary to an underlying neurodegenerative disease. The case definition includes different types of dementia syndrome and people with dementia of differing severity (from early to late dementia as well as mild cognitive impairment). We agreed to include non-ICD-10 Diagnostic and statistical Manual of Mental Disorders-Fourth Edition (DSM-IV) diagnoses but the source of, and basis for, the diagnosis would be a field within the register to allow prospective filtering to match the quality needs of future research projects.

The exclusion criteria we selected were (1) people who do not speak English, for whom an interpreter could not be located and (2) those whose clinician believed would be inappropriate to approach, for specific reasons like receiving end-of-life care, treatment for severe comorbidity or major behaviour disturbance.

Ethical approval

Although the primary aim of the register was to support research, the design team felt that it was essential to seek ethical approval, in part because diminishing capacity to consent to participation in research is a feature of dementia syndrome. In addition, the Data Protection Act⁵⁰ requires that all patients who are identified for research projects have given their consent to be identified in this way. Although other disease research registers had not sought approval from ethics committees, the design team believed that an ethics committee would provide another layer of expert opinion about how best to explain the purpose of the register. In addition, the rigorous and well-documented consenting process that has to be applied following an ethics committee's approval provides a clear, auditable and defensible pathway documenting dissemination of information about the register, the assessment of capacity and the storage of clinical documents, should challenges arise. Approval for the trial was received from Southampton & South West Hampshire REC (A): reference 08/H0502/34.

It was also clear that recruitment of large numbers of people with dementia and their carers would require Research Management and Governance approvals across multiple sites and sectors, and information management approvals for data storage. In addition, the joint team had to develop a minimum data set and database, and devise mechanisms for capturing data in primary and secondary care, and through other routes, such as care homes and third-sector organisations.

Constructing the minimum data set

A minimum data set was developed in three stages. In the first stage, comments on the secondary care requirements of the data set were gathered from the North Thames DeNDRoN's executive board, supplemented by individual discussions with researchers within the local network. In the second stage, face-to-face interviews with 39 GPs were conducted to discuss the potential for using data from the general practice reimbursement mechanism (the 'QOF') for dementia. In the third stage, members of North Thames DeNDRoN gave feedback on the minimum data set fields generated in the previous two stages, and the data set was refined based on this feedback. *Box 6* shows the contents and data fields of the minimum data set. The design group intended that the minimum data set would evolve over time to be consistent among collaborating centres, as far as pragmatically possible.

BOX 6 The minimum data set**Data to be included on the registry**

- For all *primary care practices* we recorded location (PCT) and deprivation index score.
- For all *clinics* we recorded specialist and clinic location.
- For *other services* we recorded location, e.g. care home, supported accommodation, elderly mentally infirm home, and key worker details.
- For all *participants* in the register the following information (extracted from practice or clinic notes) is recorded where possible:
 - demographic details (name, date of birth, gender, marital status, first language, ethnicity, address, postcode, housing status, NHS number)
 - carer information (name, date of birth, gender, address, postcode, relationship to person with dementia)
 - practice details (name, address)
 - specialist details (name, clinic details)
 - cognitive status (date of most recent test and score)
 - functional status (date of most recent test and score)
 - behavioural/neuropsychiatric status
 - investigations (imaging and dates)
 - specific dementia medication
 - comorbidity (e.g. depression, cardiovascular disease, diabetes)
 - history of participation in trials/studies.

We were aware that information recorded in notes would be variable across services and sites. This minimum data set was based on data known to be routinely collected in secondary care clinics assessing patients with cognitive disorders, but its applicability to primary care was unclear.

We therefore invited 25 GPs from 10 practices known to be both interested in dementia and engaged in research, to assist us with a study of the data content of the records of patients with dementia. Five accepted the invitation and four (all from different practices) were able to commit time to it. In each practice the electronic medical records were searched by the GPs for patients with dementia, and individual records were scrutinised ('hand-searched') for information in the data fields shown in *Box 6*.

Figure 22 shows how information that could be used to prescreen patients with dementia is distributed across codes, free-text and scanned documents, and which categories (e.g. functional abilities) are commonly missing. This demonstrates the amount of additional work that would be required to use existing GP electronic records as the source of data for a registry. This finding, together with a pilot recruitment study in general practice (see below and *Appendix 67*) convinced the joint team that the research register should be built primarily from patient populations that were already engaged with specialist services.

Three aspects of the minimum data set were seen as important by both researchers and PPI experts, and confirmed as such by an ethics committee: confidentiality, duplication of information and access.

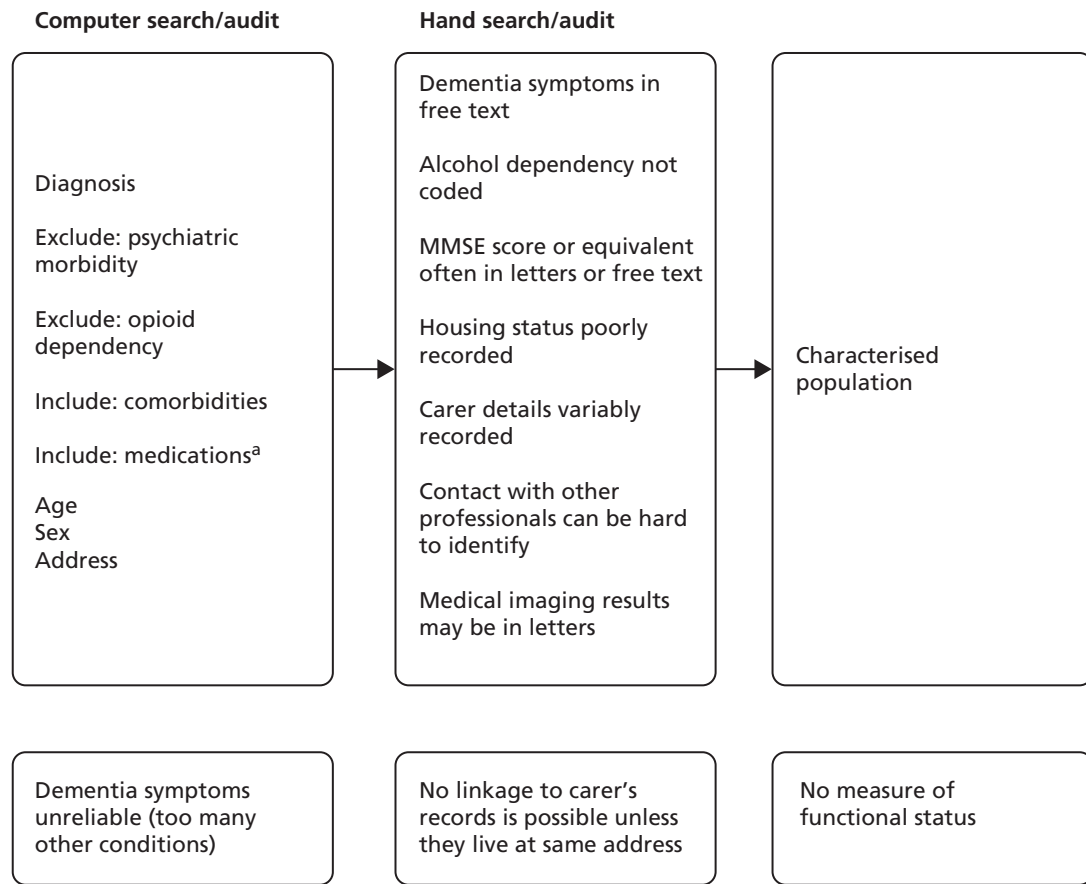


FIGURE 22 Prescreening from GP record. a, Medications may not be accurate in all cases.

Confidentiality

A unique identifier is assigned to all participants on the register so that data are held anonymously. A file linking name and unique identifier is stored separately and securely, and in accordance with the Data Protection Act.⁵⁰ This will be held until the participant indicates that s/he no longer wishes her/his data to be included on the register, and 6-monthly reviews will allow reaffirmation of register status. Six-monthly reviews were chosen because of the relatively rapid health status changes that can occur in dementia syndrome. It is intended for the register to be comprehensive and to be able to include all patients seen in the North Thames DeNDRoN region in order to be representative of the patient population.

Duplication

Information on whether or not the patient has been/is currently participating in research studies will be included on the register to avoid patients being approached for participation in multiple projects, and register managers will cross check key identifiers (name, date of birth, NHS number) of potential new participants to ensure that people with dementia and their carers are not approached repeatedly.

Access

National and regional researchers wanting to access the registry would need to approach North Thames DeNDRoN in the first instance. Prioritisation of studies within the North Thames DeNDRoN portfolio by local researchers was anticipated and access to the register would reflect this prioritisation. Governance of the registry would be managed through DeNDRoN's national co-ordinating centre, in the first instance.

Constructing the register

Physical construction of the research register and its use at the first sites provided experience of the practical problems involved in recruiting people with dementia to a research register. These included identification and invitation of potential participants, judgement of capacity, and obtaining both official permission and actual support from practitioners and administrators to recruit through NHS services.

Identification of people with dementia

This was undertaken using medical records compiled with the then-current recommendations from the Patient Information Advisory Group. These recommendations allowed only members of the patient's usual clinical care team to identify patients suitable for the register. The lead clinician (or other member of the normal clinical team responsible for the patient's care) would then make the first contact with the patients identified, either in a face-to-face meeting or by letter/telephone. This contact would be only to inform the individual or their family about the register; enrolment would usually take place separately from the clinical encounter in which the information about the register was given. There were, in practice, exceptions to this, as some people were keen to enrol immediately rather than wait until their next appointment. In cases when people feel they have had sufficient time to consider their decision, their consent can be taken on the same day as they receive the information. *Figure 23* shows the recruitment path that we developed for an individual enrolled through a memory clinic. This process is likely to vary slightly to reflect differing care pathways in different memory clinic services.

Judgement of capacity

To ensure that people at all stages of the disease process were able to join the register requires judgements about decision-making capacity. (This proved particularly difficult in primary care – see below.) A recent analysis of ability to consent to research in a therapeutic trial of Ginkgo biloba found approximately 70% of individuals with mild-moderate dementia could not give valid consent to research participation.³¹⁵ In the case of individuals who are not able to give informed consent, UK MRC and European Union-GCP guidelines and the principles of the MCA 2005¹⁷ (England and Wales) were followed, and opinion sought from a relevant consultee. This is also in accord with internationally accepted guidelines on research involving human subjects with dementia.³¹⁶

Seeking permissions

Research Management and Governance offices at each NHS trust where researchers were interested in setting up the research register were approached for permission to involve trust staff. Seeking multiple permissions across provider organisations in primary and secondary care proved to be a lengthy process, taking up to 5 months per organisation. This process was not made easier by high staff turnover rates in the DeNDRoN research network itself and the time needed for training, Criminal Research Bureau checks and research passport applications for new study officers. The steps required to engage a new clinical site as a recruitment site for the register are summed up in *Box 7*.

Recruitment in secondary care

Recruitment began in the first mental health trust in early March 2009, and three other trusts began patient recruitment in the following 12 months, with four more initiating involvement. *Figure 24* shows the gender distribution of those joining the research register, and *Figure 25* shows the age distribution. The self-reported ethnicity of those enrolled is shown in *Figure 26*; about 20% were non-white.

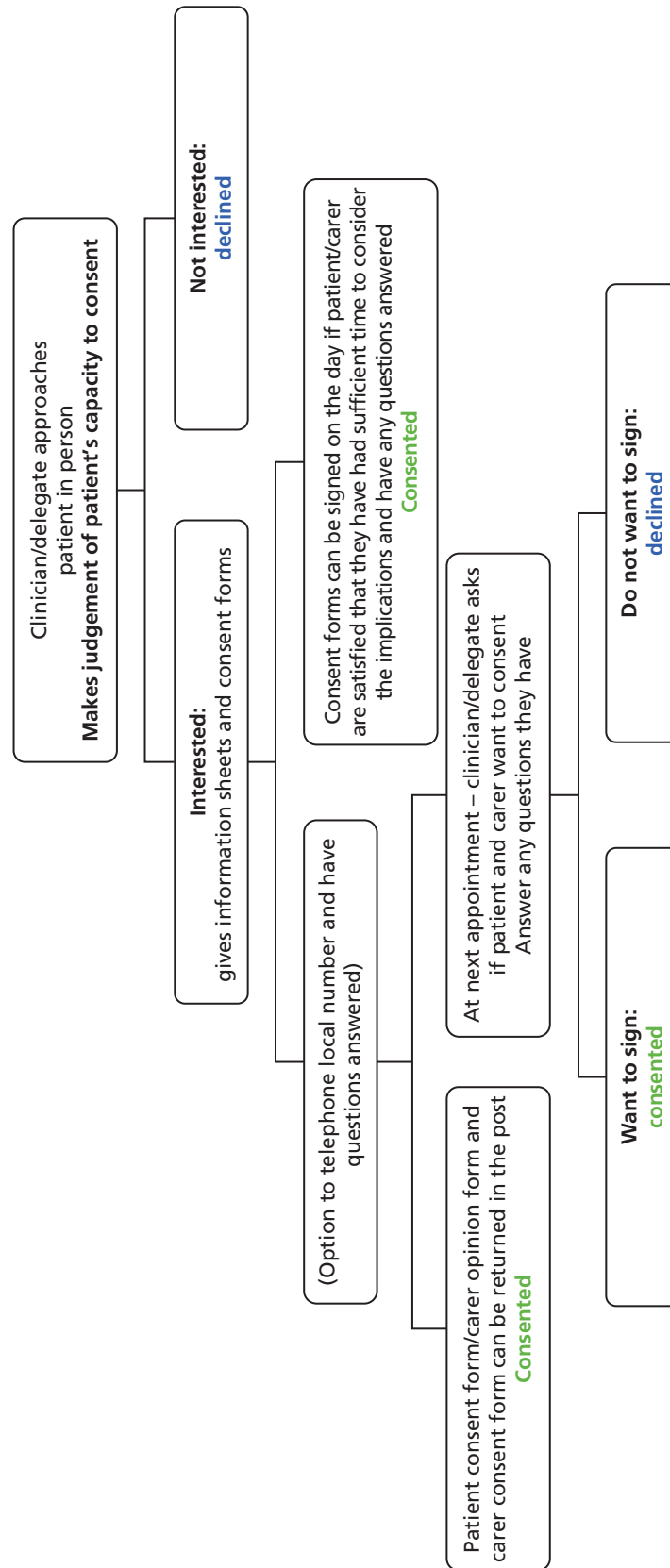


FIGURE 23 The consent process in DemReg.

BOX 7 The steps to engage a new clinical recruitment site**Getting a new specialist site to recruitment stage requires:**

- A Principal Investigator to act as champion for that site.
- Local Research Management and Governance approval.
- Resources for a local co-ordinator, who initially carries out and then co-ordinates data entry, acts as contact person for data queries, and liaises with site staff about recruiting patients. To date, the financial resources have come from different streams of research network funding. New staff may need to be recruited, or honorary contracts established, for those already in other posts.
- Agreement from local information technology departments who need to give new staff access to electronic databases, and to set up shared drives where none existed previously. The local information governance manager needs to be satisfied about data security.
- Service manager agreement to provide office space, promote the use of the register to front line clinical staff, allow computer use and staff involvement in seeking consent, as well as facilitating best working practices for each site.
- Site team involvement in supporting the lead clinician in identification of patients to inform about the study.

The initial phase of recruitment of patients and carers to the research register yielded important lessons about where best to recruit, and about data governance.

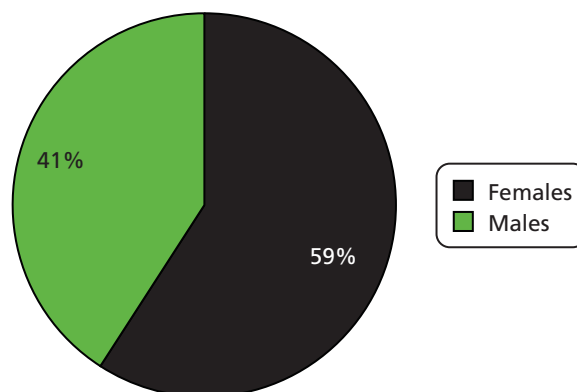


FIGURE 24 Gender distribution of enrollees in the dementia register.

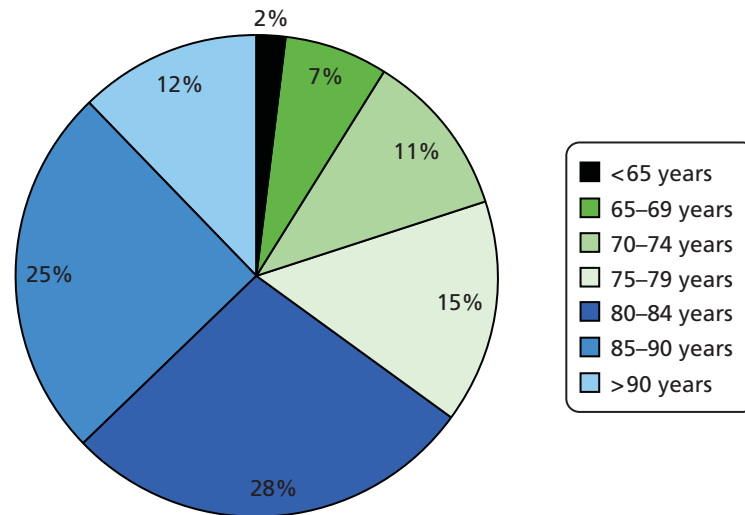


FIGURE 25 Age distribution of enrollees in the dementia register.

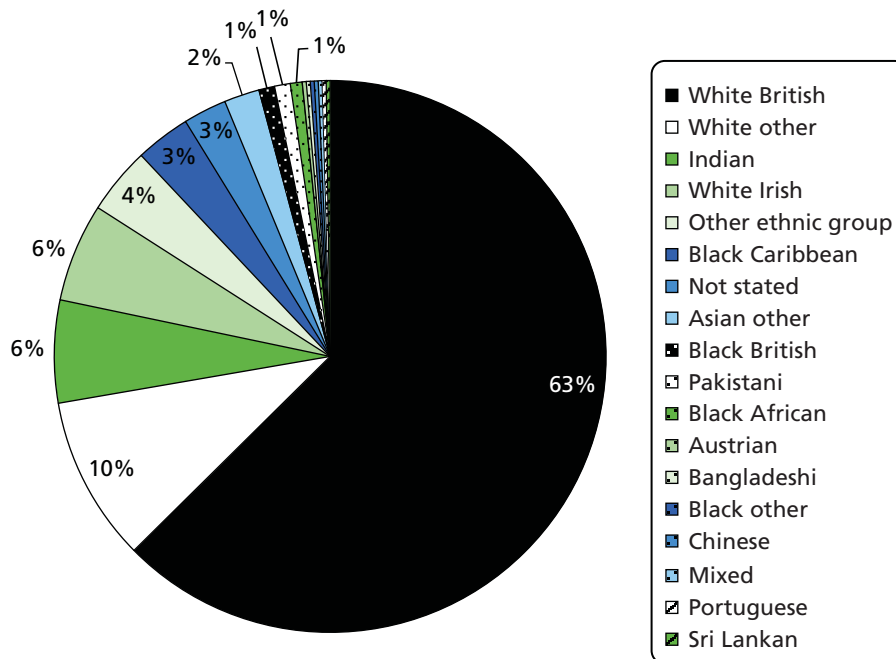


FIGURE 26 Ethnicity of enrollees in the dementia register.

Figure 27 shows the rates of invitation and recruitment to the register, and the numbers engaged through the register in trials, from the end of March 2009 to the end of December 2011. Acceptance of the invitation was high, at over 90%, but the rate of recruitment was determined by the pattern of clinic attendances, with a gap of 3–6 months between the invitation to join the register and acceptance for the majority of participants. Figure 28 shows the recruitment to DemReg and to studies across four NHS trusts at the end of February 2012 (when EVIDEM’s involvement in the register’s development process ended).

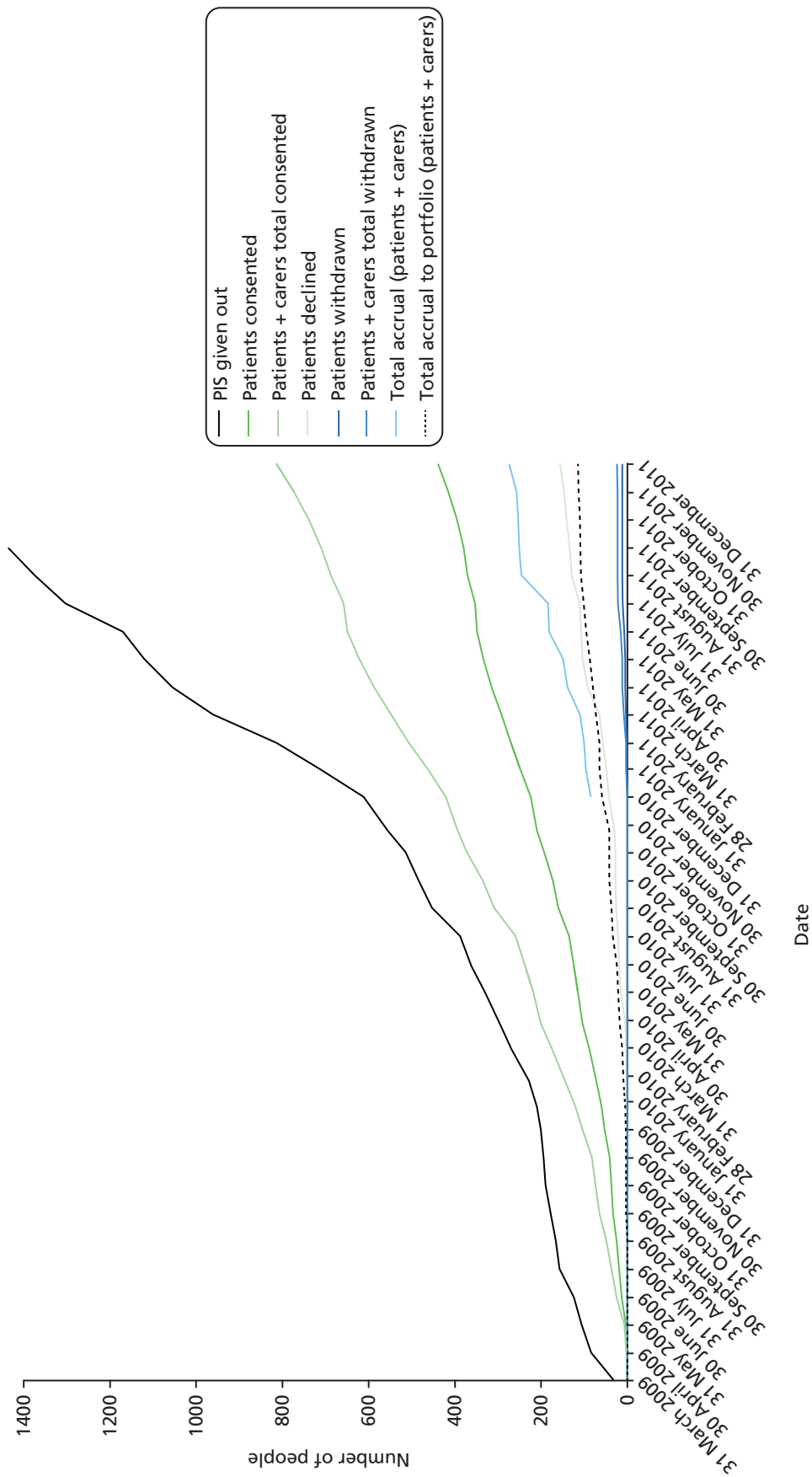


FIGURE 27 Recruitment of patients and carers to DemReg, and accrual to studies, March 2009 to December 2011. PIS, patient information sheet.

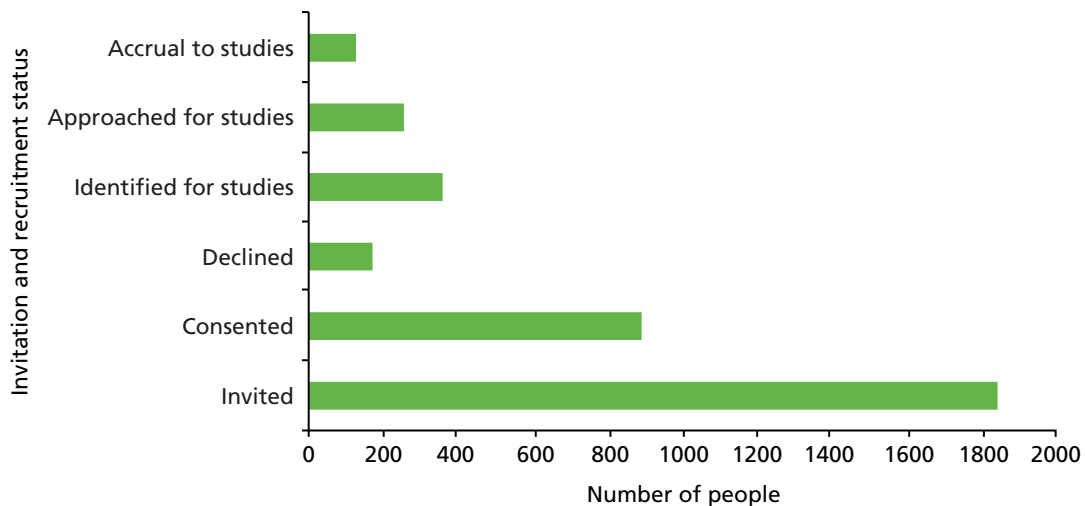


FIGURE 28 Recruitment to DemReg and accrual to studies across four trusts, February 2012.

Recruitment in primary care

Tests of recruitment began with five practices that were already part of the EVIDEM programme in autumn 2009. Of 72 people with dementia identified from these five general practices, who were sent information by post about the research register, three people responded that they were not interested in research or finding out more, and 18 people expressed interest and asked for more information. Fifty-one people did not respond to the invitation.

Among those expressing interest in the research register, 10 people were already attending specialist clinics operating the research register, and their details were passed on to the appropriate clinic. Three lived in care homes, and an assistant psychologist obtained the carer's agreement to gather data for one of them. She did not meet the resident to assess decision-making capacity, but both the GP and the care home manager judged that the resident lacked capacity for this decision but said that the person would have wanted to have participated in the study. The data gathered did not contain information about medication or MMSE score, and for one potential recruit the psychologist extracting the data was unsure which of two documented diagnoses was correct. For the other two individuals the assistant psychologist had to meet relatives (in their role as consultees), as the care home staff did not feel able to give an opinion about participation in research (which they are not able to do under the MCA).

The assistant psychologist also arranged a meeting, at a hospital site, with two of the three people with dementia who were not seen in any other NHS service. The remaining person not seen by any other service lived in an area distant from any facility that the psychologist could invite them to, and the psychologist was reluctant to make home visits, so this individual's expression of interest was not pursued.

Testing the process of recruitment in general practice was undertaken by the EVIDEM team and in specialist clinics by North Thames DeNDroN but responsibility for subsequent 6-monthly follow-up and review did not clearly belong to either party and had to be decided through discussion. The situation was complicated by the organisation of research infrastructure in England, where three research networks may be involved in dementia research: DeNDroN; the PCRN, which recruits GPs for research projects; and the Comprehensive Local Research Network, which funds the involvement of practitioners in research work. These three types of network do not have the same boundaries, so trilateral negotiations were necessary in some locations to allow the EVIDEM team to test recruitment to the register through general practice.

For these reasons, the prototype register was developed first in specialist services (particularly memory clinics), leaving recruitment in primary care (and other settings – see above) to be explored at a later stage.

Data governance

A decision had to be made about who would ultimately hold and be responsible for the data collected in this way. The project information sheets stated that documents and register data would be stored by the register team at North Thames DeNDRoN but, as North Thames DeNDRoN is not a legal entity, documents and register data are stored by West London Mental Health Trust and were accessible by only the clinical and research staff within the involved NHS trust's boundaries.

In a later development which was not part of the joint EVIDEM/North Thames DeNDRoN project, the register's software was adapted to fit within clinical systems, to facilitate recruitment and avoid duplicating data entry.

Discussion

Feasibility

The North Thames DeNDRoN dementia register was a pioneering project in the UK. This case study suggests that construction and population of a dementia research register is feasible, but that the initial development is complex because of the ethical safeguards in dementia research and the organisational difficulties in embedding research projects in NHS clinical services. Recruitment from primary care has proved problematic; enrolment of patients is particularly costly in terms of staff time, especially given the very small number of people with dementia identified who were not already known to specialist services. The logistics of recruitment in memory clinics were better because of the concentration of patients and staff as well as the use of care pathways into which the register's recruitment process could be embedded. Even then, given the time scale of clinic attendance and the restrictions on obtaining informed consent, the recruitment process may take up to 6 months.

Resource issues

Recruiting people with dementia to the register through secondary care is still a resource intensive process. Potential register members need to be identified as suitable, informed about the register, met again to obtain consent and to capture information for the minimum data set, and reviewed every 6 months to confirm their continued interest and update their data.

The preliminary steps in gaining the necessary permissions and resources to establish the register at a new site require effort (a manager able to devote sufficient time) and up to 5 months of preparatory work (decreasing as time and experience informs the process). However, early investment of effort will ensure that not only will local clinical teams be invested in the process, but also that it ensures that data collected thereafter will be both accurate and complete. The costs of developing and running the register were seen as core service support costs and were therefore borne by the NIHR Clinical Research Network. DeNDRoN funded the register's development in the short term but it is also part of DeNDRoN's 5-year strategy (2010–15) to develop a broad coalition to secure appropriate funding arrangements for research registers in the longer term.

Clinical data requirements

Identifying the components of a minimum data set was an early achievement of the design team, which is being tested as researchers begin to use the register to recruit to studies. The effectiveness of the register's minimum data set (as currently designed) as a device for prescreening potential research populations is under investigation.

Recruitment

Acceptance rates are very high in the first clinic to recruit to the register but this may reflect the efforts of register 'champions'. We have monitored recruitment in more recently recruited clinics, for which there may be less 'ownership' and hence less commitment to register development; this gives us an estimate of the likely growth of a dementia research register within usual NHS clinical practice. Easier recruitment may perpetuate potential selection biases and we are not yet able to assess the representativeness of the research-ready population recruited to the register; this is an issue that needs to be revisited as register use becomes a normal process for researchers. We know from analysis of participants in the first site to start recruitment to the register that the register included more women than men, and a substantial number of people from minority ethnic groups and from the ≥ 75 years age group. Ways of increasing recruitment through primary care, and through care homes and social care services, to offset biases inherent in clinic recruitment, need further investigation.

Conclusions

Between them the EVIDEM projects recruited 704 people with dementia to studies, along with 292 carers; EVIDEM-ED's audit of general practice included 1072 people with dementia at baseline, and at the end of the EVIDEM programme the dementia register held an additional 500 people who were not involved with EVIDEM but who have expressed an interest in being involved in dementia research.

We believe that the register will assist in connecting people with dementia and their carers with high-quality research studies that will help us answer important questions regarding the pathology, clinical pathways, aetiology, experiences of, and best treatments for, neurodegenerative disease.

The primary obstacle to the development of the register has been the complexity of permission processes within the NHS, an experience noted by others.³¹⁷ This may change, as the register is adopted by research sites that are not part of the designer group; in new sites, negative staff attitudes and competing clinical priorities may become more salient and more limiting, as found in other registries.³¹³ A number of important characteristics of the register are awaiting evaluation, including the utility to researchers of the minimum data set and the cost per person recruited to studies through the register.

The success of this prototype will be measured by the proportion of people from the register who participate in research studies and the impact over time that the register has on overall accrual to portfolio studies.

Appendix

Appendix 67 Chapter 6: Proposed data capture fields with definitions for primary care.

Chapter 7 Implications for research, policy and practice

What are the implications of the EVIDEM programme for research, policy and practice? We will attempt to answer these questions in terms of new knowledge and knowledge application, products arising from EVIDEM projects, methodology development in EVIDEM and the implications of the programme for research. We will also illustrate how the programme organisation added value to the individual projects, describing the synergies in the research process, EVIDEM's 'offspring', and research capacity building within the programme.

Diagnosis and management in primary care

New knowledge and knowledge application The EVIDEM-ED trial has shown that a high-intensity, tailored educational intervention in a context of increasing policy pressure (NDS 2009,¹⁸ the review of antipsychotic use in 2011), growing resources in some areas (e.g. pilot schemes of dementia advisors, dementia champions in general practice) and financial incentives for general practices (within the QOF reimbursement system) does not increase dementia case recognition or improve the amount or content of clinical management of people with dementia in general practice. Our view is that the less-intense, less-tailored educational activities currently being promoted as part of the NDS are unlikely to change clinical practice in primary care.

EVIDEM-ED products Although the educational intervention proved ineffective in changing documented practice, it was popular with practitioners and researchers. By the end of the EVIDEM programme the methods for carrying out learning needs assessment and the writing of educational prescriptions used in the EVIDEM-ED project had been taken up by practitioners in the English and Welsh NHS, and Ireland, and by researchers in Germany (University of Düsseldorf), the USA (at Johns Hopkins Medical School) and New Zealand (University of Auckland). The clinical themes identified by GPs as priorities for learning in EVIDEM-ED were used in the evaluation of e-learning packages on dementia, funded by the Alzheimer's Society (see www.alzheimers.org.uk/site/scripts/documents_info.php?documentID=367).

Methodology development The implementation of ENA and educational prescriptions in general practice (EVIDEM-ED) has tested this approach to learning on a scale that is unusual in educational research, and takes these methods beyond theoretical discussion into practical application.

Implications for research Educational interventions in settings in which a co-ordinated system of dementia case management operated have shown positive effects,³¹⁸ so the effective change may need to include the additional resource of case management as well as focused education. Future research may need to refocus on the additional resources needed in primary care, as in the CAREDEM study,³¹⁹ rather than in the acquisition of new skills by the existing workforce.

Exercise as therapy for behavioural and psychological symptoms of dementia

New knowledge and knowledge application The EVIDEM-E trial has demonstrated that exercise as a form of therapy for BPSD is acceptable to people with dementia and their families, and feasible for use by the NHS, but its effectiveness in reducing behavioural and psychological symptoms in people with dementia is not yet established. The secondary, but important, finding of EVIDEM-E is that the exercise intervention seemed to have a strong positive effect on carer's burden. This is important, as carer's burden is strongly associated with increased likelihood of relocation to a care home. It does not appear likely to be

cost-effective, however, showing no significant cost or effect differences for any of the outcome measures considered.

EVIDEM-E products The EVIDEM-E project has made a video about exercise as therapy in dementia, accessible via www.EVIDEM.org.uk.

Methodology development EVIDEM-E is one of the largest RCTs of exercise for BPSD. This trial has contributed to the debate about designing trials for non-pharmacological studies. Predictably, recruitment has been one of the main challenges encountered. The EVIDEM-E team largely solved the recruitment problems, and, as a consequence, learned lessons that have been reported to the wider research and clinical communities.

Implications for research The walking intervention developed and tested in EVIDEM-E is safe, simple to apply and does not need special training or equipment. Further research should focus on the mechanisms by which exercise affects carers' burden, the feasibility of deploying this tailored intervention on a wide scale without loss of fidelity, and its long-term impact on BPSD, carer burden and relocation.

Managing incontinence in community-dwelling people with dementia

New knowledge and knowledge application The EVIDEM-C project has found that the incidence of incontinence (urinary and/or faecal) in community-dwelling people with dementia is at least double that in populations matched by age, gender and comorbidity. The use of indwelling urinary catheters, a management strategy discouraged by international and national clinical guidelines, was found to be double the rate in people with dementia compared with a matched population without dementia. It has shown that incontinence in people with dementia is a deeply hidden problem, a taboo concealed within a stigma. Family carers often sought to preserve the person's dignity by not seeking help, often to the point of crisis. Professional and continence service responses to incontinence often omitted any specific consideration of the effects of dementia. Family carer management strategies emphasised the effective containment of excreta and some solutions had unintended, negative consequences for the person with dementia. FI was shown to be less common than UI among people with dementia, but found to have a greater negative effect on the carer's quality of life. The presence of FI was found to significantly increase the costs, by almost two-thirds, from both a HSC perspective and a societal perspective, compared with the costs of managing UI. This project made recommendations for practice (routine enquiry by professionals about continence problems at each encounter with carers) and developed an assessment tool for community nurses.

EVIDEM-C products The EVIDEM-C project provides tools and supporting materials for practitioners working with people with dementia and their families, and insights that require further testing and investigation by researchers.

Methodology development The analysis of a GP records database (THIN¹⁴²) by the EVIDEM-C project has clarified the methods needed to study the epidemiology of incontinence, especially when using routinely collected clinical data. The EVIDEM-C project also developed innovative analyses of costs incurred in the management of incontinence in people with dementia.

Implications for research Strategies and responses that primary care professionals and others can use to encourage greater openness, and which may reduce the taboo of incontinence within the stigma of dementia, need testing in further studies. Similarly, dementia-specific continence assessment tools and guidance for the use of primary care nurses produced by this project need evaluation for their utility and impact.

End-of-life care in dementia

New knowledge and knowledge application The EVIDEM-EoL project showed that the trajectories of the end-of-life in people with dementia are often unclear to care home staff, family members and visiting health-care practitioners. The transition from living to dying with or from dementia is often characterised by uncertainty in three key areas:

1. how different groups should work together and across the health and social (independent) care
2. whether or not a person with dementia is actively dying and how to manage the process and its related symptoms
3. whether or not the resources and services needed to support the person in the care home will always be accessible.

In settings in which there are no on-site clinical practitioners, decision-making in these three areas is a complex process reliant on how roles and relationships are negotiated between family, residents and NHS and care home staff. An intervention such as AI was able to help address 'relational uncertainties' about who does what and for whom and to develop productive working relationships between care home practitioners, family members and NHS staff. It fostered rapid and sustained engagement between care homes staff and GPs, did not increase resource use, reduced the use of emergency services and appeared to improve the management of unexpected events, crisis management and unplanned hospital admissions. This has direct implications for practice.

EVIDEM-EoL products The EVIDEM-EoL project has field-tested AI in care homes and developed a framework for the evaluation of end-of-life care interventions for people with dementia in long-term care settings, which is currently being used in a Train the Trainer evaluation funded by East of England Multi-Professional Deanery.

Methodology development The application of AI methods in care homes and primary care (in the EVIDEM-EoL project) is one of the few examples of the practical use of this quality improvement technique. The methodological testing of consent processes for people with dementia in long-term care in the EVIDEM-EoL project adds to our understanding of how to conduct research with people with impaired cognition, and contributed to the NIHR SSCRC-commissioned review of research methods for end-of-life care research in social care settings. The evaluation framework for end-of-life interventions in long-term care settings is a novel development. Collaboration with Belfast University in analysis of medication use in care homes (EVIDEM-EoL) is also innovative – see *Chapter 4* for details and outputs from this collaboration.

Implications for research AI appears to improve working relationships between NHS professionals and care home staff, with promising outcomes. It is an approach that fits with others which emphasise relational approaches to care. Nevertheless, more research is needed to test these findings further and with more robust controls.

Evaluating the Mental Capacity Act 2005

New knowledge and knowledge application The EVIDEM-MCA project found that dementia care services and practitioners have traditionally not conceptualised their practice as being framed by legal rules. The MCA 2005¹⁷ was a major challenge to this and the dementia care sector has had to adapt to this fundamental shift. There are lessons here for future changes being proposed for social care law, such as those outlined in the Care and Support White Paper of July 2012.²⁸²

EVIDEM-MCA products The EVIDEM-ED learners' manual included brief advice for practitioners on capacity assessment and the requirements of the MCA 2005,¹⁷ derived from the MCA project. Forty-four tailored learning resources have been prepared by the EVIDEM-MCA project.

Methodology development The longitudinal element of the programme enabled repeat interviews with practitioners and people with dementia and carers; this is a novel approach among some practitioner groups. EVIDEM-MCA for example, interviewed SACs four times, many of whom participated in all rounds. In contrast, on returning to care homes for repeat interviews, few staff interviewed initially were still in post at time 2. Learning from this study has contributed to the NIHR SSCR-commissioned overview of qualitative research with people with dementia.

Implications for research We need to study MCA offences and their role in providing assurance that people with dementia have access to justice and are safeguarded. It is difficult to know if the media coverage of prosecutions under the MCA is having the effect of reducing ill treatment and wilful neglect, but research might establish if emerging case law was facilitating cultural change within care services, by demonstrating that ill treatment is not simply a matter of poor practice, but potentially subject to criminal sanctions. Much dementia care has focused on efforts to improve services, support carers, promote good practice and encourage staff. We do not know if an approach that is more punitive leads to greater intolerance of abuse. We do not know the effects on services such as hospitals and care homes if cases are brought against staff or family carers, or on staff and team dynamics.

A final area for research is that of bridging the gap between professionals and carers. Our finding that many professionals have experience of dementia among family members is probably of no surprise to readers of this report. However, it has not been commented upon or its implications explored. Research might investigate the interface between care work and family care. In relation to the MCA, such personal and professional experiences appear mutually informative.

A dementia cohort

New knowledge and knowledge application The COHORT/REGISTER project, developed jointly with North Thames DeNDRoN, demonstrated that it is feasible to develop, populate and use an ethically acceptable dementia register, housed within a NHS clinical record system. However, we also showed that recruitment to such a register through primary care is costly and yields small numbers of participants, making recruitment through specialist services more cost-effective. The further development of research registers was taken up by DeNDRoN.

COHORT/REGISTER products The North Thames Dementia register (NT DemReg) was adopted and used by five NHS trusts.

Methodology development The development of the North Thames DeNDRoN research register has influenced debates within DeNDRoN about the configuration of recruitment and feasibility assessment tools for neurodegenerative diseases research.

Implications for research The pioneering work of the dementia registry has led to the development of a specification of a national registry by DeNDRoN; this work is under way. There is potential for using the registry not only to identify and recruit research interested people with dementia and their carers, but also as a research database in its own right.

The benefits of programme funding

The EVIDEM programme has had a rich research output because of its multidisciplinary nature and its connectedness to the host NHS trust, CNWL NHS Foundation Trust. Combining the expertise of different organisations and disciplines created synergies in the research programme, allowed EVIDEM to produce 'offspring' studies, and contributed to the expansion of research capacity in dementia studies.

Synergies in the research process

The interaction between projects was critical to the success of the EVIDEM programme. Some of the cross-fertilisation was about specific topics, problems and techniques. For example, the EVIDEM-ED project benefited from the knowledge of BPSD within the trial of exercise as therapy, and drew its training materials on the MCA 2005¹⁷ from EVIDEM-MCA. In turn, EVIDEM-ED provided data from interviews with carers about the experience of managing incontinence for EVIDEM-C, and about sources of legal advice provided to family carers from EVIDEM-MCA. Similarly, EVIDEM-EoL, EVIDEM-C and EVIDEM-MCA shared ethics protocols and supporting consent documents.

All projects benefited from iterative face-to-face debate within the EVIDEM programme about recruitment methods. All projects experienced challenges in recruiting people with dementia and their carers to the EVIDEM studies. The process of recruitment from where there was no on-site research presence or input was both time-consuming and resource intensive. The projects noted how recruitment could be experienced as an additional burden by practitioners, how the stigma of the diagnosis impeded recruitment, how professionals acted as gatekeepers to research in some services, and how among some NHS staff there were concerns about the ownership of research.

We also noted the variable appetite of some professionals to improve care for people with dementia. Although there were some enthusiasts among the generalists (especially GPs and community nurses), these individuals were not necessarily typical of their entire professional groups, which, although not averse to improving care, were not necessarily willing to put in any additional effort into a research activity designed to achieve this.

Nevertheless, the EVIDEM projects recruited 704 people with dementia to studies, along with 292 carers; EVIDEM-ED's audit of general practice included > 1000 people with dementia, and, at the end of the EVIDEM programme, the dementia register held an additional 500 people who were not involved with EVIDEM but who have expressed an interest in being involved in dementia research. Over 500 professionals – ranging from part-time care home staff and volunteer carer support workers to highly trained psychiatrists and dementia care nurses – were interviewed, took part in group discussions or participated in the research in other ways (e.g. in a Delphi process).

Sharing ideas within the EVIDEM programme also prompted new research initiatives within the programme, such as the use of the THIN database,¹⁴² a primary care data set, to gather epidemiological evidence about continence in EVIDEM-C.

The EVIDEM programme has run annual 'summer schools' with CNWL NHS Foundation Trust staff using the project themes to update practitioners and managers and using different styles of dissemination events and opportunities, some in the workplace and others organised centrally. Large numbers of practitioners have attended other EVIDEM presentations and new media, such as free online journals and professional outlets, webinars, tweets and blogs, have been used as communication tools.

Offspring from the EVIDEM programme

The EVIDEM programme generated further studies, as shown below.

- The Transitions study on how people with dementia experienced the process of diagnosis (NIHR Service Delivery and Organisation programme funded; project number 08/1809/229). See www.netscc.ac.uk/hedr/files/project/SDO_FR_08-1809-229_V01.pdf.
- A person-centred primary care training package, developed and field-tested in Avon and Wiltshire NHS Trust by Sarah Voss and Rachel Edwards (and funded by the Alzheimer's Society). See *Chapter 1* for details of this project or: www.alzheimers.org.uk/site/scripts/documents_info.php?documentID=1475&pageNumber=3.

- The Optimal study (funded by the NIHR Health Services and Delivery Research programme; project number 11/1021/02) on ways of optimising NHS working with care homes.
- The EVIDEM-MCA team worked with the Alzheimer's Society in devising data collection instruments, augmentation of interview data and secondary analysis of findings in its study of Financial Abuse in dementia (The 'Short Changed' report:²⁸⁷ see www.alzheimers.org.uk/site/scripts/news_article.php?newsID=1127).

Research capacity building

The EVIDEM programme has created a fruitful postdoctoral research environment allowing the further development of dementia researchers (Samsi, Thune-Boylé, Lowery). Two new researchers have undertaken PhDs within EVIDEM: (Cerga-Pashoja, Cole), and four early-career GPs have acquired research and writing skills within EVIDEM (Koch, Pealing, Davidson, Venavadem) with another experienced social scientist (Charles) participating in EVIDEM-MCA prior to moving to health services research. One exercise therapist (Lee) used his experience of working on EVIDEM-E for his Bachelor of Science dissertation. One postgraduate (Ng) secured her Master of Science in International Health Policy under the direction of Professor Martin Knapp at the London School of Economics based on her economic evaluation of the end-of-life intervention. Embedding the EVIDEM programme in the CNWL NHS Trust has assisted the trust to increase its research activity and focus it more on older adults. The NT DemReg is a powerful tool for recruiting people with dementia and their carers to studies. The EVIDEM-MCA research team has acted as research advisors on projects covering Mental Capacity Advocates, Indirect or Proxy Holding Personal Budget Arrangements, and the Deprivation of Liberty Safeguards, at the Mental Health Foundation and University of Bristol.

Conclusions

The EVIDEM programme is an addition to the small number of longitudinal studies of the dementia trajectory, and leaves behind a mechanism (the register) for recruiting further cohorts. It has shown the benefits of interdisciplinarity in dementia research, and demonstrated the value of mixed methodologies in addressing complex problems. Grounding the EVIDEM programme in an NHS trust allowed the research teams to work with the diversity of the population and the range of providers operating in dementia services.

The longitudinal element of the programme enabled repeat interviews with practitioners and people with dementia and carers, as described above in the review of EVIDEM-MCA. Both EVIDEM-C and EVIDEM-EoL had longitudinal elements in which they interviewed and followed up people with dementia and family carers for up to 3 (EVIDEM-C) and 4 (EVIDEM-EoL) years.

As discussed above, the testing of recruitment from primary and secondary care has been a feature of all projects, with different methods being used in different settings. The EVIDEM-E project, which experienced slow recruitment initially, benefited most from using the research register. In contrast, and to meet the aims of part of its study, EVIDEM-MCA gained the trust of community and voluntary groups of older people to access 'well' older people. EVIDEM-EoL developed and tested recruitment within the care home settings, providing learning which contributed to the DeNDRoN ENRICH research initiative (www.DeNDRoN.org.uk/enrich/).

Finally, the extensive involvement of lay experts at the levels of individual projects as well as in the steering group for the whole programme has shaped the development of methods and had a decisive role in the evolution of projects such as EVIDEM-C and EVIDEM-EoL.

Acknowledgements

We would like to thank Tricia Labro who provided support throughout the programme and helped with correspondence, minutes, matters of finance, organising meetings and conferences.

Chapter 1: EVIDEM-ED

A number of people have contributed to this project. We are extremely grateful to all the people with dementia who gave permission for us to include their clinical experience in the study, as well as the carers who gave so freely of their time and shared their views with us.

We are also grateful to the practice staff and primary care professionals, who were involved with us throughout the study, for the feedback, participation, access and continued interest and support.

We thank the North Thames DeNDRoN, particularly Tania Page, who assisted us with recruitment and raising the profile of the study via newsletters. The study received support from North Thames DeNDRoN and the North Central/North East London Comprehensive Local Research Networks with NIHR Flexibility and Sustainability funding (FSF) support for participating primary care practitioners. We are also grateful to the staff at the Clinical Research Networks and PCRNs, and, particularly, Eleanor Harrison, Gina Johnson and Helen Macdonald, who assisted us with recruitment in the east of England.

We are grateful to members of the study advisory group for sharing their views on various aspects, and for sharing their experience, views and guidance.

We would like to thank Kalpa Kharicha who provided maternity cover, and helped with the recruitment and ethical stages of the study.

In addition, others were involved as identified in *Table 71*.

EVIDEM-ED publications and presentations

Peer-reviewed (*Table 72*) and professional (*Table 73*) papers have been published throughout the study. In addition, some papers are awaiting publication, and others are under review.

The methods and findings of the EVIDEM-ED trial have been presented at 15 national and international conferences, including the UK National Dementia Congress, the Alzheimer's Disease International Conference, the International Association of Gerontology and Geriatrics, and the Gerontological Society of America.

TABLE 71 EVIDEM-ED: acknowledgements of contributors

Name and role		Study element to which they contributed
Steve Iliffe	Professor of Primary Care for Older People Research Department of Primary Care & Population Health University College London	Chief Investigator
Jane Wilcock	Senior Research Fellow Research Department of Primary Care & Population Health University College London	Trial Manager for EVIDEM-ED, Academic Programme Manager for EVIDEM
Priya Jain	Assistant Research Manager Research Department of Primary Care & Population Health University College London	Assistant Research Manager for EVIDEM-ED, administrator for EVIDEM
Mark Griffin	Statistician Research Department of Primary Care & Population Health University College London	Statistician for EVIDEM-ED and EVIDEM programme, member of EVIDEM-ED advisory group, member of EVIDEM management group
Ingela Thuné-Boyle	Senior Research Fellow and Chartered Health Psychologist Research Department of Primary Care & Population Health University College London	Responsible for recruitment and consent of people with dementia and their carers, undertook carer interviews
Tamar Koch	GP Research Department of Primary Care & Population Health University College London	Undertook two literature reviews, member of the advisory group
Frances Lefford	GP Research Department of Primary Care & Population Health University College London	Facilitated training in practices, member of expert and steering groups
Dave Rapp	GP Research Department of Primary Care & Population Health University College London	Assisted with data collection for primary and secondary outcome data

TABLE 72 EVIDEM-ED: published papers (until April 2014)

Authors	Title	Journal
Iliffe S, Manthorpe J, Drennan V, Goodman C, Warner J	The EVIDEM programme: a test for primary care research in London?	<i>London J Prim Care</i> 2008; 1 :69–73
Iliffe S, Manthorpe J, Warner J, Drennan V, Goodman C, Rait G, <i>et al.</i>	Making progress in psychosocial research in dementia	<i>Dementia</i> 2008; 7 :167–74
Iliffe S, Jain P, Wong G, Lefford F, Gupta S, Warner A, <i>et al.</i>	Dementia diagnosis in primary care: looking outside the educational box	<i>Aging Health</i> 2009; 5 :51–9
Manthorpe J, Iliffe S, Samsi K, Cole L, Goodman C, Drennan V, <i>et al.</i>	Dementia and dignity: nursing practice and its dilemmas	<i>Int J Older People Nurs</i> 2010; 5 :235–44
Iliffe S, Wilcock J, Griffin M, Jain P, Thuné-Boyle I, Koch T, <i>et al.</i>	Evidence-based interventions in dementia: a pragmatic cluster-randomised trial of an educational intervention to promote earlier recognition and response to dementia in primary care (EVIDEM-ED)	<i>Trials</i> 2010; 11 :13
Koch T, Iliffe S, for the EVIDEM-ED research team	Rapid appraisal of barriers to the diagnosis and management of patients with dementia in primary care: a narrative review	<i>BMC Fam Pract</i> 2010; 11 :52
Koch T, Iliffe S	The role of primary care in the recognition of and response to dementia	<i>J Nutr Health Aging</i> 2010; 14 :107–9 (editorial)
Iliffe S, Pealing L	Subjective memory complaints: a clinical review	<i>BMJ</i> 2010; 340 :c1425 (commissioned)
Koch T, Iliffe S	Dementia diagnosis and management: a narrative review of changing practice	<i>Br J Gen Pract</i> 2011; 61 :514–15
Iliffe S, Koch T, Jain P, Lefford F, Wilcock J, Wong G, <i>et al.</i>	Developing an educational intervention on dementia diagnosis and management in primary care for the EVIDEM-ED trial	<i>Trials</i> 2012; 13 :142
Thuné-Boyle I, Wilcock J, Iliffe S	Communicating with carers about dementia	<i>Int J Geriatr Psychiatry</i> 2013; 28 :438–40
Wilcock J, Iliffe S, Griffin M, Jain P, Thuné-Boyle I, Lefford F, <i>et al.</i>	Tailored educational intervention for primary care to improve the management of dementia: the EVIDEM-ED cluster randomised controlled trial	<i>Trials</i> 2013; 14 :397
Wilcock J, Jain P, Griffin M, Thuné-Boyle I, Lefford F, Rapp D	Diagnosis and management of dementia in family practice	<i>Aging Ment Health</i> ; in press 2015
Feldman L, Wilcock J, Thuné-Boyle I, Iliffe S	Carers' accounts of help-seeking behaviour for people with dementia symptoms: qualitative study	<i>Dementia</i> ; in press 2015 (published online: 23 February 2015 doi:10.1080/13607863.2015.1011082)
Gilbert C, Wilcock J, Iliffe S	A comparison of service use by people with dementia a decade apart	<i>Dementia</i> ; in press 2015

TABLE 73 EVIDEM-ED: professional publications (until April 2014)

Authors	Title	Journal
Iliffe S, Jain P, Wilcock, for the EVIDEM-ED team	Recognition of and response to dementia syndrome in primary care 1	<i>Innovait</i> 2009; 2 :230–6
Iliffe S, Jain P, Wilcock J, for the EVIDEM-ED team	Recognition of and response to dementia syndrome in primary care 2	<i>Innovait</i> 2009; 2 :237–44
Iliffe S	Detecting dementia	<i>Public Serv Rev Health</i> 2009; 20 :15–16
Iliffe S	Recognising symptom patterns will aid early diagnosis of dementia	<i>Guidelines in Practice</i> 2010; 13 :29–35
Pealing L, Iliffe S	A woman with forgetfulness and falls: a case study	<i>BMJ</i> 2011; 343 :d7412

Chapter 2: EVIDEM-E

We gratefully acknowledge the contribution of all study participants and their carers for their involvement in the trial. The study was supported by a proactive and valuable steering group that played a pivotal role during challenging times. Particular thanks are extended to Dr Ritchie (Chair).

The study drew upon a wide number of recruitment hubs and we would like to acknowledge the importance these hubs played in ensuring that we achieved our target of the largest sample in the world for such a trial. We give particular acknowledgement to North Thames DeNDRoN and the use of DemReg: Dr Nilforooshan (Surrey and Borders Partnership NHS Foundation Trust) and Dr Regan (West London Mental Health NHS Trust).

We gratefully acknowledge the support of several volunteers who kindly provided their time in exchange for experience of working on a research trial. John Aeron-Smith and Stoyanka Dimitrova collected some data and supported data entry. Data entry was also supported by Anne Theobald, Polly Pulford, Dorrie Mystris and Mirela Sula.

Randomisation was conducted by several specialist registrars (Dr Bailey, Dr Jordanova, Dr Rajenthiran and Dr Holzer) over the course of the trial.

All authors, along with the steering group contributed to the design of the study. All authors contributed to the drafting and/or critical revision of this chapter for important intellectual content, approval of the final version, and taking public responsibility for its content.

In addition, others were involved as identified in *Table 74*.

EVIDEM-E publications and presentations

Papers have been published (*Table 75*) and presentations (*Table 76*) made throughout the study. In addition, there are papers accepted for publication but not yet published, and others under review.

TABLE 74 EVIDEM-E: acknowledgements of contributors

Name and role		Study element to which they contributed
James Warner	CNWL NHS Foundation Trust and Imperial College London, Consultant Old Age Psychiatrist	Chief Investigator Conceived the idea of the study, provided clinical oversight, and wrote the first draft of this chapter
David Lowery	CNWL NHS Foundation Trust, Senior Research Manager	Oversaw the day-to-day management of the trial, led the qualitative component exploring clinician experiences of recruitment to research trials, led the development of the pilot video toolkit, conducted some of the analysis, and contributed to the interpretation of the results
Arlinda Cerga-Pashoja	CNWL NHS Foundation Trust, RW	Collected the majority of the data; entered the majority of the data; wrote the first draft of the analysis plan; conducted the majority of the analysis and contributed to the interpretation of the results
Ingela Thuné-Boyle	Research Department of Primary Care & Population Health College London, Senior Research Fellow and Chartered Health Psychologist	Led the literature review; collected a substantial proportion of the data; conducted some of the analysis; and contributed to the interpretation of the results
James Lee	Independent contractor, Exercise Therapist	Provided the exercise therapy, contributed to the development of the video toolkit, contributed to some of the analysis of data and interpretation of results
Alex Bailey	CNWL NHS Foundation Trust, Consultant Old Age Psychiatrist	Was the principal randomisation officer
Raul Bhattacharya	East London NHS Foundation Trust. Consultant Psychiatrist	Was involved in the first stages of the study design including protocol writing and at the later stages as Principal Investigator at East London NHS Foundation Trust
Mark Griffin	Research Department of Primary Care & Population Health University College London, Statistician	Provided consultancy for setting up trial databases, oversaw the statistical entry and analysis of the main trial, and contributed to the interpretation of the results
Francesco D'Amico	LSE, Research Officer	Conducted the analysis of the economic data, contributed to the interpretation of the results
Amritpal Patel	Health Economics Researcher London School of Economics	Conducted the analysis of the economic data and contributed to the interpretation of the results
Martin Knapp	London School of Economics, Professor of Social Policy	Supervised the analysis of the economic data and contributed to the interpretation of the results
Steve Iliffe	Research Department of Primary Care & Population Health University College London, Professor for Primary Care for Older People	Contributed to the interpretation of the results

TABLE 75 EVIDEM-E: published papers (until April 2014)

Authors	Title	Journal
Lowery D, Warner J	Behavioural and psychological symptoms of dementia (BPSD): the personal and practical costs of dementia	<i>J Integ Care</i> 2009; 17 :13–19
Lowery D	Exercise and dementia	<i>Alzheimer's Society Newsletter</i> , Living with Dementia, July 2010
Cerga-Pashoja A, Lowery D, Bhattacharya R, Griffin M, Iliffe S, Lee J, <i>et al.</i>	Evaluation of exercise on individuals with dementia and their carers: a randomised controlled trial	<i>Trials</i> 2010; 11 :53
Lowery D, Warner J, Cerga-Pashoja A, Thuné-Boyle I, Iliffe S	Clinicians as recruiters to dementia trials: lessons from the EVIDEM-E project	<i>Int J Geriatr Psychiatry</i> 2011; 26 :765–9
Iliffe S, Curry L, Kharicha K, Rait G, Wilcock J, Lowery D, <i>et al.</i>	Developing a Dementia Registry: a descriptive case study from North Thames DeNDRoN and the EVIDEM programme	<i>BMC Med Res Methodol</i> 2011; 11 :9
Thuné-Boyle I, Iliffe S, Cerga-Pashoja A, Lowery D, Warner J	The effect of exercise on behavioral and psychological symptoms in dementia: towards a research agenda	<i>Int Psychogeriatr</i> 2012. URL: http://dx.doi.org/10.1017/S1041610211002365
Lowery D, Cerga-Pashoja A, Iliffe S, Thuné-Boyle I, Griffin M, <i>et al.</i>	The effect of exercise on behavioural and psychological symptoms of dementia and caregiver's perceived burden: the EVIDEM-E randomised controlled clinical trial	<i>Int J Geriatr Psychiatry</i> 2014; 29 :819–27

TABLE 76 EVIDEM-E: presentations (until April 2014)

Presenter	Title	Location and date
Warner J	The use of Anti-Psychotic Medications in People with Dementia	EVIDEM Summer School, London, UK, 2008
Warner J	Exercising your Mind	Enfield over-50s Group, London, UK, 2009
Warner J	Behavioural and psychological symptoms of dementia and their management	EVIDEM Summer School, CNWL NHS Trust, UK, 2009
Lowery D	EVIDEM-E: A randomised controlled evaluation of a tailored exercise package for individuals with dementia and their carers: the impact on sleep, behaviour and quality of life	Dementia Services Development Centre's 3rd International Conference, York, UK, 2009
Warner J	The motion: people in the terminal stages of dementia are wasting their families' lives and the resources of the NHS, as opposer	Dementia Care Congress, Harrogate, UK, 2009
Cerga-Pashoja A	Evaluation of exercise on individuals and their carers: a randomised controlled trial	PRIMENT Clinical Trials Unit, University College London, UK, 2010
Lowery D	Challenging behaviour: meaning and (care) management. The National Dementia Strategy Practice Perspectives: one year on	King's College London, London, 2010
Lowery D	Evidenced based interventions in dementia: opportunities to take part and change practice in dementia care in the community	Hillingdon Carers Information Day, Hillingdon Civic Centre, 2010, UK
Cerga-Pashoja A	The importance of behavioural and psychological symptoms of dementia and a possible therapy: an invitation to participate in EVIDEM-E	Hillingdon Admiral Nurse Service Carers Information Day, Hillingdon Civic Centre, UK, 2010

TABLE 76 EVIDEM-E: presentations (until April 2014) (continued)

Presenter	Title	Location and date
Warner J	Managing Behavioural and Psychological Symptoms of Dementia: training our colleagues to identify causes and consequences	EVIDEM Summer School, CNWL NHS Trust, UK, 2011
Lowery D	Taking a stroll beyond memory lane: Can walking help with symptoms of dementia?	Alzheimer's Society Memory Lane Café, London, UK, 2011
Lowery D and Lee J	Providing people with dementia and their carers with tools to improve their levels of physical activity	Dementia Care Congress, Liverpool, UK, 2011
Lowery D	Scientists assess whether exercise helps combat dementia	BBC One/Radio 4 Breakfast News, 2011
Lowery D	Physical Activity: A tool for improving outcomes for people with dementia	Chartered Society of Physiotherapy Annual Congress, Liverpool, UK, 2011
Cerga-Pashoja A	Evaluation of exercise on individuals with dementia and their carers: a randomised controlled trial	Presentation for conversion to PhD. Research Department of Primary Care & Population Health, University College London, UK, 2011
Cerga-Pashoja A	Methodological challenges of conducting research in the NHS	Society for Academic Primary Care Regional Meeting, Cambridge, UK, 2011
Lowery D	Factors affecting clinician engagement in recruitment for dementia trials	Gerontological Society of America Annual Scientific Meeting, Boston, USA, 2011
Lee J	The role of applied health research: experiences of implementing an intervention within a trial of exercise therapy for symptoms of dementia	University of Brighton, UK, 2011
Thuné-Boyle I	The effect of exercise on behavioural and psychological symptoms in dementia	Alzheimer's Disease International, London, UK, 2012
Lowery D	Reducing caregiver burden: a curious corollary of asking a caregiver to do more! In 'The real dementia challenge: using research to change practice for older people with dementia', symposium	The British Society of Gerontologists, Oxford, UK, Autumn Meeting, 2013
Lowery D	Reducing caregiver burden: a curious corollary of asking a caregiver to do more!	Dementia Care Congress, Nottingham, UK, 2013
Lowery D	EVIDEM Exercise In 'Evidence-Based Interventions in Dementia (EVIDEM): Research Across the Dementia Trajectory', symposium	Gerontological Society of America Annual Scientific Meeting, New Orleans, USA, 2013

Chapter 3: EVIDEM-C

The authors all contributed and agreed on the final version of this chapter as shown in *Table 77*.

In addition, we would like to thank others who were involved in individual studies as identified in *Table 78*.

TABLE 77 EVIDEM-C: acknowledgements of contributors (Faculty of Health and Social Care Sciences, Kingston University and St George's, University of London)

Name and role		Study element to which they contributed
Vari Drennan	Professor of Health Policy and Service Delivery	Chief Investigator Conceived, designed, organised the overall and individual elements of the study, including data collection, analysis and interpretation, and drafted this report
Laura Cole	Research Associate	Made a contribution to the design of individual elements, the organisation of the study, data collection, analysis and interpretation of the study. In addition, helped to draft and critique the output for important intellectual content
Sheila Donovan	Research Fellow	Made a contribution to the design of individual elements, the organisation of the study, data collection, analysis and interpretation of the study. In addition, helped to draft and critique the output for important intellectual content
Robert Grant	Senior Research Fellow in quantitative methods	Provided statistical analysis and interpretation, and, in addition, helped to draft this output for important intellectual content

TABLE 78 EVIDEM C: acknowledgements of additional contributors

Name	Role	Study element contributed to
Francesco D'Amico	Research Officer, PSSRU London School of Economics	Health economics
Anna El-Jouzi	Librarian, St George's University of London	Systematic review
Mandy Fader	Professor of Continence Technology, Faculty of Health Sciences, Southampton University	Systematic review and advisory group member
Nan Greenwood	Senior Research Fellow, Faculty of Health and Social Care Sciences, St George's University of London and Kingston University	Systematic review
Steve Iliffe	Professor of Primary Care for Older People, Research Department of Primary Care & Population Health, University College London, London	Chief investigator for the programme
Martin Knapp	Director and Professor of Social Policy PSSRU, London School of Economics	Health economics
Mary Murrell	Former family carer	Member of advisory group
Caroline Norrie	Research Associate, Faculty of Health and Social Care Sciences, St George's University of London and Kingston University	Survey
Irene Peterson	Principal Research Associate, Research Department of Primary Care & Population Health, University College London, London	Cohort study
Greta Rait	Senior Lecturer in Primary Care, PRIMENT Clinical Trials Unit, Research Department of Primary Care & Population Health, University College London, London	Systematic review, cohort study and advisory group member
Amritpal Redhill	Researcher, PSSRU London School of Economics	Health economics
Jacqui Woods	Former family carer	Chair of advisory group

EVIDEM-C publications and presentations

Papers have been published (*Table 79*) and presentations [oral (*Table 80*) and poster (*Table 81*)] made throughout the study. In addition, there are papers accepted for publication but not yet published, and others under review.

TABLE 79 EVIDEM-C: published papers (until April 2014)

Authors	Title	Journal
Drennan V, Cole L	Promoting continence and managing incontinence with people with dementia living at home: one more challenge for integration	<i>J Integ Care</i> 2009; 17 :15–25
Drennan V, Cole L	Dealing with incontinence	<i>Alzheimer's Society Magazine</i> 2009:14
Drennan V, Cole L	Exploring Issues and solutions in promoting continence with people with dementia living at home	<i>J Clin Nurs</i> 2010; 19 (Suppl. 1):100
Drennan VM, Cole L, Iliffe S	A taboo within a stigma? A qualitative study of managing continence in people with dementia living at home	<i>BMC Geriatr</i> 2011; 11 :75
Drennan VM, Norrie C, Cole L, Donovan S	Addressing incontinence for people with dementia living at home: a documentary analysis of local English community nursing service continence policies and clinical guidance	<i>J Clin Nurs</i> 2012; 22 :339–46
Drennan V, Rait G, Cole L, Grant R, Iliffe S	The prevalence of incontinence in people with cognitive impairment or dementia living at home: a systematic review	<i>Neurol Urodyn</i> 2013; 32 :314–24

TABLE 80 EVIDEM-C: oral presentations (until April 2014)

Title	Event	Date	Location
Management of Incontinence in the Community: Workshop	London Centre for Dementia Care: State of Art in Dementia Care Summer School and Stakeholders event	1 July 2008	London
Workshop on incontinence as part of Dignity and dementia: where do the problems and solutions lie?	Dementia Congress	28–30 October 2008	Bournemouth
An overview of the EVIDEM programme and the EVIDEM-C study	Academic Primary Care Seminar St George's University of London	4 November 2008	London
Exploring issues and solutions in promoting continence and managing incontinence with people with memory problems and dementia living at home	Faculty of Health and Social Care Sciences Seminar, St George's University of London	14 May 2009	London
Comparing the views of people with dementia and their carers with health and social care staff on managing toilet difficulties and incontinence	British Society of Gerontology Annual Conference	2–4 September 2009	Bristol
Exploring issues and solutions in promoting continence and managing incontinence with people with memory loss and cognitive problems living at home and their carers	Dementia Services Development Centre's International Conference	14–16 September 2009	York

continued

TABLE 80 EVIDEM-C: oral presentations (until April 2014) (continued)

Title	Event	Date	Location
Exploring issues of toileting problems and continence promotion for people living at home	EVIDEM Summer School, CNWL NHS Foundation Trust	11 September 2009	Hillingdon
EVIDEM-C: Exploring issues and solutions in promoting continence and managing incontinence with people with memory problems and dementia living at home	Annual Meeting of the North West of England Annual Association of Continence Advisors	9 December 2009	Preston
Research Support: EVIDEM-C	Association for Continence Advice (ACA) North East Thames Continence Advisors Group	22 January 2010	London
The Last Taboo? Managing toileting problems and incontinence with people with dementia living in their own homes	Making Research Count in Social Work and Social Care Practice: The National Dementia Strategy. King's College London	1 March 2010	London
Exploring issues and solutions in promoting continence and managing incontinence with people with memory loss and cognitive problems living at home and their carers	Royal College of Nursing International Nursing Research Conference	11–13 May 2010	Newcastle
The last taboo? Managing toileting problems and incontinence with people with dementia living in their own homes	Dementia Care Conference, Hertfordshire Adult Care Services	22 June 2010	Hertfordshire
Promoting continence and managing incontinence with people with memory problems living at home	Hillingdon Admiral Nurse Service Carers' Information Day	8 July 2010	Hillingdon
Exploring issues and solutions in promoting continence with people with dementia living at home	Fourth European Nursing Congress: Older Persons: The Future Of Care	4–7 July 2010	Rotterdam
Issues in managing continence problems with people with dementia living at home: the EVIDEM-C study	Faculty of Health and Social Care Sciences Seminar, St George's University of London	28 October 2010	London
Managing incontinence and dementia at home: a feasibility study of preferences and effectiveness of different types of absorbent products	Royal College of Nursing Continence Conference	2–3 November 2010	York
Managing incontinence and dementia at home: a feasibility study of preferences and effectiveness of different types of absorbent products	Royal College of Nursing International Nursing Research Conference	16–18 May 2011	Harrogate
Issues in managing continence problems with people with dementia living at home: the EVIDEM-C study	CNWL NHS Foundation Trust Occupational Therapists Study Day	1 September 2011	London
Issues in managing continence problems with people with dementia living at home: the EVIDEM-C study	EVIDEM Summer School and Central and North West London NHS Foundation Trust	7 October 2011	London
Developing a continence assessment tool for use by district nursing services sensitive to the needs of people with dementia	Royal College of Nursing International Research Conference	22–24 April 2012	London

TABLE 81 EVIDEM-C: poster presentations (until April 2014)

Title	Event	Date	Location
EVIDEM-C Promoting continence and managing incontinence with people with dementia and their carers living at home: A review of Evidence	DeNDRoN Conference	14 October 2008	Newcastle
Promoting continence and managing incontinence with people with dementia and their carers living at home: EVIDEM-C	St George's University of London Research Conference	3 December 2008	London
Exploring issues and solutions in promoting continence and managing incontinence with people with dementia living at home and their family carers	St George's University of London Research Conference	2 December 2009	London
Managing incontinence at home: preferences, effectiveness and ease of use of different types of absorbent products	The Dementia Services Development Centre's 4th International Conference: Coming of Age	19–21 October 2010	London
Managing incontinence at home: preferences, effectiveness and ease of use of different types of absorbent products	St George's University of London Research Day	30 November 2011	London
Developing a continence assessment tool sensitive to the needs of people with dementia living at home and their family carers	Alzheimer's Disease International Conference	13 April 2012	London

Chapter 4: EVIDEM-EoL

A large number of people have contributed to this project. We are very grateful to all of the older people in the care homes, and their relatives, who participated in the study. Hosting a research study in a care home is time-consuming and often inconvenient. We are particularly grateful to the care home managers and staff who welcomed us as a research team, facilitated our work and engaged enthusiastically with all the demands of the project.

We are also grateful to the primary care professionals who were involved with us throughout the study. Their participation, and continued interest made Phase 2 possible.

The study received support from North Thames DeNDRoN and Hertfordshire NHS Community Trust with FSF support.

We are grateful to members of the study advisory group (for membership, see *Appendix 54*) for their commitment over the 4 years of the study. Their experience, robust views, input and guidance were invaluable.

In addition, others were involved as identified in *Tables 82* and *83*.

TABLE 82 EVIDEM-EoL: acknowledgements of contributors

Name and role		Study element they contributed to
Claire Goodman	Professor of Health Care Research, CRIPACC, University of Hertfordshire	Chief Investigator. Conceived the idea of the study, provided clinical oversight and wrote the first draft of this chapter
Sarah Amador	Research Fellow, CRIPACC, University of Hertfordshire	Made a significant contribution to the organisation, data collection, analysis and interpretation of Phase 2. In addition, helped draft and critique the output for important intellectual content
Elsbeth Mathie	Research Fellow, CRIPACC, University of Hertfordshire	Made a significant contribution to the development of the AI intervention, the organisation of the study, data collection, analysis and interpretation of Phase 2
Natasha Baron	Research Assistant, Cambridge Centre for Health Services Research, University of Cambridge	Made a significant contribution to the organisation, data collection, analysis and interpretation of Phase 1
Ina Machen	Research Fellow, CRIPACC, University of Hertfordshire	Made a significant contribution to the organisation, data collection, analysis and interpretation of Phase 1
CRIPACC, Centre for Research in Primary and Community Care.		

TABLE 83 EVIDEM-EoL: acknowledgements of additional contributors

Name and role		Study element to which they contributed
Catherine Evans	NIHR Clinical Lecturer in Palliative Care, Cicely Saunders Institute, King's College London	Review study set-up and care home recruitment, and member of advisory group
Carole Parsons	Lecturer in Pharmacy Practice, School of Pharmacy, Queen's University Belfast	Analysis of sedative load and potentially inappropriate prescribing
Yi Ting Ng	Postgraduate student, London School of Economics	Economic analysis
Derek King	Research Fellow, PSSRU, London School of Economics	Economic analysis
Caroline Nicholson	Postdoctoral Research Fellow, Florence Nightingale School of Nursing and Midwifery, King's College London	Development and facilitation of AI intervention
Liz Stevenson	Research assistant, CRIPACC, University of Hertfordshire	Data collection in care homes
David Stott	CLiCIR, University of Hertfordshire	Survival analysis
CLiCIR, Centre for Lifespan and Chronic Illness Research; CRIPACC, Centre for Research in Primary and Community Care.		

EVIDEM-EoL publications and presentations

Papers have been published (*Tables 84–87*). A Master's thesis has been submitted (*Table 88*). In addition, study newsletters (*Table 89*), presentations (*Table 90*) and posters (*Table 91*) have been made throughout the study.

TABLE 84 EVIDEM-EoL: published papers (until April 2014)

Authors	Title	Journal
Evans C, Goodman C	End-of-life care for people with dementia living in a care home	<i>J Integ Care</i> 2008; 16 :15–25
Illiffe S, Manthorpe J, Drennan V, Goodman C, Warner J	The EVIDEM programme a test for primary care research in London	<i>London J Prim Care</i> 2008; 1 :69–73
Robinson L, Illiffe S, Brayne C, Goodman C, Rait G, Manthorpe J, <i>et al.</i>	Primary care and dementia: 1. diagnosis, screening and disclosure	<i>Int J Geriatr Psychiatry</i> 2009; 24 :9895–901
Goodman C, Evans C	Innovation section: changing practice in dementia care for people in care homes towards the end of life	<i>Dementia</i> 2009; 8 :424–31
Goodman C, Evans C, Wilcock J, Froggatt K, Sampson E, Drennan V, <i>et al.</i>	End-of-life care for community-dwelling older people with dementia: an integrated review	<i>Int J Geriatr Psychiatry</i> 2010; 25 :329–37
Robinson L, Illiffe S, Brayne C, Goodman C, Rait G, Manthorpe J, <i>et al.</i> , for the DeNDRoN Primary Care Clinical Studies Group	Long-term care at home: psychosocial interventions, information provision, carer support and case management	<i>Int J Geriatr Psychiatry</i> 2010; 25 :657–64
Manthorpe J, Illiffe S, Samsi K, Cole L, Goodman C, Drennan V, <i>et al.</i>	Dementia, dignity and quality of life: nursing practice and its dilemmas	<i>Int J Older People Nurs</i> 2010; 5 :235–44
Goodman C, Baron NL, Machen I, Stevenson E, Evans C, Davies SL, <i>et al.</i>	Culture, consent, costs and care homes: enabling older people with dementia to participate in research	<i>Ageing Ment Health</i> 2011; 15 :475–81
Parsons C, Haydock J, Mathie E, Baron N, Machen I, Stevenson E, <i>et al.</i>	Sedative load of medications prescribed for older people with dementia in care homes	<i>BMC Geriatr</i> 2011; 11 :56
Goodman C	The organisational culture of nursing staff providing long-term dementia care is related to quality of care	<i>Evid Based Nurs</i> 2011; 14 :88–9
Davies SL, Goodman C, Bunn F, Victor C, Dickinson A, Illiffe S, <i>et al.</i>	A systematic review of integrated working between care homes and health-care services	<i>BMC Health Serv Res</i> 2011; 11 :320 (highly accessed)
McMurdo MET, Roberts H, Parker S, Wyatt N, May H, Goodman C, <i>et al.</i> on behalf of the Age and Ageing Specialty Group, NIHR, Comprehensive Clinical Research Network	Improving recruitment of older people to research through good practice	<i>Age Ageing</i> 2011; 40 :659–65
Goodman C, Davies S	ENRICH: an initiative to facilitate dementia research in care homes	<i>Br J Community Nurs</i> 2012; 17 :277
Parsons C, Johnston S, Mathie E, Baron N, Machen I, Stevenson I, <i>et al.</i>	Potentially inappropriate prescribing in older people with dementia in care homes: a retrospective analysis	<i>Drugs Aging</i> 2012; 29 :143–55
Siegel EO, Anderson R, Calkin J, Chu C, Corazzini K, Dellefield ME, <i>et al.</i>	Supporting and promoting personhood in long term care settings: contextual factors	<i>Int J Older People Nurs</i> 2012; 7 :295–302
Goodman C, Amador S, Elmore N, Machen I, Mathie E	Preferences and priorities for end-of-life care: A qualitative study of older people with dementia resident in care homes.	<i>Int J Nurs Studies</i> 2013; 50 :1639–74
Amador S, Goodman C, King D, Ng YT, Elmore N, Machen I, <i>et al.</i>	Exploring resource use and associated costs in end-of-life care for older people with dementia in residential care homes	<i>Int J Geriatr Psychiatry</i> 2014; 29 :758–66

TABLE 85 EVIDEM-EoL: forthcoming papers at January 2014

Authors	Chapter title	Book title/editors
Amador S, Goodman C, King D, Machen I, Elmore N, Mathie E, <i>et al.</i>	Emergency ambulance service involvement with residential care homes in the support of older people with dementia: an observational study	<i>BMC Geriatr</i> (under review)
Goodman C, Amador S, Elmore N, Machen I, Mathie E	A framework for the evaluation of interventions and future research in end-of-life care of older people with dementia	In preparation
Amador S, Goodman C, Elmore N, Mathie E, Machen I	A modified Appreciative Inquiry in care homes: promoting cooperative working for end-of-life care of older people with dementia	In preparation

TABLE 86 EVIDEM-EoL: chapters (until April 2014)

Authors	Chapter title	Book title/editors
Wilcock J, Froggatt K, Goodman C	End-of-life care for people with dementia	In Downs M, Bowers B, editors. <i>Excellence in dementia care: Research in to practice</i> . Maidenhead: Open University Press; 2008
Goodman C, Davies S, Leyshon S, Fader M, Norton C, Gage H, <i>et al.</i>	Collaborating with Primary Care: promoting shared working between district nurses and care home staff	In Froggatt K, <i>et al.</i> , editors. <i>Understanding Care Homes: A Research and Development Perspective</i> . London: Jessica Kingsley Publishers; 2009
Goodman C, Davies SL	Good practice outside the care homes	In Denning T, Milne A, editors. <i>Mental Health in Care Homes</i> . Oxford: Oxford University Press; 2011

TABLE 87 EVIDEM-EoL: monographs (until April 2014)

Authors	Chapter title	Book title/editors
Goodman C, Froggatt K, Mathie E	End of life research methods in social care. Research Methods in Social Care series	NIHR School for Social Care Research. 2012. URL: www2.lse.ac.uk/LSEHealthAndSocialCare/pdf/SSCR-Methods-Review_12_web.pdf

TABLE 88 EVIDEM-EoL: master thesis/unpublished manuscripts (until April 2014)

Authors	Title	
Ng YT	<i>Resource implications of supporting end-of-life care for older persons with dementia in the care homes in England</i>	Unpublished Master's Thesis. London: Department of Social Policy, London School of Economics

TABLE 89 EVIDEM-EoL: newsletters (until April 2014)

Authors	Title	Newsletter
Evans C, Goodman C	Spotlight on the End of Life Project	Alzheimer's Society magazine, 2008. URL: http://alzheimers.org.uk/site/scripts/documents_info.php?documentID=809&pageNumber=3
Evans C, Goodman C	Spotlight on the End of Life Project	EVIDEM Newsletter 2 :5
Baron N, Goodman C	An update on the End of Life study	EVIDEM Newsletter 5 :3–4

TABLE 90 EVIDEM-EoL: presentations (until April 2014)

Authors	Title	Event
Goodman C, Wilcock J, Bisset M, Froggatt K, Drennan V, Blanchard M, <i>et al.</i>	Integrative review of end-of-life care for community-dwelling older people with dementia	Royal Society of Medicine, London, 2008
Goodman C, Evans C	Setting the scene: introduction to providing care in NHS care homes	Royal Society of Medicine, London, 2008
Goodman C, Evans C	EVIDEM-EoL: changing practice in dementia care in care homes: developing and testing evidence based interventions at the end of life	Symposium Presentation King's College London, London, 2008
Evans C, Goodman C, Davies SL	Research in care homes. Bulletin issue 11	PCRN_GL Masterclass, 2008
Goodman C	Understanding the experience of living and dying in a care home	Presentation to Quantum Homes, Herts, 2008
Goodman C	Research in end-of-life care in care homes	Dementia and end-of-life care study day St Nicholas Hospice, Ipswich, 2008
Iliffe S, Manthorpe J, Goodman C, Drennan V, Warner J	Dignity and dementia: where do the problems and solutions lie?	Dementia Care Congress, Bournemouth, 2008
Goodman C	Supporting people with dementia and their carers at the end of life in care homes and primary care	EVIDEM Summer School, CNWL NHS Foundation Trust, London 2009
Goodman C, Baron N	Living and dying with dementia in care homes: the EVIDEM-End of Life study	The Dementia Service Development Centre 3rd International Conference, York, 2009
Goodman C, Baron N, Stevenson E, Machen I	Culture consent and care home: enabling older people with dementia to participate in research	British Society of Gerontology Annual Conference, Bristol, 2009
Goodman C	Addressing uncertainty: end-of-life care in residential settings	The National Dementia Strategy Practice Perspectives: One Year On, King's College London, London, 2010
Goodman C	End-of-life care for people with dementia	DeNDRoN, 2010
Goodman C	EVIDEM-End of Life: recognising and supporting end-of-life care for people with dementia living in care homes	Delivering Better Health Services: The Health Services Research Network, Manchester, 2010
Mathie E, Goodman C	Living and dying in residential care homes: views of residents: 'a good death'	NHS Luton and Bedfordshire Quality Summit – Care Homes, Flitwick, 2011
Goodman C	The role of care homes in HSC integration	Navigating the Future: Partnership and Integration in a Changing World. Seminar of ADASS and BGS, London, 2011
Goodman C	Dementia research in care homes	Presentation at Dementia Research: Knowledge into Care. NIHR CLAHRC, Cambridge, 2011
Nicholson C	Good gossip: using appreciative inquiry to further end-of-life care in care homes	Presentation at the Margaret Butterworth Care Home Forum, London, 2011
Goodman C	The role of care homes in HSC integration	Workshop session at Navigating the future: Partnership and Integration in a Changing World. Seminar of ADASS and BGS, London, 2011
Goodman C	New research into partnership working with dementia	Presentation at the Hertfordshire Care Providers Association Members Meeting, Welwyn Garden City, 2011

continued

TABLE 90 EVIDEM-EoL: presentations (until April 2014) (continued)

Authors	Title	Event
Mathie E, Goodman C, Nicholson C, Amador S	End of life care in residential care homes – an appreciative inquiry	Presentation at the Assets for Health and Wellbeing Across the Life Course International Conference, British Library Conference Centre, London, 2011
Goodman C	Dementia research in care homes	Presentation at Dementia Research: Knowledge into Care, NIHR CLAHRC, Cambridge, 2011
Goodman C, Mathie E, Nicholson C, Amador S	Dealing with uncertainty at the end of life for people with dementia: appreciative inquiry as an intervention to improve working between primary healthcare and care homes	Presentation at the UK Dementia Congress Liverpool, 2011
Goodman C, Mathie E, Nicholson C, Amador S	Using what we do well to improve end of life care for older people with dementia	Presentation at the Hertfordshire County Council Good Practice in Dementia Care Conference, Hatfield, 2011
Mathie E	EVIDEM-End of Life: working with primary healthcare supporting people with dementia living and dying in care homes	Presentation at Working Together: Valuing Each Other. New Approaches to Working Between Care Homes and Primary Care. Hertfordshire AGENET meeting, Hatfield, 2012
Nicholson C	An appreciative inquiry: end of life care in residential care	Presentation at Working Together: Valuing Each Other. New Approaches to Working Between Care Homes and Primary Care Hertfordshire AGENET meeting, Hatfield, 2012
Mathie E	Supporting people with dementia: living and dying in residential care homes	Community Care Conference, London, 2012
Goodman C, Nicholson C, Mathie E, Amador S	End-of-life care for people with dementia: an intervention to promote integrated working between care home staff and healthcare practitioners	Presentation at the Alzheimer's Disease International Conference London, 2012
Nicholson C, Mathie E, Machen I, Amador S, Goodman C	Working appreciatively in end-of-life care: an intervention to promote collaborative working between care home staff and healthcare practitioners	Presentation at the RCN UK's International Nursing Research Conference London, 2012
Goodman C	Care homes: working with and working for the NHS	Presentation at the BGS Community Geriatrics Meeting, The Met Hotel, Leeds, 2012
Goodman C	An intervention to promote integrated working between care homes and healthcare practitioners for end-of-life care of older people with dementia	Presentation at Delivering Better Health Services HSRN symposium, Manchester Central, 2012
Goodman C	Maximising quality in residential care	Presentation at the New Dynamics of Ageing/My Home Life workshop, RIBA, London, 2012

TABLE 90 EVIDEM-EoL: presentations (until April 2014) (*continued*)

Authors	Title	Event
Amador S, Mathie E, Nicholson C, Goodman C	End of life care for people with dementia: researching uncertainty	Presentation at Developing a Research Culture, CLCH NHS Trust Annual Conference, Mary Ward House, London, 2012
Amador S, Mathie E, Nicholson C, Goodman C	Participatory research in care homes: promoting collaborative working between care homes and healthcare professionals for end-of-life care of older people with dementia	Presentation in Conducting Healthcare Research with Care Homes: Residents, Researchers and Healthcare Professionals' Perspectives Symposium, BSG Annual Conference, Keele, 2012

ADASS, Association of Directors of Adult Social Services; BGS, British Geriatrics Society; BSG, British Society of Gerontology; CLAHRC, Collaborations for Leadership in Applied Health Research and Care; CLCH, Central London Community Healthcare; HSRN, Health Services Research Network; RCN, Royal College of Nursing; RIBA, Royal Institute of British Architects.

TABLE 91 EVIDEM-EoL: posters (until April 2014)

Authors	Title	Event
Goodman C, Evans C	EVIDEM-End of Life (EoL): changing practice in dementia care in care homes – developing and testing interventions towards the end of life	Poster session at the DeNDRoN Annual Conference, Newcastle upon Tyne, 2008
Goodman C, Baron N, Machen I, Stevenson L	EVIDEM-EoL: living and dying with dementia in care homes	Poster session at the DeNDRoN Annual Conference, 2009
Goodman C, Baron N	Ensuring equity of participation for people with dementia: strategies to support inclusionary research	Poster session at the Biennial symposium of ICCHNR, Edmonton, Canada, 2011
Goodman C, Nicholson C	End-of-life care in residential care homes: an Appreciative Inquiry	Poster session at the fourth National Care Homes Congress, Birmingham, 2011
Nicholson C, Goodman C, Mathie E, Amador S, Baron N, Machen I	End of life care for people with dementia: an intervention to promote collaborative working between care home staff and healthcare practitioners	Poster session at the 9th Palliative Care Congress, The Sage Gateshead, Gateshead, UK, 2012. URL: http://spcare.bmj.com/content/2/Suppl_1/A23.1
Nicholson C, Mathie E, Machen I, Amador S, Goodman C	Working appreciatively in end-of-life care: an intervention to promote collaborative working between care home staff and healthcare practitioners	Poster session at the RCN UK, 2012. The 2012 International Nursing Research Conference

ICCHNR, International Conferences in Community Health Nursing Research; RCN, Royal College of Nursing.

Chapter 5: EVIDEM-MCA

A number of people have contributed to this project. We are extremely grateful to all of the participants for their time and for sharing their views. We are most grateful to Joan Rapaport, Hazel Heath, Jess Harris, Philip Rapaport, Tayavnie Nagendran, Nigel Charles and Lynn Phair who conducted a number of interviews and assisted with data analysis. We thank Karishma Chandaria for the opportunity to work with the Alzheimer's Society and for contributing to our linked study of financial abuse among people with dementia. We are grateful to members of the study advisory group and of the Social Care Workforce Research Unit advisory group for sharing their views on various aspects. Thanks are also due to Steve Chamberlain, Maria Grey, Priya Jain and Frances Lefford for their contributions to a consensus group meeting.

The authors all contributed and agreed on the final version of this chapter as shown in *Table 92*.

TABLE 92 EVIDEM-MCA: acknowledgements of contributors (Social Care Workforce Research Unit, King's College London)

Name and role		Study element to which they contributed
Jill Manthorpe	Professor of Social Work	Chief Investigator. Conceived the idea of the study, conducted interviews, report writer, member of EVIDEM project team, data analysis and dissemination lead; drafted final report
Jessica Harris	Research Associate	Assistance with interviewing at initial stage of the study
Kritika Samsi	Lecturer	Project researcher and co-investigator. Interviews, analysis and project manager, assisted with drafting of final report and all study outputs

EVIDEM-MCA publications and presentations

Papers have been published (*Table 93*) throughout the study. In addition, there are papers accepted for publication not yet published and under review (*Table 94*). Please see *Table 95* for a list of all of the presentations at seminars, events and conferences.

TABLE 93 EVIDEM-MCA: published papers (until April 2014)

Authors	Title	Journal
Manthorpe J, Rapaport J, Harris J, Samsi K	Realising the safeguarding potential of the Mental Capacity Act 2005: early reports from adult safeguarding staff	<i>J Adult Protect</i> 2009; 11 :13–24
Manthorpe J, Samsi K	Implementing the Mental Capacity Act 2005: challenges for commissioners	<i>J Integ Care</i> 2009; 17 :39–47
Manthorpe J, Iliffe S, Samsi K, Cole L, Goodman C, Drennan V, <i>et al.</i>	Dementia, dignity and quality of life: nursing practice and its dilemmas	<i>Int J Older People Nurs</i> 2010; 5 :235–44
Manthorpe J, Samsi K, Heath H, Charles N	'Early days': Knowledge and use of the Mental Capacity Act 2005 by care home managers and staff	<i>Dementia</i> 2011; 10 :283–98
Manthorpe J, Samsi K	Improving practice in communication with older people and support networks living in housing with care schemes: aspirations and ambitions	<i>Br J Soc Work</i> 2012; 42 :1495–512
Samsi K, Manthorpe J, Rapaport P	'As people get to know it more': Experiences and expectations of the Mental Capacity Act 2005 amongst local information, advice and advocacy services	<i>Soc Pol Soc</i> 2011; 10 :41–54
Samsi K, Manthorpe J	'I live for today': A qualitative study investigating older people's attitudes to advance planning	<i>Health Soc Care Community</i> 2011; 19 :52–9
Samsi K, Manthorpe J, Nagendaran T, Heath H	Challenges and expectations of the Mental Capacity Act 2005: The perspectives of community-based specialist nurses working in dementia care	<i>J Clin Nurs</i> 2012; 21 :1697–705
Phair L, Manthorpe J	The use of the Mental Capacity Act among hospital patients: findings from a case study of one Acute Hospital Trust in England	<i>J Adult Protect</i> 2012; 14 :259–70

TABLE 93 EVIDEM-MCA: published papers (until April 2014) (continued)

Authors	Title	Journal
Manthorpe J, Samsi K, Rapaport J	When the profession becomes personal: dementia care practitioners as family caregivers	<i>Int Psychogeriatr</i> 2012; 24 :902–10
Manthorpe J, Samsi K, Rapaport J	'More of a leg to stand on': Views and usage of the Mental Capacity Act 2005 among local Alzheimer's Society and Caregiver groups: findings from the EVIDEM MCA project	<i>Aging Ment Health</i> 2012; 16 :102–9
Manthorpe J, Samsi K	Mental capacity: the force of law	<i>J Dementia Care</i> 2012; 20 :12–13
Manthorpe J, Samsi K, Rapaport J	Dementia nurses' experience of the Mental Capacity Act 2005; a follow-up-study	<i>Dementia</i> 2014; 13 :131–43
Manthorpe J, Samsi K	Inherently risky? Personal budgets for people with dementia and the risks of financial abuse: findings from an interview-based study with Adult Safeguarding Coordinators	<i>Br J Soc Work</i> 2013; 43 :889–903
Manthorpe J, Samsi K, Rapaport J	Responding to the financial abuse of people with dementia: a qualitative study of safeguarding experiences in England	<i>Int Psychogeriatr</i> 2012;1–11. doi:10.1017/S1041610212000348
Manthorpe J, Samsi K	Mental Capacity and dementia: A review, Part 1	<i>J Dementia Care</i> 2012; 20 :35–8
Manthorpe J, Samsi K	<i>Making Decisions in Dementia Care: Has the Mental Capacity Act Helped Social Work Practice in England and Wales?</i>	Community Care, 28 November 2012. URL: www.communitycare.co.uk/articles/28/11/2012/118730/making-decisions-in-dementia-care-has-the-mental-capacity-act-helped-social-work-practice-in-england-and-wales.htm
Manthorpe J, Samsi K	Mental Capacity and dementia: A review, Part 2	<i>J Dementia Care</i> 2013; 21 :35–8
Manthorpe J, Samsi K, Rapaport J	'Capacity is the key': Investigating new legal provisions in England and Wales for adult safeguarding	<i>J Elder Abuse Negl</i> 2013; 25 :355–73
Samsi K, Manthorpe J	Everyday decision-making amongst people with dementia and carers: findings from a longitudinal interview study of people with dementia and family carers	<i>Int Psychogeriatr</i> 2013; 25 :949–61
Manthorpe J, Samsi K	Changing practice: adapting to the Mental Capacity Act 2005	<i>Soc Care Neurodisabil</i> 2013; 4 :124–33
Manthorpe J, Iliffe S, Goodman C, Drennan V, Warner J	Working together in dementia research: reflections on the EVIDEM programme	<i>Working with Older People</i> 2013; 17 :138–45
Samsi K, Manthorpe J, Chandaria K	Risks of financial abuse of older people with dementia: findings from a survey of UK voluntary sector dementia community services staff	<i>Journal Adult Protect</i> 2014; 16 :3
Manthorpe J, Samsi K	Care professionals' understanding of the new criminal offences created by the Mental Capacity Act 2005	<i>Int J Geriatr Psychiatry</i> 2014; doi:10.1002/gps.4147

TABLE 94 EVIDEM-MCA: forthcoming papers at April 2014

Authors	Title	Journal
Manthorpe J, Samsi K	Care homes and the Mental Capacity Act 2005: changes in understanding and practice over time	<i>Dementia</i> [being revised]
Samsi K	Negotiating capacity and consent in substance misuse	In Crome I, Wu L-T, Rao R, Crome P, editors. <i>Substance Use and Older People</i> . Chichester, West Sussex: John Wiley & Sons Inc.; 2014
Manthorpe J, Samsi K	Briefing note on MCA offences for care homes	National Care Home Forum (in press 2015)

TABLE 95 EVIDEM-MCA: presentations and posters (until April 2014)

Author	Title	Event
Manthorpe J, Samsi K	Early views of local Alzheimer's Society staff regarding the Mental Capacity Act 2005	Dementia Congress, Harrogate, November, 2009
Manthorpe J, Samsi K	'Can you help me think about my future?': Exploring the role of information and advice organisations	Dementia Services Development Centre Annual Conference, York, July, 2009
Samsi K, Manthorpe J, Heath H	Early findings from interviews with care home staff	Care Home Congress, Birmingham, July, 2009
Manthorpe J, Samsi K.	Putting the Mental Capacity Act into practice in care homes: emerging findings and research challenges	National Care Home Research and Development Forum, London, April, 2009
Samsi K, Manthorpe J	Making plans for the unknown: transitions in cognitive impairment Alzheimer's disease and other dementias	Annual Gerontological Society of America Conference, Atlanta, GA, November, 2009
Manthorpe J, Seminar Series	Money management and the Mental Capacity Act	Centre for Policy on Ageing, London, 2010
Samsi K, Manthorpe J	Planning for retirement and later life: 'Hope nothing is going to happen and we carry on as long as we can'	Annual Conference of BSG, London, 5 July, 2010
Samsi K, Manthorpe J	'It helps us to give people something concrete that they can work with': early views of local Alzheimer's Society staff on the Mental Capacity Act 2005	North East London NHS Foundation Trust Older People's Conference, July 2010
Samsi K, Manthorpe J	Futurescopes: older people's attitudes and knowledge of making plans	Annual Conference of Dementia Services and Development Centre, London, May 2010
Manthorpe J, Samsi K	Developmental steps in building a toolkit to challenge wilful neglect and ill-treatment under the Mental Capacity Act	Dementia Congress, Liverpool, 10 November 2011 (poster)
Samsi K, Manthorpe J	Wilful neglect and ill-treatment under the Mental Capacity Act 2005: identifying thresholds and safeguarding pathways	Annual Conference of International Psychogeriatrics Association, Den Haag, Netherlands, 5 September 2011
Samsi K, Manthorpe J	Use and views of the Mental Capacity Act 2005	Annual Conference of British Society of Gerontology, Plymouth, 10 July 2011
Manthorpe J, Samsi K	Developing a toolkit to understand the offences of wilful neglect and ill-treatment under the Mental Capacity Act	Annual Conference of Gerontological Society of America, Boston, November 2011
Manthorpe J, Samsi K, Chandaria K	Safeguarding people with dementia from financial abuse	Alzheimer's Disease International Conference, London, 7-9 March 2012 (poster)

TABLE 95 EVIDEM-MCA: presentations and posters (until April 2014) (continued)

Author	Title	Event
Manthorpe J, Samsi K	When psychosocial interventions go wrong	INTERDEM meeting, Alzheimer's Disease International Conference, London, 7 March 2012
Samsi K	Championing dementia	Addressing equalities in older people's social care, A Joint Conference of Making Research Count, Age UK London and the Social Care Workforce Research Unit, 26 January 2012
Manthorpe J	Lessons from England on mental capacity working	International conference on Squalor and Neglect, Sydney, Australia, 22 February 2012
Manthorpe J	Making decisions in dementia care: how new law helped practice in England and messages for social work practice in other jurisdictions	European Social Work Research Conference, Basle, 23 March 2012
Manthorpe J	Elder abuse and mental capacity (pod broadcast and audience)	Age UK staff group seminar, London, 11 April 2012
Manthorpe J	Care and Control: Mental Health, Mental Capacity and Social Care Futures	Manchester Metropolitan University Social Work Conference, 26 April 2012
Manthorpe J	Interventions in elder abuse	International Elder Abuse Day, National Centre for the study of Elder Abuse, Dublin, 24 June 2012
Manthorpe J, Samsi K	Crime against residents with dementia	Margaret Butterworth Care Home Forum, London, 10 July 2012
Manthorpe J, Samsi K	Everyday independent and joint decision-making by people with dementia and carers	British Society of Gerontology Annual Conference, University of Keele, Stoke, 12 July 2012
Manthorpe J, Samsi K	Preventing financial abuse among people with dementia	British Society of Gerontology Annual Conference, University of Keele, Stoke, 11 July 2012
Manthorpe J, Samsi K	Everyday decision-making among people with dementia and carers	Gerontological Society of America's 65th Annual Scientific Meeting, San Diego, 14 November 2012
Manthorpe J, Samsi K	Planning in advance for long-term care needs	2nd International Conference on Evidence-based Policy in Long-term Care, London, September 2012
Manthorpe J, Samsi K, Chandaria K	Who should protect people with dementia from financial abuse?	Alzheimer Europe, Vienna, 6 October 2012 (poster)
Samsi K, Manthorpe J	'How do carers decide for their relatives with dementia?'	Alzheimer Europe, Vienna, 6 October 2012
Manthorpe J, Samsi K, Chandaria K	'Protecting people with dementia from financial abuse' (poster)	7th UK Dementia Congress, Brighton, 30 October to 1 November, 2012
Samsi K, Manthorpe J	Everyday decision-making among people with dementia and carers	Gerontological Society of America's 65th Annual Scientific Meeting, San Diego, CA, 14 November 2012
Manthorpe J, Samsi K	Use and views of the Mental Capacity Act 2005	Evidence Based Interventions in Dementia: Findings, London, 16 April 2013
Manthorpe J	Learning about Lasting Powers of Attorney	Making Research Count, London, 22 September 2013
Manthorpe J, Samsi K	Understanding the new criminal offences created by the Mental Capacity Act 2005	Annual Conference of the British Society of Gerontology, University of Oxford, 11 September 2013

continued

TABLE 95 EVIDEM-MCA: presentations and posters (until April 2014) (*continued*)

Author	Title	Event
Manthorpe J, Samsi K	The mistreatment and neglect of people with dementia	Alzheimer Europe, Malta, 12 October 2013
Manthorpe J, Samsi K	From professional to the personal dementia care practitioners as family carers	INTERDEM/Alzheimer Europe, Malta, 10 October 2013
Manthorpe J, Samsi K	Making decisions in dementia care	Gerontological Society of America, New Orleans, 26 November 2013
Manthorpe J	The relevance of the MCA for audiologists in practice	University College London Audiology Masterclass, London, 5 December 2013

BSC, British Society of Gerontology.

Chapter 6: EVIDEM: from cohort to research register

The authors all contributed and agreed on the final version of this chapter as shown in *Table 96*.

EVIDEM: from cohort to research register – publications and presentations

The following peer-reviewed papers have been published (*Table 97*).

Additional publications on behalf of the EVIDEM group: publications and presentations

The following peer-reviewed papers have been published (*Table 98*).

TABLE 96 EVIDEM, from cohort to research register: acknowledgements of contributors

Name and role	Study element to which they contributed
Steve Iliffe Research Department of Primary Care & Population Health, University College London	Project development, management committee member
Lisa Curry West London Mental Health Trust	Cohort manager
Jane Wilcock Research Department of Primary Care & Population Health, University College London	Project development, field research and management committee member
Greta Rait Research Department of Primary Care & Population Health, University College London	Project development, management committee member
David Lowery CNWL NHS Foundation Trust	Management committee member
Kalpa Kharicha Research Department of Primary Care & Population Health, University College London	Management committee member
Archana Tapuria Centre for Health Informatics and Multiprofessional Education, University College London, London	Information technology development
Dipak Kalra Centre for Health Informatics and Multiprofessional Education, University College London, London Information Technology Development	
Craig Ritchie West London Mental Health Trust	Project leader

TABLE 97 EVIDEM-COHORT: published papers (until April 2014)

Authors	Title	Journal
Iliffe S, Curry L, Kharicha K, Rait G, Wilcock J, Lowery D, <i>et al.</i>	Developing a Dementia Research Registry: a descriptive case study from North Thames DeNDRoN and the EVIDEM programme	<i>BMC Med Res Methodol</i> 2011; 11 :9

TABLE 98 EVIDEM: published papers (until April 2014)

Authors	Title	Journal
Iliffe S, Manthorpe J, Warner J, Drennan V, Goodman C, Rait G, <i>et al.</i>	Making progress in psychosocial research in dementia	<i>Dementia</i> 2008; 7 :167–74
Iliffe S, Manthorpe J, Drennan V, Goodman C, Warner J	The EVIDEM programme: a test for primary care research in London?	<i>London J Prim Care</i> 2008; 1 :69–73
Manthorpe J, Iliffe S	The Mental Health of Older People: Taking a Long View	<i>J Integr Care</i> 2008; 16 :4–13
Manthorpe J	Mental Health in Later Life: Better Outcomes through Wise Commissioning	<i>J Integr Care</i> 2009; 17 :15–22
Manthorpe J, Iliffe S, Rait G, Goodman C, Drennan V, Warner J	Keeping on Track	<i>Sign post</i> 2009; 14 :26–30
Manthorpe J, Iliffe S, Samsi K, Cole L, Goodman C, Drennan V, <i>et al.</i>	Dementia, dignity and quality of life: nursing practice and its dilemmas	<i>Int J Older People Nurs</i> 2010; 5 :235–44
Manthorpe J, Iliffe S, Goodman C, Drennan V, Warner J	Working together in dementia research: reflections on the EVIDEM programme	<i>Working With Older People</i> 2013; 17 :1–8

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Appendix 1 *Chapter 1: Findings from literature reviews of interventions in primary care designed to alter clinical practice with patients with dementia*

TABLE 99 A descriptive comparison of controlled trials

Authors, date and country	Size	Recruitment	Intervention	Method	Outcomes	Results	Conclusions
Waldorff et al. 2003, ²² Denmark	413 GPs in intervention, 122 in control group	GPs identified from medical association and organisational database	Assessment of a multifaceted strategy to implement guidelines	Controlled before-and-after study	Included dementia screening, thyroid function and vitamin B ₁₂ tests, cognitive testing and referrals to specialists; also, questionnaire examining acceptability of guidelines	No significant difference between control and intervention group was found in the number of diagnostic evaluations undertaken, the number of ordered, or the amount of cognitive testing performed	After a multifaceted strategy for implementation, there was no improvement in the adherence to a guideline for diagnosing dementia. However, the outcomes were measured only 4–7 months after implementation, and although the intervention was delivered at GP level, the outcomes were measured at practice level
Downs et al. 2006, ²¹ central Scotland and London	35 practices	Local group meetings, postal and phone invitations, practice visits	Three arms: (1) tutorial on CD-ROM; (2) decision-support software; and (3) practice-based workshops	Unblinded, cluster randomised before-and-after controlled trial	Detection rates. Concordance with guidelines	Significant increase in the detection of dementia in arms 2 and 3 No improvement in adherence to guidelines	Might be useful to examine potential cumulative effects of combining educational interventions
Rondeau et al. 2008, ²³ France	684 GPs, 214 specialists, 3021 patients	Random selection from a list of GPs throughout France	Group educational meeting and training in use of neuropsychological tests	Cluster RCT	Primary outcome: Suspicion of dementia by GP Secondary outcome: Diagnosis of dementia by GP	No difference in diagnosis of dementia in intervention group	Education ineffective

Authors, date and country	Size	Recruitment	Intervention	Method	Outcomes	Results	Conclusions
Chodosh <i>et al.</i> 2006, ²⁴ USA	166 primary care clinics	Questionnaires sent to all primary care health providers at 16 clinics	Survey of knowledge, attitudes and perceptions following participation in the ACCESS study (Vickrey <i>et al.</i> ²⁵)	Survey following a cluster RCT of a care management intervention	Practitioners' knowledge about capacity determination, evaluation, treatment and patient safety Measures of attitude, and perceptions of quality of care	Intervention group knew more about determining capacity and more felt that management of dementia patients in primary care was difficult; no other difference in knowledge, attitudes or perceptions of quality of care	Care management programmes may have a positive effect on care despite lack of educational gain
Wenger <i>et al.</i> 2009, ²⁶ USA	357 intervention and 287 control community-dwelling patients	Patients aged > 75 years, with difficulty in falls, continence or cognition; two medical groups participated, each having two sites, with one acting as a control and one as an intervention site	Patients' problems were identified by a telephone call then the physician triggered a condition-specific process of management and resulted with formulating a plan for the patient. Physicians in the intervention group had a 3-hour educational session on ACOVE quality indicators. ³²⁰ Patients also completed questionnaires. Data were collected from medical records	Controlled trial	Percentage of quality indicators met after 13 months of medical record extraction	For cognitive impairment, care as triggered by quality indicators did not differ; however, more attention was given to caregiver education, decision-making capacity, and discussion about driving occurred in the intervention group	Care did not improve for patients with cognitive impairment. All physicians provided more recommended care for patients who presented with their symptoms (compared with those identified by screening)

continued

TABLE 99 A descriptive comparison of controlled trials (continued)

Authors, date and country	Size	Recruitment	Intervention	Method	Outcomes	Results	Conclusions
Vollmar et al. 2010, ²⁷ Germany	389 GPs from 26 QCs	All QCs within a 50-km radius of Witten University were contacted by telephone or letter to the QC moderator	QCs were randomly allocated to either arm of the trial: online learning plus structured case discussion ('blended learning') or lecture plus structured case discussion. Both groups received pocket books of the guidelines. Control group received only the pocket book. Knowledge tests were carried out pre and post intervention, and at 6 months	Cluster RCT	<i>Primary outcome:</i> Knowledge gain from before to after the intervention <i>Secondary outcome:</i> Comparison of knowledge gain of the two groups	Both groups showed a significant gain in knowledge following the interventions However, there was no difference in knowledge gains between the two groups Subgroup analysis showed that GPs who self-reported using the online learning had significant knowledge gain compared with the other group The control group showed a knowledge gain that was significantly less than the intervention groups	Blended learning was not more effective than traditional learning in improving dementia knowledge in GPs. However, when GPs self-report use of online modules, results suggest that blended learning techniques could be more effective
Perry et al. 2008, ²⁸ Holland	151 patients	54 GPs recruited patients > 70 years into DGIP	Secondary analysis of data examining whether the DGIP (an in-home assessment) improves rates of detection of dementia in primary care In-home assessment performed by specialist nurse, assessed function, mood, cognition and caregiver burden A management plan was formulated	Blinded RCT	<i>Primary outcome:</i> The number of new dementia diagnoses <i>Secondary outcome:</i> The level of under-registration of dementia cases	The number of dementia diagnoses in the control group (9%) was significantly less than those in intervention group (29%); $p = 0.02$	An in-home assessment and management programme is effective in detecting dementia in the primary care setting compared with controls of usual care

Authors, date and country	Size	Recruitment	Intervention	Method	Outcomes	Results	Conclusions
Callahan 2006, ²⁹ USA	153 patients with Alzheimer's disease	Primary care centres	Collaborative care management	RCT	NPI cognitive function, carer stress, service use	Intervention group had lower NPI scores but no difference in depression, cognitive status, or functional scores. Carers showed less stress. Intervention group had higher number of contact visits with physician/nurse, but no difference in hospital or nursing home admissions	Collaborative care can reduce behavioural/psychological symptoms in patients, and stress in carers
Vickrey 2006, ²⁵ USA	408 patient-caregiver dyads from 18 clinics	Patients identified from organisational database	Dementia care manager with web-based support software for care planning and co-ordination Interactive educational seminars for practitioners in intervention group	Cluster RCT	<i>Primary outcome:</i> Adherence to guidelines <i>Secondary outcomes:</i> Use of cholinesterase inhibitors, patient QoL, caregivers' knowledge, QoL, social support and confidence	Intervention group care more adherent to guidelines, received more community services and were prescribed more cholinesterase inhibitors Caregivers were more confident in intervention group	Systems change by introducing care managers can improve quality of care, but is costly
Fortinsky et al. 2009, ³⁰ USA	84 caregivers	Family caregivers of patients with dementia were recruited from the Alzheimer's Association and primary care	Intervention group received educational materials which were discussed with a dementia care consultant	Cluster RCT	<i>Primary outcome:</i> Admission to a nursing home in the study period <i>Secondary outcomes:</i> Caregiver self-efficacy, caregiver burden, depression, health, satisfaction with the service	Those in the intervention group were 40% less likely to end up in a nursing home than those in the control group but this did not achieve statistical significance	No difference was found between groups for secondary outcomes Inadequately powered study

continued

TABLE 99 A descriptive comparison of controlled trials (*continued*)

Authors, date and country	Size	Recruitment	Intervention	Method	Outcomes	Results	Conclusions
Clark 2004, ³¹ USA	89 participants with a symptom of memory loss or diagnosis of dementia, but no mention of how many in control and how many in intervention groups	Patients registered with Kaiser with diagnosis of dementia on medical records or symptoms indicative of cognitive impairment	Intervention group received care consultation: telephone interaction between Alzheimer's Association staff and patient/caregiver	RCT	Hospital admissions A&E visits, number of physician contacts, satisfaction with service, depression, strain on patient	Intervention group reported more memory symptoms but were less likely to have hospital admissions or A&E visits, and had fewer physician contacts. Also experienced less embarrassment, isolation and relationship strain	Overall, patients who had a care consultant had lower levels of negative consequences from memory problems and reduced usage of certain services

ACOVE, Assessing Care of Vulnerable Elders; DGIP, Dutch EASYcare Study Geriatric Intervention Program; QC, quality circle; QoL, quality of life.

TABLE 100 Descriptions of the content of the interventions

Trial	Description of intervention
Waldorff <i>et al.</i> 2003 ²²	<p>Local GPs and specialists collaborated in the design of the multifaceted strategy</p> <p>Interventions included:</p> <ol style="list-style-type: none"> 1. seminars on specific clinical practice guidelines and screening tools, brain imaging as a diagnostic procedure and pharmaceutical treatments for dementia 2. three reminder letters covering the main recommendations in the clinical practice guidelines 3. an individualised small-group educational programme 4. outreach visits by a trained GP facilitator, who underwent a 5-hour symposium of training
Downs <i>et al.</i> 2006 ²¹	<p>Three interventions trialled:</p> <ol style="list-style-type: none"> 1. Decision-support software – written inside medical electronic records and used prompts for the investigation and management of dementia; assisted clinical reasoning and planning in real time 2. CD-ROM – electronic tutorial using case analysis, reflections on knowledge, and considering complex clinical problems; designed as electronic book format using indexing and hypertext links 3. Small-group workshop – GPs with experience in postgraduate education facilitated a small-group workshop using clinical scenarios and case discussions in multidisciplinary groups
Rondeau <i>et al.</i> 2008 ²³	<p>Training on a battery of cognitive screening tests (the Short Cognitive Evaluation Battery³²¹), which tests four cognitive areas that are often impaired in Alzheimer's disease (with a sensitivity of 93.8%); 2-hour group educational meetings on Alzheimer's disease and other forms of dementia</p>
Chodosh <i>et al.</i> 2006 ²⁴	<p>Intervention participants were offered five educational modules comprising 100 minutes of presentation and discussion in small-group format (and available on the web). These were:</p> <ol style="list-style-type: none"> 1. assessment of capacity for making medical decisions 2. an overview of the dementia care management programme 3. the role of care managers 4. the recognition and treatment of dementia and depression 5. the recognition and treatment of dementia and delirium
Wenger <i>et al.</i> 2009 ²⁶	<p>The survey instrument measured different facets of understanding: five MCQs addressing knowledge base on capacity, delirium, patient safety and depression, and three MCQs on perceived value of screening, value of dementia care and perceived difficulty in management; also questioned on perceived quality of resources and ability to co-ordinate care, and value of correspondence from other providers</p> <p>Educational sessions for practitioners and structured prompts on management and care for patients. For positively screened patients, a prompt initiated collection of specific data, triggered recommendations of specific investigations and suggested specific care processes. The prompt supported the facilitation of an impression and plan for the patient, and included decision-support materials and patient education resources and information about local services. Three-hour educational session learning an 'efficient approach' to the condition, using ACOVE quality indicators (ACOVE investigators 2001³²⁰). After piloting, practices met to share experiences of clinicians and to modify the structure of the intervention as necessary. Clinicians/practices were able to review and adapt the prompts to suit their local services and personnel</p>

continued

TABLE 100 Descriptions of the content of the interventions (continued)

Trial	Description of intervention
Vollmar <i>et al.</i> 2010 ²⁷	<p>Two interventions:</p> <ol style="list-style-type: none"> 1. Online learning modules plus structured case discussion. Online modules covered: the guideline and interactive case stories relating to guidelines 2. Lecture plus structured case discussion. Lecture covered 30-minute slide presentation on dementia-related training. Structured case discussion for 45 minutes <p>Participants in both groups completed knowledge test pre and post intervention, and at 6 months, as well as an evaluation form. The knowledge test comprised 10 MCQs on diagnosis and 10 MCQs on management of dementia. All participants received printed pocket book of the guidelines. A control group received the printed pocket book of the guidelines only</p>
Perry <i>et al.</i> 2008 ²⁸	<p>GPs referred patients to the study, who were then randomised to control or intervention. A geriatric specialist nurse visited patients at home for assessment using the EASYcare instrument.³² This tool assesses ADL, mood, cognition and has goal-setting elements. This was followed by up to six visits in 3 months for management planning. The nurse, primary care physician and geriatrician met regularly to discuss cases</p>
Callahan <i>et al.</i> 2006 ²⁹	<p>Collaborative care management, by the primary care physician and a geriatric nurse practitioner, for 12 months. All patient contacts were with the nurse. All intervention patients recommended for anticholinesterase inhibitors. Assessments on patient's behaviour and memory were made regularly and management planned accordingly. Primary care physicians were consulted to prescribe medications to help if non-pharmacological interventions had not been successful. Caregiver and patient education given, as well as regular psychological support for both caregiver and patient. Weekly meetings with multidisciplinary teams, who reviewed care and adherence to guidelines. Support given by web-based system, which helped with monitoring and multidisciplinary communication</p>
Vickrey <i>et al.</i> 2006 ²⁵	<p>Twenty-three guideline recommendations identified (by a multidisciplinary group) as care goals. The same group designed an assessment and protocols and organised care co-ordination. Care managers (mainly social workers) were trained and carried out the assessments. Follow-up was arranged, based on need but regular 6-monthly format assessments were carried out. Assessments were made, software assisted in providing a care plan, and recommendations to primary care physician were made. The software also facilitated multidisciplinary communication and referrals to other agencies. Up to five interactive seminars of 90 minutes were offered to primary care physicians, educating on issues such as behaviour changes, determining capacity and depression</p>
Fortinsky <i>et al.</i> 2009 ³⁰	<p>Care consultant initiated monthly contacts with patient and caregiver over 12 months. Educational material for caregivers was given to intervention and control groups, including information about the course of disease, legal/financial issues and community services. The intervention group was able to discuss these with the care consultants. Contacts were used to assess symptoms and concerns and compose action plans for caregivers. The agenda was set by the caregiver. Primary care physicians were faxed care plans with the hope that they would discuss/review with caregiver and patient during consultations</p>
Clark <i>et al.</i> 2004 ³¹	<p>Care consultation offered by Alzheimer's Association specially trained staff. The care consultants conducted structured assessments and developed care strategies using family and community resources. These might include education/training programmes or support groups. Regular follow-ups arranged initially biweekly then monthly or 3-monthly</p>

ACOVE, Assessing Care of Vulnerable Elders; MCQ, multiple choice question.

TABLE 101 A PEDro (Physiotherapy Evidence Database) scale evaluation of studies in the review

Study design	Waldorff <i>et al.</i> 2003 ²²	Controlled before-and-after study	Downs <i>et al.</i> 2006 ²¹	Cluster randomised trial ^a	Rondeau <i>et al.</i> 2008 ²³	Cluster RCT	Chodosh <i>et al.</i> 2006 ²⁴	Cluster RCT	Wenger <i>et al.</i> 2009 ²⁶	Controlled trial	Vollmar <i>et al.</i> 2010 ²⁷	Cluster RCT	Perry <i>et al.</i> 2008 ²⁸	RCT	Callahan <i>et al.</i> 2006 ²⁹	RCT	Vickrey <i>et al.</i> 2006 ²⁵	Cluster RCT	Fortinsky <i>et al.</i> 2009 ³⁰	Cluster RCT	Clarke <i>et al.</i> 2004 ³¹	RCT
Eligibility criteria were specified	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Random allocation to intervention	No	No	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Allocation concealed	No	No	Yes	No	No	Yes	Yes	No	No	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Intervention groups similar at baseline	No ^b	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No ^c	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No ^d	Yes	Yes	Yes
Blinding of all participants	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	No	No	No
Blinding of all therapists	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes
Blinding of all assessors	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	Partial	Yes	No	Yes
Measures of at least one outcome obtained from > 85% of participants	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Intention-to-treat analysis	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	No
Results of between interventions group statistical comparisons are reported for at least one outcome	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Study provides both point measures and measures of variability for at least one key outcome	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Total (max. points = 11)	4	4	6	5	5	8	8	5	5	5	5	5	6	6	9	9	8	8	7	7	8	8

a Unblinded, cluster randomised, before-and-after controlled study.

b Except all from geographically similar areas.

c Groups of patients similar, but there were more single-handed GPs in the 'classical learning' group than the 'blended learning' group, and significance for this difference has not been calculated.

d Groups of patients similar, but some statistically significant differences in caregiver group, for example age and male sex.

Appendix 2 Chapter 1: Advisory and steering group membership

EVIDEM-ED: expert group members

First name	Role
Professor Steve Iliffe	Research team, University College London
Ms Jane Wilcock	Research team, University College London
Ms Priya Jain	Research team, University College London
Dr Geoff Wong	GP with educational role, Queen Mary, University of London, Centre for Health Sciences
Dr Frances Lefford	GP with educational role, University College London
Dr Alex Warner	GP without educational role, University College London
Dr Susham Gupta	Specialist registrar in adult and old age psychiatry, Chelsea and Westminster Hospital
Mr Mark Griffin	Statistician, University College London
Mr Andrew Kingston	Social worker
Mr Horton Kennedy	Carer
Ms Kate Wolfe	Dementia and mental health advocate
Dr Alexandra Davidson	Clinical research associate
Ms Anna Dowrick	Campaigns officer, Alzheimer's Society

EVIDEM-ED: expert panel members

First name	Category
Dr James Hickling	GP, Alzheimer's Society
Dr Peter O'Brien	GP without educational role
Dr Lucy Farley	GP without educational role
Ms Sally Murnaghan	Practice nurse
Ms Clare Morris	Admiral Nurse
Ms Jane Langton	Social worker
Professor John Keady	Educationalist
Mr Peter Ashley	Person with dementia
Mrs Deborah Stone	Carer
Mrs Karen Weech	Carer
Mrs Stephanie Palmer	Carer
Ms Karen Thompson	Carer

Appendix 3 Chapter 1: Diagnostic and management processes identified by the expert team

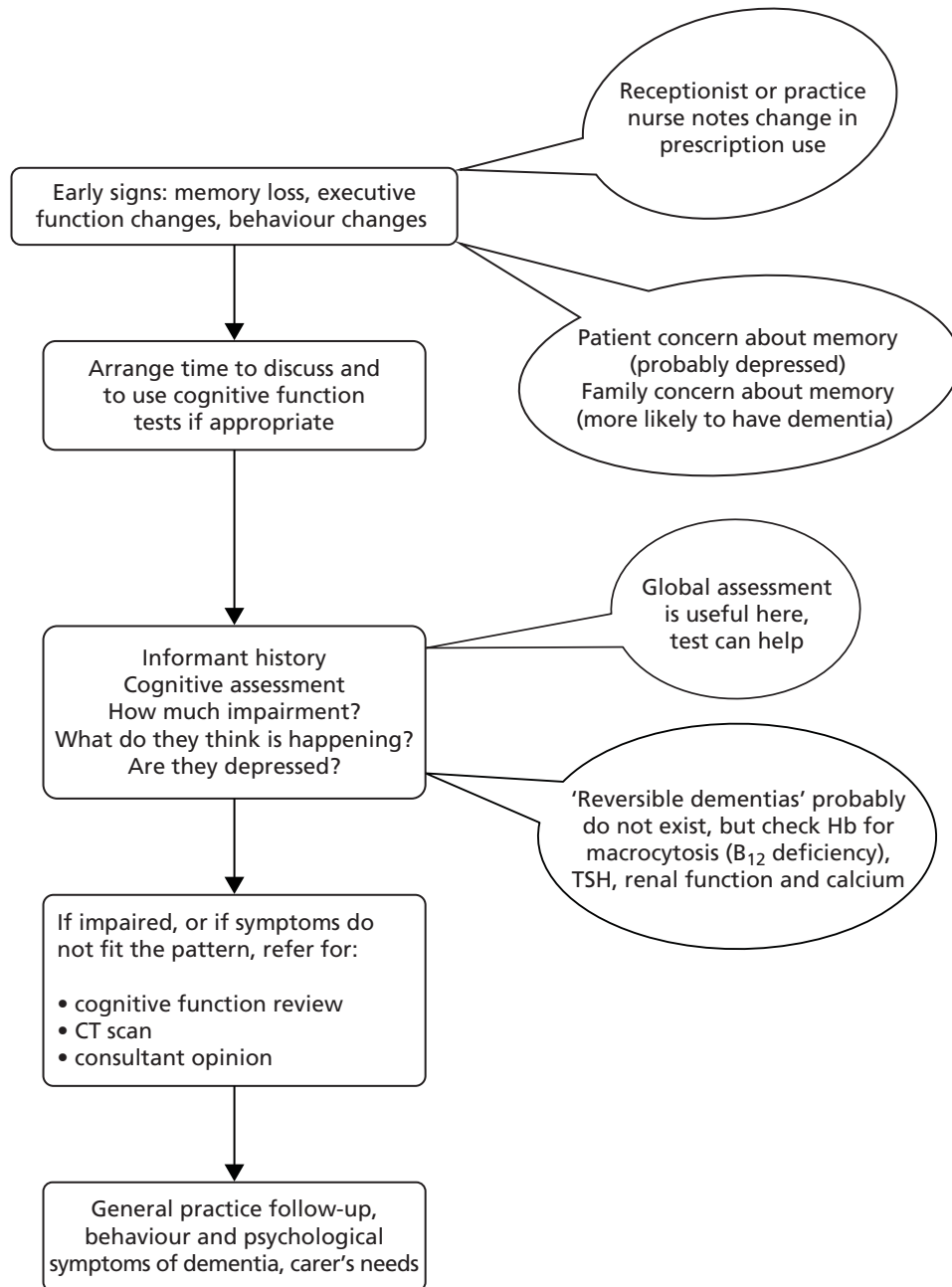


FIGURE 29 Diagnosis of dementia; care pathway for community-dwelling patients. Hb, haemoglobin; TSH, thyroid-stimulating hormone.

Appendix 4 Chapter 1: Changing clinical practice in dementia: elements of a training programme – for primary care team

TABLE 102 Changing clinical practice in dementia: elements of a training programme – for primary care teams

The task	Objectives	How to achieve
Pattern recognition [interpreting the meaning of accumulating symptom(s)]	Growing personal awareness/knowledge of members of the public, as well as professional experience among practitioners	<ul style="list-style-type: none"> Personal experiences offer a lot of lessons; see the other side: professional who is also a carer/relative/friend Producing a video for professionals about the life of people with dementia at home
	Understanding the difficulties of the diagnostic process	<ul style="list-style-type: none"> Recognition of complexity/uncertainty Listening to carers and family members
	A raised profile for dementia in the GP's work environment (increasing 'receptiveness')	<ul style="list-style-type: none"> The professional and organisational culture of the practice is important; create a learning environment Include reminders and templates in electronic medical records Greater understanding of cognitive symptoms and their effects on patient Should be tailored to individual practice team's needs
	Practice team awareness of the issues	<ul style="list-style-type: none"> Partners need to allow and encourage nurses and receptionists to attend training; doctors also need to be prepared to learn from non-medical professionals Non-clinical staff need to be empowered to alert clinicians to changes in individuals' behaviour (e.g. repeated requests for regular medication, repeated defaults from consultations) Involvement of whole team in clinical meetings
	Practice systems for intelligence gathering, collation of information and knowledge of individual's family circumstances and social networks, and responsibility for acting on that gathered knowledge	<ul style="list-style-type: none"> 'Key worker' roles in bigger practices Having 'at risk' registers In smaller practices, all team members meet with the patient and carer at some point of time Named family or carer main contact important, especially for those living alone Establishing relationships with patient's neighbours/milkman, etc.
	Continuity of care for individuals, which deepens knowledge, allows observation over time and permits trust to develop	<ul style="list-style-type: none"> Systems for maintaining continuity of care need to be discussed explicitly, especially in large group practices Needs active management by the practice
Managing expectations of patients and carers by Primary Care Team	<ul style="list-style-type: none"> Promote their role in early diagnosis by explaining their roles in a simple language Promote a message for those attending for a first consultation that they will be taken seriously and their needs listened to 	

continued

TABLE 102 Changing clinical practice in dementia: elements of a training programme – for primary care teams (*continued*)

The task	Objectives	How to achieve
Assessing the degree of impairment	Getting all sides of the story: patient, carer, others (including own team and local social services in case known to them)	<ul style="list-style-type: none"> ● Promote understanding that presenting for this initial consultation may be at the end of a hard road/decision for individuals/families and that ‘we’ are there to promote the interests and care to all parties caught up in this process ● Experience matters here, so exchanging experience may be a mechanism ● If known to allied health professionals, they can provide useful insights ● Role of key worker is important as it may be difficult to collate information from many people ● Visit at home and seeing patients in typical environment with typical others
	Assess the risks and challenges	<ul style="list-style-type: none"> ● Think about the level of concern of patients/carers and others ● What is patient like in out of ‘normal’ environment, for example on holiday, in hospital – provides insight into level of impairment
	Consider other long-term conditions and their relationship to the symptoms of dementia and other functional abilities (hearing or visual impairments, mobility problems)	<ul style="list-style-type: none"> ● Information and explanation crucial but with many people having an information cascade is useful
	Using locally preferred (standardised) assessment tools, knowing their limits	<ul style="list-style-type: none"> ● There is guidance on the usefulness of the different tools (for reference see NICE guidelines³⁶ and Culverwell <i>et al.</i>³²³) ● Agreement between psychiatrists about what they use and then information to GPs
	Using tacit knowledge (instincts, hunches, acquired experience)	<ul style="list-style-type: none"> ● Acknowledge that tacit knowledge is useful
	Self-awareness of changes in thinking abilities (planning, calculating) and recognition of compensatory adaptations by other people (someone else takes over the bill paying)	<ul style="list-style-type: none"> ● Ask about the methods that they are using to cope with their disabilities
Discussing possible diagnoses	Disclosure – who, when and to whom? (This is no different from breaking bad news for any other condition.)	<ul style="list-style-type: none"> ● Attention to context when giving diagnosis – where it should be done, who is present, how will they get home/be spending the rest of the day; involving/initiating support network can greatly help future management <ul style="list-style-type: none"> ○ For example: <ul style="list-style-type: none"> (i) A support package should be given, with names and addresses of the various bodies, etc., who may provide help in any shape or form can be given (ii) A follow-up visit should be arranged with a support nurse in a week or two to enable questions to be asked when patients and their families have had a little time to think things through

TABLE 102 Changing clinical practice in dementia: elements of a training programme – for primary care teams (*continued*)

The task	Objectives	How to achieve
Responding	Negotiate disclosure of the diagnosis with patient/carer	<ul style="list-style-type: none"> Consider patient's confidentiality. Think about when to regard the patient as dependent, as in the case of a dependant child A mechanism for communications between specialists is required to take the responsibility of follow-up after disclosure This could be tied up with end of care and ACP – breaking bad news and discussing options for the future
	Maintain a positive attitude about dementia: 'something can be done' – based on awareness of local resources	<ul style="list-style-type: none"> Wider understanding about differential diagnosis (Alzheimer's disease/vascular dementia/Lewy body dementia, etc.), which means different treatment and management issues Awareness of range of possible interventions than just medical treatment, e.g. training packages for improving communication and use of activities, such as Sonas training Forming closer links between GP surgeries and local dementia specialist support services
	Getting support and involvement of secondary care	<ul style="list-style-type: none"> Specialist services offer assessment and diagnostic services. Having a responsive local specialist service makes a difference to GP behaviour May be useful if special services could provide a summary of how their cognitive symptoms translate into ADL and some strategies of dealing with them Lack of accessibility and approachability of the resources could lead GPs to feel unsupported and frustrated. Training of psychogeriatricians and improved communication could help
	Phase in responses involving resources/ services	<ul style="list-style-type: none"> Professional requires clear understanding of what is available Requires an assessment of that person's needs and those of their family or other supporters
	Locate services and assess if they make a difference	<ul style="list-style-type: none"> Think in terms of advanced support systems, care packages, alarm systems, simple behavioural strategies for carers Map local and national services, including voluntary organisations
	Medication for dementia and 'shared care' systems	<ul style="list-style-type: none"> Take cultural factors of the practice and local specialist services into consideration
	Support for carers (practical, information, psychological support) means understanding how and why family members respond differently to dementia	<ul style="list-style-type: none"> Liaise with local carers' group, for example names and addresses of other patients at a similar stage of the illness made available (if there is consent) for perhaps a 'buddy' system

TABLE 102 Changing clinical practice in dementia: elements of a training programme – for primary care teams (*continued*)

The task	Objectives	How to achieve
		<ul style="list-style-type: none">• Be aware that stigma applies to services as well as dementia itself; this may influence your source of advice• Assess capacity and affect of the MCA/importance of discussing POA early on, while the patient still has capacity• Record patient's views early on in the disease process so that can use this as a guide later

Appendix 5 Chapter 1: General practitioner questionnaire

General practitioner questionnaire

Thank you for agreeing to complete this questionnaire.

Most responses involve you only circling a number, and we have avoided questions which might require you to refer to your records.

We would ask that when the questionnaires are completed that colleagues do not confer, or cross-check textbooks for responses, because it is very important that we get an accurate picture of any change in knowledge as a consequence of the interventions. The responses will not be divulged to anyone.

Please return to your practice manager or a member of the research team

www.EVIDEM.org.uk

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Hosted by Central and North West London NHS Foundation Trust in Collaboration with UCL,
King's College London, St George's University of London, Kingston University London and the
University of Hertfordshire.

Part A: Current practice

Date..... Name.....

(We ask your name so that we can follow-up in twelve months time. You will be given a unique alphanumeric code for the purposes of data entry and your responses will remain confidential).

1. Gender: Male 1 Female 2 Age □□ Year qualified □□□□

2. Are you a: (please circle one)

Principal GP 1 Locum 2 GP Registrar 3

Salaried GP 4 Other (specify) 5

3. Are you: Full time (over 30 hours per week) 1 Part time 2 (state hrs/wk) □□

4. What relevant Postgraduate training have you had? *(Please circle all that apply)*

Elderly medicine 1 Old Age Psychiatry 2 General Psychiatry 3

None of these 4

5. Have you discussed the implications of the National Dementia Strategy (2009) for your patients:

a) In your practice? Yes 1 No 2 Don't know 88

b) In another professional development arena? Yes 1 No 2 Don't know 88

c) With your specialist colleagues? Yes 1 No 2 Don't know 88

6. Have your local specialist services offered you training in dementia diagnosis and management in the last 3 years?

Yes 1 No 2 Don't know 88

7. Could you estimate the number of consultations for any problem that you have in a typical month with **patients** with dementia?

Enter number □□□ Don't know 88

8. In a typical month, how many consultations (incl. Telephone consultations) with carers of people with dementia do you have for any health problem?

Enter number □□□ Don't know 88

9a. How confident are you about reaching a diagnosis of dementia?

Very 1 Somewhat 2 A little 3 Not at all 4

9b. How confident are you about the advice you usually give about managing dementia-related symptoms?

Very 1 Somewhat 2 A little 3 Not at all 4

10. From your experience, please rate the difficulty of these aspects of dementia care, from 1 (not at all difficult) to 6 (extremely difficult) by circling the appropriate number on the scale.

Reaching a probable diagnosis yourself	1	2	3	4	5	6	88
Discussing the probable diagnosis with the patient	1	2	3	4	5	6	88
Discussing the probable diagnosis with the family	1	2	3	4	5	6	88
Responding to behaviour or psychological symptoms	1	2	3	4	5	6	88
Responding to co-existing behaviour problems	1	2	3	4	5	6	88
Responding to any psychiatric symptoms	1	2	3	4	5	6	88
Getting information about support services for people with dementia	1	2	3	4	5	6	88
Getting information about support services for carers	1	2	3	4	5	6	88
Co-ordinating support services for people with dementia	1	2	3	4	5	6	88
Co-ordinating support services for carers	1	2	3	4	5	6	88
Getting specialist advice by telephone	1	2	3	4	5	6	88
Getting information about anti-dementia medication	1	2	3	4	5	6	88

11. How do you rate the following in regard to dementia care in your area?

	Available and satisfactory	Available but not satisfactory	Needed, but not available	Not needed	Can't say
Information about what old age psychiatry services offer	1	2	3	4	99
Protocol for assessment and investigation of a patient with possible dementia	1	2	3	4	99
Brief screening instrument for early identification	1	2	3	4	99
Nurse with mental health training working in association with the practice	1	2	3	4	99
Shared care protocol for cholinesterase inhibitors	1	2	3	4	99
Information about benefits (attendance allowance, council tax, etc.	1	2	3	4	99

12. Please indicate on the scale below your responses to the following statements regarding dementia in primary care

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Can't Say
Providing a patient with a diagnosis is usually more helpful than harmful	1	2	3	4	5	99
Managing dementia is more often frustrating than rewarding	1	2	3	4	5	99
Much can be done to improve the quality of life for people with dementia	1	2	3	4	5	99
Dementia is best diagnosed by specialist services rather than by the primary care team	1	2	3	4	5	99
It's better to talk in euphemistic terms when discussing the condition with someone with dementia	1	2	3	4	5	99
Families would rather be told about their relative's dementia as early as possible	1	2	3	4	5	99
The primary care team has a very limited role to play in the ongoing care of people with dementia	1	2	3	4	5	99
Much can be done to improve the quality of life of carers of people with dementia	1	2	3	4	5	99
Patients with dementia can be a drain on resources with little positive outcome	1	2	3	4	5	99
There is little point in referring families to services as they don't want to use them	1	2	3	4	5	99

13. Have you discussed the implications of the Mental Capacity Act 2005 for your patients with dementia:

a) In your practice?	Yes	1	No	2	Not relevant	77
b) In your professional development?	Yes	1	No	2	Not relevant	77
c) With your specialist colleagues?	Yes	1	No	2	Not relevant	77

14. Which of the following **prevent you from doing as much as you would like** for people with dementia and their carers?

	YES PREVENTS	NO DOES NOT	DON'T KNOW
Too busy: not enough time during consultations	1	2	88
Unfamiliar with advances in the management of dementia-related symptoms	1	2	88
Unfamiliar with available services to help keep patients at home	1	2	88
Unsure how to refer patients to available services to help keep them at home	1	2	88
Lack of team staff in the practice	1	2	88
Lack of funding within the practice	1	2	88
Lack of Social Service support available to the practice	1	2	88
Other (Please specify).....			3

15. How would you rate your own current knowledge, on a scale of **1–10**, about diagnosis and care of people with dementia and their families? (1 = insufficient, 10 = up to date in all aspects).



Part B. Pre-training knowledge quiz

Please answer the following questions from your current knowledge without consulting colleagues or reference materials. Indicate your answer to each question by circling only one of the responses.

1. A GP with a list of 1,500 – 2,000 patients can expect to have the following number of people with dementia on their list:

A. 1-6	1
B. 7-11	2
C. 12-20	3
D. 21 or more	4
E. I don't know	5

2. By 2021, the prevalence of dementia in the general population in the UK is expected to:

A. Decrease slightly	1
B. Remain approximately the same	2
C. Increase slightly	3
D. Nearly double	4
E. I don't know	5

3. One of the risk factors for the development of Alzheimer's disease is:

A. Atherosclerosis	1
B. Age	2
C. Nutritional deficiencies	3
D. Exposure to aluminium	4
E. I don't know	5

4. All of the following are potentially treatable aetiologies of dementia except:

A. Hypothyroidism	1
B. Normal pressure hydrocephalus	2
C. Creutzfeldt-Jacob disease	3
D. Vitamin B12 deficiency	4
E. I don't know	5

5. A patient suspected of having dementia should be evaluated as soon as possible as:
- | | |
|---|---|
| A. Prompt treatment of dementia prevents worsening of symptoms in the majority of cases | 1 |
| B. Prompt treatment of dementia may reverse symptoms | 2 |
| C. It is important to rule out and treat reversible disorders | 3 |
| D. It is best to engage social services early in the course of the disease | 4 |
| E. I don't know | 5 |
6. Which one of the following procedures is required to definitely confirm that symptoms are due to dementia?
- | | |
|------------------------------|---|
| A. Cognitive test score | 1 |
| B. Post mortem | 2 |
| C. CAT scan of the brain | 3 |
| D. Blood test for biomarkers | 4 |
| E. I don't know | 5 |
7. Which of the following is not a necessary part of the initial evaluation of someone with possible dementia?
- | | |
|--------------------------------|---|
| A. Thyroid function test | 1 |
| B. Serum electrolytes | 2 |
| C. Vitamin B and folate levels | 3 |
| D. Protein electrophoresis | 4 |
| E. I don't know | 5 |
8. Which of the following sometimes resembles dementia?
- | | |
|----------------------------|---|
| A. Depression | 1 |
| B. Acute confusional state | 2 |
| C. Stroke | 3 |
| D. All of the above | 4 |
| E. I don't know | 5 |
9. When a patient develops a sudden onset of confusion, disorientation, and inability to sustain attention, this presentation is most consistent with the diagnosis of:
- | | |
|----------------------------|---|
| A. Alzheimer's disease | 1 |
| B. Acute confusional state | 2 |
| C. Major depression | 3 |
| D. Vascular dementia | 4 |
| E. I don't know | 5 |

10. Which of the following is nearly always present in dementia?

- | | |
|--------------------------------------|---|
| A. Loss of memory | 1 |
| B. Loss of memory and incontinence | 2 |
| C. Loss of memory and hallucinations | 3 |
| D. None of the above | 4 |
| E. I don't know | 5 |

11. Which of the following clinical findings best differentiates vascular dementia from Alzheimer's?

- | | |
|--|---|
| A. Word finding problems | 1 |
| B. Short term (2 minute span) visual memory loss | 2 |
| C. Stepwise disease course | 3 |
| D. Presence of depression | 4 |
| E. I don't know | 5 |

12. The effect of cholinesterase inhibitors is to:

- | | |
|--|---|
| A. Temporarily halt the disease in all cases | 1 |
| B. Temporarily halt the disease in some cases | 2 |
| C. Temporarily halt the disease in some cases but often causing liver damage | 3 |
| D. Permanently halt the disease in some cases | 4 |
| E. I don't know | 5 |

13. Which statement is true concerning the treatment of people with dementia who are depressed?

- | | |
|--|---|
| A. It is usually useless to treat them for depression because feelings of sadness and inadequacy are part of the disease | 1 |
| B. Treatments may be effective in alleviating depressive symptoms | 2 |
| C. Anti-depressant medication should not be prescribed | 3 |
| D. Anti-depressant medication may alleviate symptoms of depression and also prevent further intellectual decline | 4 |
| E. I don't know | 5 |

14. The NICE/SCIE guidelines on dementia (2006) recommend:
- | | |
|--|---|
| A. CT scanning for all patients with suspected dementia | 1 |
| B. Treatment of patients with Alzheimer's disease whilst their MMSE score is between 10 and 20 | 2 |
| C. Treatment of patients with Alzheimer's disease who have significant impairment | 3 |
| D. All of the above | 4 |
| E. I don't know | 5 |
-

Thank you for completing this questionnaire

Appendix 6 Chapter 1: Carer semi-structured interview schedule

EVIDEM-ED: carer schedule

Acknowledgements

Question 10 (Dementia Quiz) includes items from CSRD Nursing Home study (Buckwalter)³²⁴ (items 1, 3, 5, 10, 16, 17, 18, 19); Cutler 1987 (items 6, 7, 8);³²⁵ Gilleard and Groom 1984 (item 12);³²⁶ other quiz items formulated by Steve Turner and Michelle Bryans (items 2, 4, 9, 13, 14, 15, 20) and Steve Turner and Ailsa Cook (item 11).

Questions 18, 28–32, 34–36, 66 and 67 adapted with permission from The General Practice Assessment Survey (GPAS).³²⁷ GPAS is copyright of Safran/The Health Institute and National Primary Care Research and Development Centre.

Questions 21 and 22 from Sloper and Turner 1991.³²⁸

Questions 59–61 adapted from Bowman *et al.* 1994.³²⁹

Question 63 (Carer Stress Measure) Zarit *et al.* 1997.³³⁰

Interview information

Carer study number ED_RT□□_C□□□

General practice ref number ED_RT□□_T□

Interviewer (tick) I T-B PJ JW TG Other

Interview date □□ □□ □□□□

Interview time **1** Baseline **2** Follow-up

Location of interview with carer

1 Patient's home **2** Carer's home **3** GP surgery**4** Hospital **5** Residential home **6** Nursing home**7** Day centre **8** Carer's workplace**9** Other.....**10** Patient and Carer's home

Interview start time □□□□

Interview end time □□□□

Introduction

Thank you for seeing me today.

Points to cover with carer pre interview:

- 1. I'll just go over what the study is about again. We plan to talk to families who are registered with twenty GP practices in the area, all with a relative with memory problems (or who have been diagnosed with dementia). This involves asking about the time you first became concerned something was wrong with your relative, about when and how the diagnosis was made, and what's happened since.**
- 2. A lot of the questions are about any contact you have had with your GP practice.....We ask these questions because we are working with some of practices to try and improve their service to people with these problems. Then we plan to talk to the families again to see if they have noticed any difference.**
- 3. As we said in the letter.....**

Your involvement is VOLUNTARY

Information is kept confidential, and nothing will be passed on to the practice. So no one at the practice will know what you have said and there will be no detrimental effect on the care you or your relative gets from the doctor.

Please say if I ask a question you don't understand or feel unhappy about: I'll try to explain why we are asking it, but we can always skip a question if you are still not happy with it.

Please let me know if you would like to take a break or continue the interview at another time.

- 4. Any questions or things not understood? Yes No Can we start?**

I'd like to start by asking you some background questions about you and your family. This will help us understand the differences between people in the study.

- 1a). Could you tell me how you are related to (name)?**

Carer is :	Wife	1	Son	5
	Husband	2	Other relative	6
	Daughter	3	Other (specify))	7
	Daughter-in-law	4		

b). Record carer gender Male 1 Female 2

c). Record patient gender Male 1 Female 2

2 a). Could you tell me whether you are:

Married/Co-habiting	1	Divorced	4
Single	2	Separated	5
Widowed	3		

b). Is your (relative):

Widowed	1	Divorced	4
Married/Co-habiting	2	Separated	5
Single	3		

3 a). Do you have any children under 18 living at home? RECORD NUMBER

b). Are you responsible for looking after anyone else other than (your relative)(and your children)?

Yes (details) 1 No 2 NA 99

4. Are you:

Working full time (30hrs/wk or more)	1	Family commitments/homemaker	5
Part time (29 hrs/wk or less)	2	Retired (when))	6
Unemployed	3	Studying/training	7
Unable to work for health reasons	4	Other (specify)	8

5 a). Could you tell me your date of birth?

b). How old were you when you finished education?

c). Did you do any further studies after you left school?

d).How old was your relative when they finished school? DK 88

IF NO: GO TO Q9

b). **IF YES:** Who?

NA 99....

c). After you, who helps the most?

 NA 99...

These next questions are about how it first became noticed (your relative) might be having problems with their memory or getting confused:

9 a). First, can I just check, has (your relative) been with the same doctors' practice since the time these problems were first noticed? **Yes 1 No 2 DK 88**

b). And with same GP?

Yes, same GP throughout	1	Same practice, any GP	2
Same practice, changed GP	3	No, changed practice	4
Can't remember	77	Don't know	88

IF CHANGED:

c). Why did (your relative) change GP/Practice?

When moved address	1
Other	2
Can't remember	77
DK	88
NA	99

d). When did (your relative) change practice?

Before diagnosis of d. made	1
After diagnosis made	2
Other	3
Can't remember	77
DK	88
NA	99

IF CHANGED PRACTICE AFTER DIAGNOSIS- GO TO Q23

10 a). Can you tell me how long ago it was first noticed that something was wrong?

□□□mths ago	Can't remember	77	DK	88
-------------	-----------------------	-----------	-----------	-----------

b). Who noticed it?

Main Carer	1	GP	4
Other Relative	2	Nurse	5
Friend/Neighbour	3	Social Services	6
Other (who)	7		

c). What was it that was noticed?

.....

.....

d). What did you think was causing it?

Dementia	1	Age	2		
Other	3 GO TO (e)	Can't remember	77	Don't know	88

IF OTHER:

e). (Detail)

..... **NA 99**

11 a). Was anyone at the practice contacted about it when you first noticed it?

Yes	1	No	2	IF NO: GO to 11(f)
Can't Remember	77	DK	88	

IF YES:

b). Who contacted them?

Interviewee	1	Social Services	5
Other Relative	2	Other (who)	6
Friend	3	Can't remember	77
Neighbour	4	DK	88
NA	99		

c). Who was contacted?

GP	1	Practice nurse	2
Other.....	3	Other nurse	4

Can't Remember 77 DK 88
 NA 99

d). What did she say?

Can't remember 77 DK 88 NA 99

e). What did she do?

Can't remember 77 DK 88 NA 99

IF NO:

f). How long was it after you noticed something was wrong before someone talked to the GP about it?
mths later Can't remember 77 DK 88 NA 99

g). Who contacted the GP at this time?

Interviewee	1	Social Services	5
Other Relative	2	Other (who).....	6
Friend	3	Can't remember	77
Neighbour	4	DK	88
NA	99		

h). What did she say?

Can't remember 77 DK 88 NA 99

i). What did she do?

Can't remember 77 DK 88 NA 99

12 a). What did you think of the way the GP responded to the concern about (your relative)? (CARD A)

Very poor 1 Poor 2 Fair 3

Good	4	Very good	5	Excellent	6
Can't say	77	NA	99		

b). Why do you say that?

.....

.....

c). What did you think of the way the practice team as a whole responded? (CARD A)

Very poor	1	Poor	2	Fair	3
Good	4	Very good	5	Excellent	6
Can't say	77	NA	99		

d). Why do you say that?

.....

.....

.....

13 a). How long was it after it was noticed something was wrong before Social Services /The Council were contacted?

mths later

Straight away	1	Already in contact	2	Not contacted	3
Can't remember	77	DK	88		

IF NOT CONTACTED: GO TO Q14

IF CONTACTED:

b). Did anyone contact them for you?

Yes	1	No	2	Can't remember	77	DK	88	NA	99
------------	----------	-----------	----------	-----------------------	-----------	-----------	-----------	-----------	-----------

IF NO: GO TO 13d

IF YES:

c). Who contacted Social Services?

GP	1	Practice nurse	2	Other nurse	3
-----------	----------	-----------------------	----------	--------------------	----------

other(who) 4 Can't remember 77 DK 88
 NA 99

d). What did Social Services say when they were contacted about your relative?

.....
 NA 99

e). What did they do?

.....
 NA 99

f). What did you think of Social Services' response? (CARD A)

Very poor	1	Poor	2	Fair	3
Good	4	Very good	5	Excellent	6
Can't say	77	NA	99		

g). Why do you say that?

.....
 NA 99

These next questions are about what was done to establish what was wrong:

14 a). What was done by the GP to establish what was wrong?

GP did something	1	GP did something- DK what	2
GP did nothing	3	DK if GP did anything	88

CODE BELOW

b). Did anyone else do anything to establish what was wrong?

Yes 1 **No** 2 **Can't remember** 77 **DK** 88 **NA** 99

IF YES, 1:

CODE BELOW (PROMPT)

	Done By GP	Done by other (who)	Done but DK by who	Not done	Can't remember
Took a blood sample	1	2	3	77	88
Took a urine sample	1	2	3	77	88
Took blood pressure	1	2	3	77	88
Did a physical examination	1	2	3	77	88
Arranged a brain scan	1	2	3	77	88
Tested your relative's memory	1	2	3	77	88
Prescribed medicine for depression	1	2	3	77	88
Referred to a specialist/hospital/unit	1	2	3	77	88
Told you about help and support organisations, i.e. the Alzheimer's Society?	1	2	3	77	88
Other	1	2	3	77	88

15 a). All in all, how would you rate the way the problem was investigated? (CARD A)

Very poor 1 **Poor** 2 **Fair** 3
Good 4 **Very good** 5 **Excellent** 6
Can't say 77 **NA** 99

b). Why do you say that?

.....
 NA 99

Now I'd like to ask about how you were told what the problem was:

16 a). Can you remember who first gave you a diagnosis for your relative's problem?

GP	1	GO TO (c)
Other prof (title)	2	GO TO (d)
Not given by anyone	3	GO TO (b)
Other (.....)	4	
Can't remember	77	
DK	88	

IF 3 (Not given): CHECK

b). So how did you find out what the problem was?

.....

IF CLEAR NO DISCLOSURE OCCURRED, SKIP TO Q18

IF GP:

c). Which GP was that? **NA 99**

d). How long ago was that? mths **Can't remember 77** **NA 99**

e). What was the diagnosis you were given? (What did you find out the diagnosis to be?)

AD	1	Senile dementia	3	Mixed type	5	DK	88
Vascular	2	Dementia	4	Other	6	NA	99

f). Apart from the diagnosis, were you told (did you find out) anything else at that time?

PROMPT

	Yes	No	Can't rem.	DK	NA
Course, prognosis	1	2	77	88	99
Tranqu/sedative medication	1	2	77	88	99
Available services	1	2	77	88	99
Prim care team support	1	2	77	88	99
Anti-dem medication	1	2	77	88	99
Carer support	1	2	77	88	99
Cause	1	2	77	88	99
Other	1	2	77	88	99
Other	1	2	77	88	99

17 a). All in all, how would you rate the way you were told (found out about) the diagnosis? (CARD

A)

Very poor	1	Poor	2	Fair	3
Good	4	Very good	5	Excellent	6
Can't say	77	NA	99		

b). Why do you say that?

.....

 NA 99

IF NO DISCLOSURE OCCURRED, SKIP TO Q18

The next questions are about how things are now. The first ones are about your relative's usual doctor. If you don't feel she has a usual doctor just think about the doctor in the practice who you feel knows your relative best. IF NONE OF THE DOCTORS KNOWS BEST ASK ABOUT THE DOCTORS AT THE PRACTICE IN GENERAL.

18 a). In the last 12 months, how many different doctors from the practice has she seen?

DK 88

b). IF DOESN'T SEE OWN OR SAME GP CONSISTENTLY: Can you tell me why not?

.....
NA 99

c). Are you with the same practice yourself? **Yes 1 No 2**

19. In the **past 12 months**, how many times have you seen a doctor from the practice about your relative?

times Don't know 88

20. In the **past 12 months**, has your relative seen a doctor from the practice on her own?

Yes 1 No 2 Don't know 88

IF YES:

b). How many times? **times Don't know 88 NA 99**

21. Overall, how satisfied are you with the? (CARD D)

	Very Satisfied	Satisfied	Dissatisfied	Very Dissatisfied	No Contact	Can't Say	DK
a). Doctor's care for your relative?	1	2	3	4	5	77	88
b). Help the Doctor gives you to care for your relative?	1	2	3	4	5	77	88

22.	Def.	Prob.	Prob.	Def.	Not	DK
	not	not	yes	yes	Sure	
Would you recommend your relative's usual doctor to someone else looking after someone with dementia? (CARD F)	1	2	3	4	5	88

I'd like to ask now about the practice as a whole – nurses, receptionists and so on who work with the GPs.

23 a). Can I just check: have you talked to any of these people at your relative's practice about her care?

FOR EACH SEEN:

b). How helpful did you find the? (Card E)

	Seen	Not seen	Very Helpful	Quite helpful	Neither helpful	Notvery helpful	Notatall	Madethings worse	Does not apply
Practice nurse	1	2	1	2	3	4	5	6	99
Practice manager	1	2	1	2	3	4	5	6	99
Community nurse	1	2	1	2	3	4	5	6	99
Health Visitor	1	2	1	2	3	4	5	6	99
CPN	1	2	1	2	3	4	5	6	99
Nurse (unspecific)	1	2	1	2	3	4	5	6	99
Receptionist	1	2	1	2	3	4	5	6	99
Other.....	1	2	1	2	3	4	5	6	99

24. Would you recommend your relative's practice as a whole to someone else looking after a person with dementia? (CARD F)

1	2	3	4	5	88
Definitely	Probably	Probably	Definitely	Not	DK
Not	Not	Yes	Yes	Sure	

These next questions are about what your relative can and can't do for herself, and whether they get or want extra help, advice or information. The help might be from your GP or someone else at the practice, from social services, from a voluntary agency or just someone that you know. For each sort,

I'd like you to tell me how helpful it's been for you, using this scale, with 1 for very helpful to 6 for makes things worse. (CARD E)

25 a). First, is she able to manage her own personal care by herself – washing and dressing?

1	2	88	
Yes	No	DK	IF YES: GO TO Q26

IF NO:

b). Does she get any help with that?

1	2	88	99	
Yes	No	DK	NA	IF NO: GO TO

Q25f

IF YES AT (b):

c). Who from? (identify prof if possible)

..... NA 99

IF NOT FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)

Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e). Do you feel this is enough help?	1	2	88	99
	Yes	No	DK	NA

IF NO AT (b):

f). Do you feel she needs help with that?	1	2	88	99
	Yes	No	DK	NA

26 a). Is she able to manage her medication by herself ?

1	2	88	
Yes	No	DK	IF YES: GO TO Q27

IF NO:

b). Does she get any help with that?

1	2	88	99
----------	----------	-----------	-----------

Yes No DK NA IF NO: GO TO
Q26f

IF YES AT (b):

c). Who from? (identify prof if possible)

..... NA 99

IF NOT FAMILY MEMBERS (CARD E)

d). How helpful would you say that was?

Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e). Do you feel this is enough help?	1	2	88	99
	Yes	No	DK	NA

IF NO AT (b):

f). Do you feel she needs help with that ?	1	2	88	99
	Yes	No	DK	NA

27 a). Is she able to prepare her food by herself?

1	2	88	
Yes	No	DK	IF YES: GO TO Q28

IF NO:

b). Does she get any help with that?

1	2	88	99	
Yes	No	DK	NA	IF NO: GO TO

Q27f

IF YES AT (b):

c). Who from? (identify prof if possible)

..... NA 99

IF NOT FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)

Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e). Do you feel this is enough help?	1	2	88	99
	Yes	No	DK	NA

IF NO AT (b):

f). Do you feel she needs help with that?	1	2	88	99
	Yes	No	DK	NA

28 a). Is she able to get around the house safely by herself?

1	2	88	
Yes	No	DK	IF YES: GO TO Q29

IF NO:

b). Does she get any help with that?

1	2	88	99	
Yes	No	DK	NA	IF NO: GO TO

Q28f

IF YES AT (b):

c). Who from? (identify prof if possible)

.....NA 99

IF NOT FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)

Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e.) Do you feel this is enough help?	1	2	88	99
	Yes	No	DK	NA

IF NO AT (b):

f). Do you feel she needs help with that?	1	2	88	99
	Yes	No	DK	NA

29 a). Is she able to go to the toilet by herself? (ie. stay continent) (toileting problems) (any accidents?)

1	2	88	
Yes	No	DK	IF YES: GO TO Q30

IF NO:

b). Does she get any help with that?

1	2	88	99	
Yes	No	DK	NA	IF NO: GO TO

Q29f

IF YES AT (b):

c). Who from? (identify prof if possible)

..... NA 99

IF NOT FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)

Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e). Do you feel this is enough help?	1	2	88	99
	Yes	No	DK	NA

IF NO AT (b):

1	2	88	
Yes	No	DK	IF YES: GO TO Q32

IF NO:

b). Does she get any help with that?

1	2	88	99	
Yes	No	DK	NA	IF NO: GO

TO Q31f

IF YES AT (b):

c). Who from? (identify prof if possible)

..... NA 99

IF NOT FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)

Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e). Do you feel this is enough help?	1	2	88	99
	Yes	No	DK	NA

IF NO AT (b):

f). Do you feel she needs help with that?	1	2	88	99
	Yes	No	DK	NA

32 a). Is she able to do the housework?

1	2	88	
Yes	No	DK	IF YES: GO TO Q33

IF NO:

b). Does she get any help with that?

1	2	88	99
----------	----------	-----------	-----------

Yes **No** **DK** **NA** IF NO: GO
 TO Q32f

IF YES AT (b):

c). Who from? (identify prof if possible)

..... NA 99

IF NOT FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)

Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e). Do you feel this is enough help?	1	2	88	99
	Yes	No	DK	NA

IF NO AT (b):

f). Do you feel she needs help with that?	1	2	88	99
	Yes	No	DK	NA

33. Is she able to manage her money and bills?

1	2	88	
Yes	No	DK	IF YES: GO TO Q34

IF NO:

b). Does she get any help with that?

1	2	88	99	
Yes	No	DK	NA	IF NO: GO

TO Q33f

IF YES AT (b):

c). Who from? (identify prof if possible)

..... NA 99

IF NOT FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)

Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e). Do you feel this is enough help?	1	2	88	99
	Yes	No	DK	NA

IF NO AT (b):

f). Do you feel she needs help with that?	1	2	88	99
	Yes	No	DK	NA

34 a). Does she ever become aggressive verbally? (eg. threatening to harm you, swearing)

1	2	88	
Yes	No	DK	IF NO: GO TO Q35

IF YES:

b). Do you get any advice on how to manage that?

1	2	88	99	
Yes	No	DK	NA	IF NO: GO

TO Q34f

IF YES AT (b):

c). Who from? (identify prof if possible)

..... NA 99

IF NOT FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)

Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e). Do you feel that you get enough advice?	.1	2	88	99
	Yes	No	DK	NA

IF NO AT (b):

6	Support group	1	2	
7	Residential/nursing home respite care	1	2	
8	Sitting service	1	2	Hrs/week <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> NA 99
9	Meals on Wheels	1	2	Hrs/week <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> NA 99
10	Home care	1	2	Hrs/week <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> NA 99
11	Day Care	1	2	Hrs/week <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> NA 99
12	Lunch club	1	2	Hrs/week <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> NA 99
13	Privately funded carer	1	2	Hrs/week <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> NA 99

37. Is there anyone else who helps your relative that I haven't already mentioned?

1 2 88
YES **NO** **DK** IF NO: GO TO Q38

IF YES:

Who?

.....
NA 99

Now I'd like to ask about different issues or questions that might have come up in relation to your relative's care. Can you tell me for each one if its something that's come up for you – by that I mean you might have worried about it or got advice or help about it from someone.

38 a). Have you had any advice about what to tell your relative (about their diagnosis)?

1 2 88
Yes **No** **DK** IF NO: GO TO Q38f

IF YES:

b). Who from? (identify prof if possible)

..... NA 99

c). What advice?

..... NA 99

IF NOT FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)

Very	Quite	Neither	Not very	Not at all	Makes things	NA
helpful	helpful	helpful	helpful	helpful	worse	

1	2	3	4	5	6	99
e). Do you feel that you got enough advice?						
			1	2	88	99
			Yes	No	DK	NA
IF NO AT (a):						
f). Do you feel you needed advice about that?						
			1	2	88	99
			Yes	No	DK	NA

39 a). Have you had any advice about how to keep your relative as independent as possible?

	1	2	88	
	Yes	No	DK	IF NO: GO TO Q39f

IF YES:

b). Who from? (identify prof if possible)

NA 99

c). What advice?

..... **NA 99**

IF NOT FROM FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)						
Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e). Do you feel that you got enough advice?						
			1	2	88	99
			Yes	No	DK	NA

IF NO AT (a):

f). Do you feel you needed advice about that?						
			1	2	88	99
			Yes	No	DK	NA

40 a). Have you had any advice about equipment and adaptations for the home?

	1	2	88	
	Yes	No	DK	IF NO: GO TO Q40f

IF YES:

b). Who from? (identify prof if possible)

..... NA 99

c). What advice?

..... NA 99

IF NOT FROM FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)

Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e). Do you feel that you got enough advice?	1	2	88	99
	Yes	No	DK	NA

IF NO AT (a):

f). Do you feel you needed advice about that?	1	2	88	99
	Yes	No	DK	NA

41 a). Have you had any advice about your relative driving?

1	2	88	99
Yes	No	DK	NA

IF NO: GO

TO Q41f

IF YES:

b). Who from? (identify prof if possible)

..... NA 99

c). What advice?

..... NA 99

IF NOT FROM FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)

Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e). Do you feel that you got enough advice?	1	2	88	99
---	----------	----------	-----------	-----------

	Yes	No	DK	NA
IF NO AT (a):				
f). Do you feel you needed advice about that?	1	2	88	99
	Yes	No	DK	NA

42 a). Have you had any advice about pensions and 'social security benefits' and grants?

1	2	88	
Yes	No	DK	IF NO: GO TO Q42f

IF YES:

b). Who from? (identify prof if possible)
NA 99

c). What advice?
 **NA 99**

IF NOT FROM FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)						
Very	Quite	Neither	Not very	Not at all	Makes things	NA
helpful	helpful	helpful	helpful	helpful	worse	
1	2	3	4	5	6	99

e). Do you feel that you got enough advice?	1	2	88	99
	Yes	No	DK	NA

IF NO AT (a):

f). Do you feel you needed advice about that?	1	2	88	99
	Yes	No	DK	NA

43 a). Have you had any advice about costs of services?

1	2	88	
Yes	No	DK	IF NO: GO TO Q43f

IF YES:

b). Who from? (identify prof if possible)
NA 99

c). What advice?
 **NA 99**

IF NOT FROM FAMILY MEMBERS:

d. How helpful would you say that was?	(CARD E)					
Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e. Do you feel that you got enough advice?	1	2	88	99
	Yes	No	DK	NA

IF NO AT (a):

f. Do you feel you needed advice about that?	1	2	88	99
	Yes	No	DK	NA

44 a). Have you had any advice about legal aspects like Enduring Power of Attorney (prompt regarding making decisions about future care and wishes and note specifics)?

1	2	88	
Yes	No	DK	IF NO: GO TO Q44f

IF YES:

b. Who from? (identify prof if possible)
NA 99

c. What advice?
 **NA 99**

IF NOT FROM FAMILY MEMBERS

d. How helpful would you say that was?	(CARD E)					
Very helpful	Quite helpful	Neither helpful	Not very helpful	Not at all helpful	Makes things worse	NA
1	2	3	4	5	6	99

e. Do you feel that you got enough advice?	1	2	88	99
	Yes	No	DK	NA

IF NO AT (a):

f. Do you feel you needed advice about that?	1	2	88	99
	Yes	No	DK	NA

45 a). Have you had any advice about day care?

1	2	88	
Yes	No	DK	IF NO: GO TO Q45f

IF YES:

b). Who from? (identify prof if possible)

NA 99

c). What advice?

NA 99

IF NOT FROM FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)

Very	Quite	Neither	Not very	Not at all	Makes things	NA
helpful	helpful	helpful	helpful	helpful	worse	
1	2	3	4	5	6	99

e). Do you feel that you got enough advice?	1	2	88	99
	Yes	No	DK	NA

IF NO AT (a):

f). Do you feel you needed advice about that?	1	2	88	99
	Yes	No	DK	NA

46 a). Have you had any advice about how to get a break?

1	2	88	
Yes	No	DK	IF NO: GO TO Q46f

IF YES

b). Who from? (identify prof if possible)

NA 99

c). What advice?

NA 99

IF NOT FROM FAMILY MEMBERS:

d). How helpful would you say that was? (CARD E)

Very	Quite	Neither	Not very	Not at all	Makes things	NA
helpful	helpful	helpful	helpful	helpful	worse	

a). What do you feel your relative needs to give her the best possible life in, say, 12 months time?

.....
.....
.....
.....

b). And what about for yourself: what do you think would help you over the next 12 months ?

.....
.....
.....
.....

56. What advice would you give to someone else who has started caring for their relative?

.....
.....
.....
.....
.....

I've finished, thank you very much for all your help. I would like to come back in a year's time and talk to you again, to see how things have changed. Do you think that would be OK? I'll contact you again nearer the time. (Check morale)

Again, thank you very much for your help.

Interview end time □□□

Appendix 7 *Chapter 1: Medical records data extraction tool – baseline (time 1)*

EVIDEM: ED**Patient****ID:** _____

Based on the NICE & SCIE Audit criteria November 2006 and the Audit support 2009 to accompany NICE clinical guideline 42

Patient ID: (<i>study code- see list</i>)	Date of data extraction:	Date of randomisation (control=TL)/end of training (intervention=TE) (<i>see list</i>):	Data extracted by:
Practice ID: (<i>study code- see list</i>)	Patient: Time 1 (anything before randomization/end of training) 1 Time 2 (anything 12 months after randomization/ end of training) 2		Data coded by: PJ 1 I T-B 2 JW 3 _____ 4

1) Gender: M 1 F 2		3) Marital Status: Married/Co-habiting 1 Single 2 Widowed 3 Divorced 4 Separated 5 D/K 88		4) Ethnicity: D/K 88		5) Patient location at Time 1 Community 1 Care home 2	
2) DOB:		6) Date registered with current practice: D/K 88		7) Changed practice last 40 months or since original diagnosis if longer Y 1 N 2 D/K 88			
8) Carer details recorded: Yes 1 No 2 D/K 88 N/A 99		9) Gender of carer: M 1 F		10) Relationship of person with dementia with carer: D/K 88 N/A 99			
11) Date of Index: (Any dementia related symptom reported by patient/carer/relative and there is evidence of a dementia related response by GP e.g. doing bloods, memory tests etc.)		12a) No. of consultations recorded (6 months pre Index → 2 years post Index) D/K 88 N/A 99		12b) Time span covered 30 monthsmonths D/K 88 N/A 99			
D/K 88 N/A 99							

<p>13) Symptoms recorded at Index:</p> <p>Memory loss 1 Forgetfulness 2 Behavioural Changes 3 Disorientation 4 Confusion 5 Functional abilities & complex tasks 6 Personality change 7</p> <p>Decline in test scores 8 Speech problems 9 Morale, mood, depression 10 Carer's report, concern 11 Cognitive decline, deterioration 12 Global deterioration 13</p> <p>Wandering 14 Change in self-care 15 Toileting problems 16 17</p> <p>..... 18 19 D/K 88 N/A 99</p>		
<p>14) Date of Diagnosis: (When diagnosis appears in the GP records e.g. from secondary care.)</p> <p>D/K 88 N/A 99</p>	<p>15) Months INDEX TO DIAGNOSIS</p> <p>D/K 88 N/A 99</p>	<p>16) Diagnosis made by:</p> <p>Primary care 1 Secondary care 2 D/K 88 N/A 99</p>
<p>17) Diagnosis:</p> <p>Senile dementia /Dementia 1 Alzheimer's Disease 2 Vascular dementia 3 Dementia with Lewy Bodies 4 Mixed dementia 5 Mild Cognitive Impairment 6 Other 7 D/K 88 N/A 99</p>		

<p>18) Does this diagnosis change over time?</p> <p>Yes 1 No 2 D/K 88 N/A 99</p> <p>If yes...</p>	<p>19) Date of new diagnosis:</p> <p>New Diagnosis: Senile dementia/ Dementia 1 Alzheimer's Disease 2 Vascular dementia 3 Dementia with Lewy Bodies 4 Mixed dementia 5 Other 6</p> <p>D/K 88 N/A 99</p>
---	---

20) Problem History and co-morbidity	21) Current medications
<p>1.....</p> <p>...</p> <p>2.....</p> <p>...</p> <p>3.....</p> <p>...</p> <p>4.....</p> <p>...</p> <p>5.....</p> <p>...</p> <p>Other comments:</p>	<p>1.....</p> <p>.....</p> <p>2.....</p> <p>.....</p> <p>3.....</p> <p>.....</p> <p>4.....</p> <p>.....</p> <p>5.....</p> <p>.....</p> <p>6.....</p> <p>.....</p> <p>7.....</p> <p>.....</p> <p>8.....</p> <p>.....</p> <p>9.....</p> <p>.....</p> <p>10.....</p> <p>.....</p>

Criterion	Definition	Comments
AT DIAGNOSIS & ASSESSMENT IN PRIMARY CARE: (anything between index and diagnosis)		
22) Was a Dementia Blood Screen performed by the practice? Yes (all) 1 No 2 Some (tick) 3 D/K 88 N/A 99	Includes: Urea & Electrolytes (U&E) Calcium (Ca) Glucose (BS) Renal (U&E) Liver function (LFT) Thyroid function tests (TFT) Vitamin B12 Folate FBC	If some, which? Tick: Urea & Electrolytes (renal, U&E) <input type="checkbox"/> Calcium (Ca) <input type="checkbox"/> Glucose (BS) <input type="checkbox"/> Liver Function Test (LFT) <input type="checkbox"/> Thyroid Function Tests (TFT; TSH, T4, T3) <input type="checkbox"/> Vitamin B12 <input type="checkbox"/> Folate <input type="checkbox"/> Full Blood Count (FBC) <input type="checkbox"/>
23) Was Syphilis Serology tested by the practice? Yes 1 No 2 D/K 88 N/A 99	Note: Not recommended in NICE/SCIE guideline	

Criterion	Definition	Comments
<p>24) Was a Cognitive Function Test performed by the practice? Yes 1 No 2 D/K 88 N/A 99</p>	<p>For example: MMSE 6-CIT GPCOG 7 minute screen Mini-cog AMTS Other.....</p>	<p>If yes, which: MMSE (30-items) 1 6-CIT 2 GPCOG 3 7 min screen 4 Minicog 5 AMTS (10-items) 6 (sometimes referred to as 10-items MMSE, e.g. MMSE 8/10 is actually an AMTS score) Other..... 7</p>
<p>25) Was the Informant History considered by the practice? Yes 1 No 2 D/K 88 N/A 99</p>	<p>Any concerns relevant to dementia mentioned to the GP by nurse, next of kin, friend etc. between index and diagnosis (anyone other than the patient).</p>	<p>If yes, what?</p>

Criterion	Definition	Comments
26) Was a Referral made by the practice at or after index? Yes 1 No 2 D/K 88 N/A 99	E.g. referral from Primary Care to Old Age Psychiatry, Neurologist, Psychologist etc.	To Whom:
27) Was Depression and/or Psychosis considered by the practice? Yes 1 No 2 D/K 88 N/A 99		
28) Were Carer Concerns recorded by the practice? Yes 1 No 2 D/K 88 N/A 99		If yes, what?
29) Were Behavioural and Psychological Symptoms	For example, aggression, agitation, apathy, anxiety, pacing, wandering, sleep disturbance,	If yes, which?

Criterion	Definition	Comments
<p>related to the Dementia (BPSD) recorded by the practice (apart from depression)?</p> <p>Yes 1 No 2 D/K 88 N/A 99</p>	<p>repetitive speech and behavior etc.</p>	<p>If yes, what action was taken?</p>
<p>30) Was information given by the practice to either the carer or patient or both, on:</p>		
<p>a) Signs and symptoms?</p> <p>Yes 1 No 2 D/K 88 N/A 99</p>	<p>See BPSD list in Q 29 but also memory loss and change in abilities.</p>	
<p>b) Course and prognosis?</p> <p>Yes 1 No 2 D/K 88 N/A 99</p>		
<p>c) Treatments?</p> <p>Yes 1 No 2 D/K 88 N/A 99</p>		
<p>d) Local care and support services?</p>		

Criterion	Definition	Comments
Yes 1 No 2 D/K 88 N/A 99		
e) Support groups? Yes 1 No 2 D/K 88 N/A 99		
f) Sources of financial and legal advice and advocacy? Yes 1 No 2 D/K 88 N/A 99	E.g. the Alzheimer's Society, Age Concern/Age UK, Citizen's Advice Bureau, DISC etc.	
g) Medico-legal issues? Yes 1 No 2 D/K 88 N/A 99	Includes driving, advance directives, capacity of patients to make health care decisions...	
h) Local information sources, including libraries and voluntary organizations? Yes 1 No 2 D/K 88 N/A 99		

Criterion	Definition	Comments
<p>31) Has the patient been offered Anti-Dementia Medication (cholinesterase inhibitors)?</p> <p>Yes 1 No 2 D/K 88 N/A 99</p>	<p>E.g. by secondary care and prescribed by either secondary or primary care.</p>	<p>Which?</p> <p>If no, what reason?</p>
<p>32) Was a Medication Review conducted around the time of the Index case and during assessment, e.g. to identify any drugs that may impair/improve cognitive functioning (added, stopped, changed)?</p>	<p>For example:</p> <p>Aspirin</p> <p>Risperidone, Sulpiride, (Thioridazine)</p> <p>Benzodiazepines (e.g. Temazepam, Diazepam, nitrazepam, Triazolam,</p>	

Criterion	Definition	Comments
Yes 1 No 2 Not clear 3 D/K 88 N/A 99	Zopiclone Anticholinergic drugs (e.g. Procyclidine, Biperiden, HCL, Benztropine)	
33) Was the patient referred for a CT/MRI scan by the GP? Yes 1 No 2 D/K 88 N/A 99		
DURING MANAGEMENT IN PRIMARY CARE:		
34) Since diagnosis, has Anti-Psychotic Medication been	(E.g. Risperidone, Aripiprazone, Haloperidol,	If yes, which?

Criterion	Definition	Comments
<p>prescribed by the GP?</p> <p>Yes 1 No 2 D/K 88 N/A 99</p>	<p>Olanzapine etc.)</p>	<p>If yes, why?</p>
<p>35) Consent and Capacity:</p> <p>a) Does the health record show evidence of continuing valid consent from the patient, or that the provisions of the Mental Capacity Act have been followed if the person lacks capacity?</p> <p>Yes 1 No 2 D/K 88 N/A 99</p>	<p>Read Codes E000 senile dementia and E001 presenile dementia should be used to identify patients.</p> <p>The health record should include notes of a discussion about consent with the patient, including how understanding was checked and that the patient continues to consent over</p>	<p>If yes, what does it say?</p>

Criterion	Definition	Comments
<p>b) Is there evidence of recall, reasoning, decision making and if relevant, agreement from next of kin?</p> <p>Yes 1 No 2 D/K 88 N/A 99</p>	<p>time. If appropriate, the record should include notes of a decision-specific test to establish whether the person had the capacity to give valid consent.</p> <p>The patient should be asked to sign the record to note that they understand and give consent.</p>	
<p>36) Is there a Care Plan evident?</p>	<p>E.g. there is a care plan scanned into the medical records or there is a</p>	

Criterion	Definition	Comments
Yes 1 No 2 D/K 88 N/A 99	mention of a care plan being followed/adhered to. A care plan could also be a letter from secondary care if specified as such.	
37) Is there evidence that Behavioural and Psychological Symptoms have been addressed and managed? Yes 1 No 2 D/K 88 N/A 99	These may cover the patient's: -physical health -depression -possible undetected pain or discomfort -side effects of medication -physical environmental factors -individual biography (e.g. beliefs, spiritual and	

Criterion	Definition	Comments
	<p>cultural identity) -psychosocial factors -specific behavioural and functional analysis conducted by trained professionals in conjunction with family carers and care workers.</p>	
38) Is there mention of the following in primary care:		
a) Advance statements? Yes 1 No 2 D/K 88 N/A 99	A written statement, drawn up and signed when the person is well, which sets	

Criterion	Definition	Comments
	out how s/he would prefer to be treated (or not treated) if s/he were to become ill in the future.	
b) Living will? Yes 1 No 2 D/K 88 N/A 99	A living will is one form of advance directive, leaving instructions for treatment.	
c) Lasting power of attorney? Yes 1 No 2 D/K 88 N/A 99	An authorization to act on someone else's behalf in a legal or business matter.	
d) Preferred Priorities (previously 'Preferred Place') of Care? Yes 1 No 2 D/K 88 N/A 99	An example of Advance Care Planning; A document for writing down wishes and preferences of care.	

Criterion	Definition	Comments
	This means that everyone involved in the care of someone knows what they want and how they wish to be cared for. It is also called an ' <i>Advanced Care Plan</i> '.	
e) Direct payments / Personal budgets? Yes 1 No 2 D/K 88 N/A 99	Cash payments made to individuals who have been assessed as needing services, in lieu of social service provisions.	
39) Is there a mention of the patient's Functional Abilities/ADLs or the use of measures of Global	Functional ability refers to the ability to conduct activities of daily living (ADL) such as eating,	

Criterion	Definition	Comments
Assessments? Yes 1 No 2 D/K 88 N/A 99	dressing and bathing.	
40) Is there a mention of discussions with a main carer about what their own needs are and whether their needs are being met? Yes 1 No 2 D/K 88 N/A 99		
41) Was information given by the practice to either the carer or patient or both, during management period on: a) Local care and support		

Criterion	Definition	Comments
services? Yes 1 No 2 D/K 88 N/A 99		
b) Support groups? Yes 1 No 2 D/K 88 N/A 99		
c) Sources of financial and legal advice and advocacy? Yes 1 No 2 D/K 88 N/A 99	E.g. the Alzheimer's Society, Age Concern/Age UK, Citizen's Advice Bureau, DISC etc.	
d) Medico-legal issues? Yes 1 No 2 D/K 88 N/A 99	Includes driving, advance directives, capacity of patients to make health care decisions...	
e) Local information sources, including libraries and voluntary organizations?		

Criterion	Definition	Comments
Yes 1 No 2 D/K 88 N/A 99		
42 a) How many formal Dementia Annual Reviews have been conducted in the last 12 months (prior to randomization/ end of training)?	Any mentioning of a 'Dementia Review'.	No:..... D/K 88 N/A 99
42 b) How many Opportunistic Dementia Reviews have been conducted in the last 12 months (prior to randomization/ end of training)?	Any mentioning of issues around dementia and related problems in any consultation. E.g. patient attends for other conditions such as diabetes and during consultation the doctor deals with dementia related issues in addition. This	No:..... D/K 88 N/A 99

Criterion	
Definition	should be clearly documented.
Comments	

Appendix 8 Chapter 2: Research protocol EVIDEM-E study

Version 8.1 May 2009

Randomised Control Evaluation of Exercise on Individuals with Dementia and their Carers as a Therapy for BPSD

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Protocol development history

June–September 2008 – initial development
September 2008 EVIDEM advisory group
October 2009 EVIDEM-E steering group
February 2009 EVIDEM E protocol development group
February 2009 EVIDEM-E steering group

Abbreviations

AE	Adverse event
CNWL NHS	Central & North West London NHS Foundation Trust
CRF	Case Report Form
DAP	Data Analysis Plan
DeNDRoN	Dementia & Neuro-Degenerative Diseases Research Network
DMG	Data Monitoring Group
EOT	End of Trial
ET	Exercise Therapist
GCP	Good Clinical Practice
ICF	Informed Consent Form
TAU	Treatment as Usual
NHS	National Health Service
PCT	Primary Care Trust
PI	Principal Investigator
PIS	Participant Information Sheet
IR	Independent Researcher
RW	Research Worker
REC	Research Ethics Committee
R&D	Research and Development Department
SAE	Serious Adverse Event
TSC	Trial Steering Committee

Summary

Background

Over 700,000 people in the UK have dementia. The deterioration associated with dementia is distressing for patient and carer alike and often leads to institutionalisation. Behavioural and Psychological Symptoms of Dementia (BPSD) are common and are core symptoms of the disease. However, research on interventions has traditionally focused on treating the cognitive components of dementia. Over 80% of people suffering from dementia experience BPSD including symptoms such as agitation and aggression. These symptoms cause considerable distress to the person with dementia and their carers and predict early institutionalisation and death. Historically, BPSD has been managed with medication, typically anti-psychotic drugs. Though effective in symptom control, recent data show that anti-psychotic medications increase mortality and the risk of stroke in people with dementia. Consequently, there is a need to evaluate the impact that non-pharmacological interventions such as physical exercise have on BPSD.

Design

A pragmatic, randomised, single-blind controlled trial. The two arms of the trial are: a graded programme of dyadic exercise (walking) in addition to treatment as usual (TAU) in the intervention arm and treatment as usual alone as the control arm.

Setting

The study will be conducted in a community cohort in the UK nested within the EVIDEM research programme.

Sample

Participants with a clinical diagnosis of dementia or 'suspected dementia' (age related difficulty with thinking or memory loss not related to an acute confusional episode) with at least one significant BPSD symptom defined by the Neuropsychiatric Inventory (NPI) (excluding the domains of delusions and hallucinations) will be eligible for the trial. Diagnosis of dementia will be confirmed in accordance with ICD-10 Diagnostic Criteria for Research (DCR-10).

Participants will be recruited directly through the North Thames DeNDRoN's registry of participants with Dementia, as well as primary and secondary care, carer homes and self-referrals.

Interventions

A 6-week supervised incremental course of walking outside, at a pace and distance to suit the participant and carer for at least 5 days per week. Walking is a useful exercise which is considered acceptable by participants, and is easily delivered and measured (in terms of time and distance) but rarely incorporated in a daily routine. A physiotherapist or exercise therapist will oversee the delivery of the exercise programme. The sustainability of this intervention will be assessed by evaluating adherence and impact during an unsupervised interval (weeks 6–12) and by further telephone contact at 6 months.

Treatment as usual includes attendance at day care facilities, visits by health professionals, receipt of medication.

Outcome assessment

The primary outcome measure will be behavioural and psychological symptoms measured by the Neuropsychiatric Inventory (NPI).

Secondary outcome measures will be:

1. participants' mental health (GHQ)⁸⁵
2. participants' quality of life (DEMQOL-Proxy)⁸⁶
3. caregivers' burden of caring (short ZBI)⁸⁷
4. participants' level of physical activity and compliance with the intervention (diaries, blood pressure and heart rate monitors)
5. economic evaluation (Client Service Receipt Inventory)⁸⁸
6. participants' and carers' views about the intervention (Diaries and semi-structured questionnaires).

Aims and objectives of the project

Primary objective

To determine the effectiveness of physical exercise delivered through a programme of incremental walking for treating behavioural and psychological symptoms of dementia compared with treatment as usual (TAU).

Secondary objectives

1. To determine the impact of physical exercise (involving the carer) on the carers' assessment of participant's functioning and their quality of life.
2. To determine the effect of a dyadic walking programme on caregivers' perceived level of burden.
3. To explore participants' views about the intervention and barriers to treatment.

Background

Dementia and BPSD

Dementia is defined as 'progressive brain atrophy due to nerve cell loss leading to a characteristic worsening of memory and global intellectual deterioration without impairment of consciousness'.³³¹ The increase in degenerative diseases through the inversion of the age pyramid in industrialised societies has brought about an increase in the prevalence of dementia. Approximately 5% of people aged over 65 years have some form of dementia, with the population prevalence rising to 20% in those aged over 80 years.³³² Over 80% of people with dementia will experience related changes of personality and behaviour, including apathy, aberrant motor behaviour, disinhibition, verbal and physical aggression.⁶⁵ Behavioural symptoms sometimes cause distress for people with dementia and their carers, and can often contribute to the breakdown in care at home leading to institutional care.³³³

Conventional treatments for BPSD

Conventional treatment for dementia involves the use of cholinesterase inhibiting drugs (such as donepezil, rivastigmine or galantamine). However these drugs are expensive,⁹⁰ have limited efficacy,³³⁴ minimal impact for participant related quality of life³³⁵ and the evidence base for impact on BPSD is weak. Though there is some evidence base in treating BPSD with antipsychotics (e.g. haloperidol, risperidone and olanzapine), there has been increasing concerns over the safety of these drugs for people with dementia. In the UK the Medicines and Healthcare products Regulatory Agency (MHRA) has issued a warning about the increased risk of cerebro-vascular events for people taking a course of risperidone and olanzapine. In the US, the Food and Drug Administration (FDA) has issued a warning against the use of all anti-psychotics in dementia. Therefore, in the absence of effective and safe pharmacological options, non-pharmacological alternatives should be explored and appraised more thoroughly.

Health and social care professionals are faced with a significant challenge in managing BPSD, which is critical in enabling participants to continue to live in their own homes. This is made all the more important by the demographical changes of our future. There is insufficient evidence for non-pharmacological interventions in managing BPSD sustainably, and supporting the participant and carer with a degree of safety in such a situation. The use of pharmacological interventions often poses a dilemma in balancing risk and benefit. Interventions such as the exercise dyad may offer a safer alternative, which if effective may not only have all the benefits of an effective intervention, it could also be empowering to the participant and carer due to its dyad modality of delivery.

Exercise as treatment for BPSD

Physical Exercise is defined by the American Diabetes Association as 'physical activity or anything that gets you moving'.³³⁶ Exercise has an impact on the cardio-vascular and musculo-skeletal systems and has been shown to have a modest positive impact on mood,⁷⁴ including for those with dementia.⁷⁵

There has been some research on non-pharmacological interventions in the treatment of BPSD, mainly in the US.³³⁷ Impact of exercise on cognitive symptoms has also been studied particularly in residential home settings in Australia³³⁸ and France.³³⁹ Heyn *et al.* carried out meta-analysis of exercise in dementia and reported data on 30 trials of exercise.⁷⁶ The authors reported on trials that included strength, cardiovascular or flexibility regimes; and analysed for functional, cognitive or behavioural outcomes. The authors reported a significant positive effect size of exercise on behavioural outcomes. However, most trials included in the analysis on behavioural outcomes were relatively small ($n < 65$), and only two of eight reported on samples that included in excess of 100 participants. Further, exercise interventions were often combined with behavioural interventions and so it is difficult to isolate the impact that exercise has had on behavioural outcomes.

Perhaps, of greater importance, is the feasibility and sustainability of any exercise regime. Many of the trials reported in Heyn *et al.*'s meta-analysis were relatively complex, required equipment or sustained interaction with a trained therapist and so are potentially not suitable for the community setting. We are

aware of one trial of tailored walking for community-dwelling people with dementia–carer dyads³⁴⁰ that has demonstrated a significant reduction of the frequency of ‘aggressive incidents’ within the dyad. However, this trial was restricted to a relatively small sample and the impact on other important BPSD was not captured. Therefore, we propose a simple walking regime, provided it is of sufficient pace and distance, meets the criteria for exercise yet is more likely to be acceptable and sustainable in a community setting. We believe there is a need to assess the impact of a regular regime of walking on a wide range of behavioural domains by means of a randomised controlled trial.

Experimental design and methods

Study design

We will undertake a pragmatic, randomised, controlled, single-blind, parallel-group trial. Individuals with a diagnosis of dementia or suspected dementia (age related difficulty with thinking or memory loss not related to an acute confusional episode), which will be confirmed with ICD-10 criteria using the DCR-10, will be recruited to the study. In order to be eligible, participants will present with at least one behavioural and psychological symptom in one of the sub-scales of the Neuropsychiatric Inventory (NPI) (except hallucinations or delusions occurring in isolation); and will score at least 2 for severity (‘causes distress’) and 2 for frequency (‘often- about once a week’) in the NPI rating sub-scale. Suitability for inclusion into the trial is assessed, based on availability of an identified carer and ability to perform exercise regime safely.

Community-dwelling individuals including those living in residential and care facilities will be recruited through the EVIDEM network, CNWL NHS Foundation Trust and North Thames DeNDRoN.

Risk assessment will be performed to assess the suitability of participants for the intervention at baseline. Assessment will include measurement for risk of falls through Falls Risk Assessment Tool (FRAT)⁸¹ and Timed Unsupported Steady Standing (TUSS)⁸² If the person has neurological, mobility related or sensory impairment, which might limit their ability to involve in walking regime, attempts will be made to modify their exercise regime with advice from the Association of Chartered Physiotherapists in Exercise Therapy (UK). Acute confusional state will be assessed by The Confusion Assessment Method (CAM).³⁴¹

After confirming eligibility and obtaining patient and carer consent to treatment, initial baseline assessments will be carried out. Participants will then be randomised into one of two arms: the treatment arm which includes receipt of the intervention in addition to treatment as usual (TAU) or the control arm which receives TAU only. Both the treatment and control arms will be re-assessed for all outcomes at week 6 and week 12. At 18 weeks, qualitative data will be gathered from a smaller sample of participants using semi-structured questionnaires. Further telephone contact will occur at 26 weeks to assess adverse events and mortality, change in domiciliary status and adherence to exercise regime.

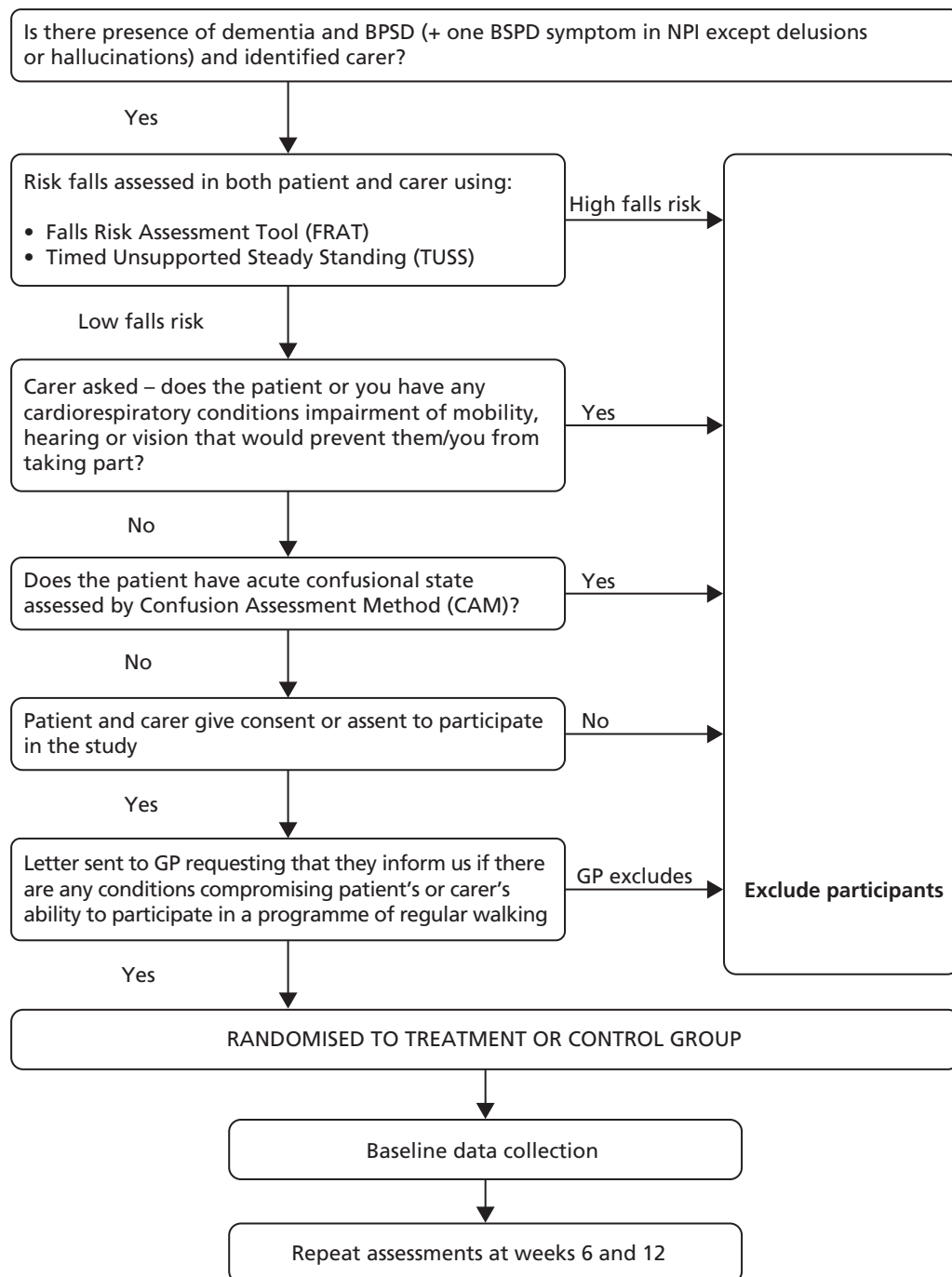


FIGURE 30 Study design: Recruitment protocol of subjects for structured exercise as an intervention for dementia with BPSD.

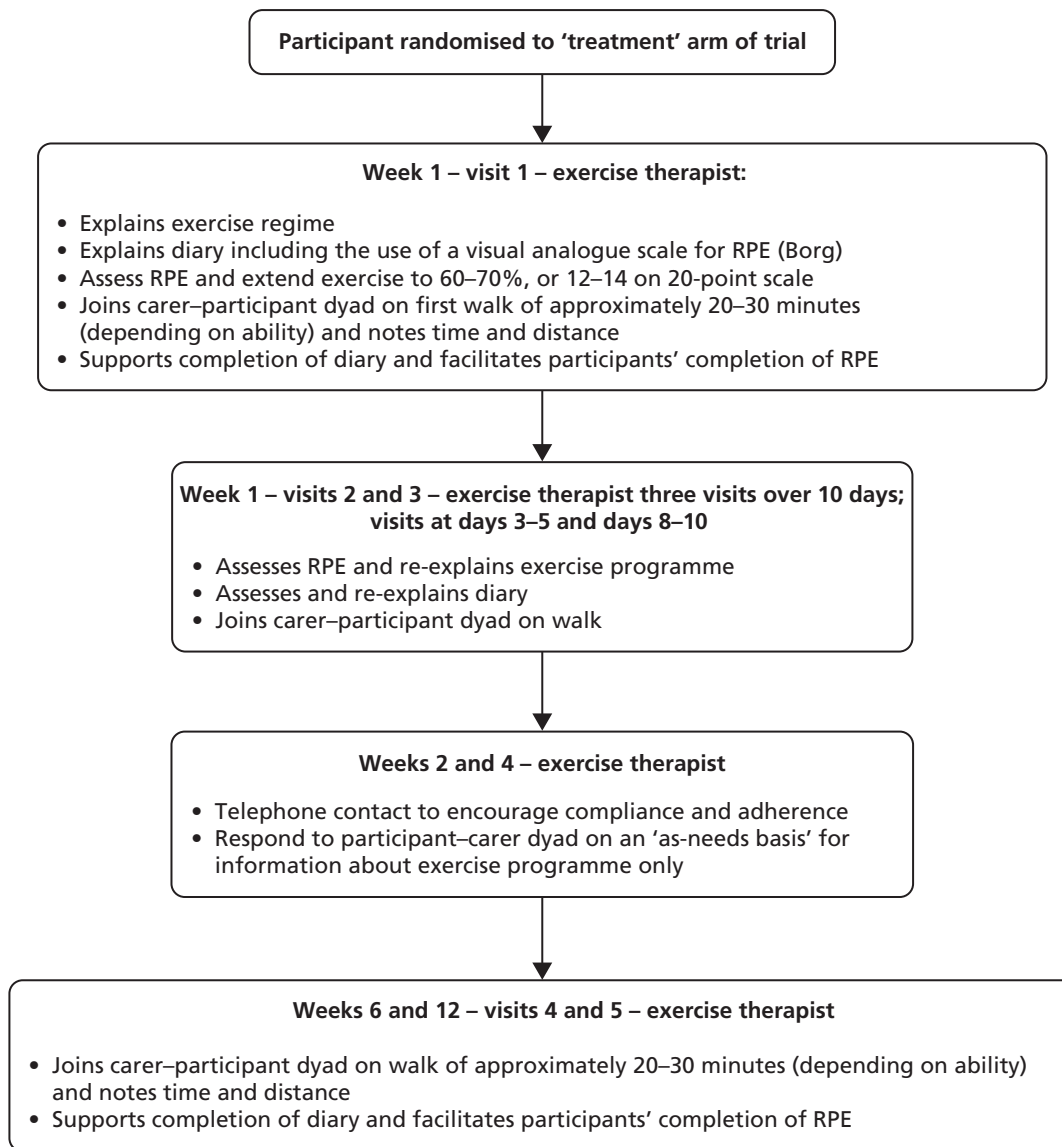


FIGURE 30 Study design: Recruitment protocol of subjects for structured exercise as an intervention for dementia with BPSD. (*continued*)

Safety variables and end points

Safety variables will include falls' risk assessments and functional abilities. Safety endpoints will be falls and significant adverse events (AEs) spontaneously reported during the study and discontinuations due to AEs.

Stopping rules and discontinuation

If there is a significant statistical difference ($p < 0.05$) between the number of reported AE/SAE by the intervention and control groups the TSC and PI will consider the discontinuation of the trial. See risk management procedures (section below).

Interventions

Physical Exercise will be delivered as an individually tailored regime of walking designed to become progressively intensive. This will be facilitated by a qualified exercise therapist or physiotherapist and delivered to participants in the treatment arm of the trial. The exercise therapist would facilitate physical exercise in the participant–carer dyad with the expectation that the participant–carer dyad would perform the exercise regime regularly and independently of the therapist.

Participant involvement

People with a clinician's diagnosis of dementia or 'suspected dementia' (age related difficulty with thinking or memory loss not related to an acute confusional episode) with at least one significant BSPD symptom defined by the Neuropsychiatric Inventory (NPI) (excluding the domains of delusions and hallucinations) would be eligible for the trial. Diagnosis of dementia will be confirmed in accordance with the ICD-10 Diagnostic Criteria for Research (DCR-10).

We will recruit participants with dementia with an identified carer. The carer can be a family member or a professional. We shall ensure about their level of physical health and their ability to support the participant with dementia in the trial.

Recruitment base

Participant recruitment will be both retrospective and prospective: individuals with dementia known to the GP or secondary care will be identified and suspected new cases would be further investigated to confirm diagnosis. Regular reminders about the study will be sent to participating practices and secondary care teams with the network catchments area. A central register of all referrals will be maintained.

There are four potential sources of recruitment:

- North Thames Dementia & Neuro-Degenerative Diseases Research Network (DeNDRoN) – Registry of people with dementia interested in participating in research (DemReg)
- GP practices that are affiliated to the EVIDEM Research Group – Practices will be asked to interrogate their lists for people with a diagnosis of dementia or memory impairment
- Memory assessment services and community mental health services, (e.g. Admiral Nurses) will be recruited via CNWL NHS Foundation Trust
- Self-referral.

Recruitment process

An assigned clinical support officer (CSO) from DeNDRoN will inspect their registry for people that are eligible to participate in our study. This worker will identify lists of people with dementia who are eligible to participate in our study and post the following information to the person with dementia and the carer:

- a covering letter signed by the clinical lead for North Thames DeNDRoN
- a participant information sheet
- a response letter and stamped addressed envelope.

The clinical support officer from DeNDRoN will contact participants by phone 1 week after the date of the mail-out to confirm interest, presence of BSPD and carer availability. The clinical support officer will ask for permission to pass on their contact details to the research worker. The CSO will provide the trial manager and research worker with details of the interested individuals within 24 hours.

GP practices recruited through the EVIDEM Research Group will be asked to inspect their patient lists using QoF (quality outcomes framework) data and READ codes to identify patients with dementia. Lists of people with dementia identified by practices, Memory Clinics and Community Mental Health Teams will be checked by their lead clinician. Practitioners will be asked for their opinion about the capacity of the person with dementia to give informed consent, using the Mental Capacity Act 2005 as the framework for their judgement.

The practices will post the following information to the person with dementia and/or the carer:

- a covering letter signed by the lead clinician
- a participant information sheet
- a response letter and stamped addressed envelope.

Participants will be directed to return letters to the research team or contact the research team by phone or e-mail. A researcher will arrange to see those people with dementia and their carers who express an interest in participating in the study. During the meeting the researcher will explain the study, respond to any queries, screen for eligibility and seek consent/assent for participation in the study.

For those judged as lacking capacity to consent, a consultee will be identified and consulted about involvement in the trial. In the event that a consultee cannot be identified, the person with dementia will be excluded from participation in the trial.

The researcher will undertake an initial telephone screen to confirm interest, and likelihood of at least one BPSD symptom and then arrange an initial interview at a time and venue convenient to the participants (ideally their home). The potential participants will receive a written and verbal explanation of the trial (appendix 1). If the participant meets inclusion and exclusion criteria we will seek consent from both participant and carer, using the consent protocol. Once obtained (or in the case of an individual who is not capable of giving informed consent, the assent of the participant with agreement of carer in accordance with accepted guidelines),³¹⁶ participants will proceed to the baseline interview/assessment and then be randomised. As the NPI score is an outcome this will be administered at the baseline interview once consent has been obtained along with the DEMQOL-Proxy, CSRI, GHQ, ZBI and vital signs (i.e. blood pressure and heart rate).

Inclusion criteria

- Diagnosis of:
 - dementia in primary or secondary care *or*
 - suspected dementia confirmed by the researcher to ensure the DCR-10 criteria are met.
- Presence of a carer (professional, friend or family member, who does not necessarily have to live with the participant).
- NPI score in any one sub-set except only hallucination or delusion more than or equal to 2 in severity and more than or equal to 2 in frequency.
- Consent of participant, or in the case of an individual who is not capable of giving informed consent, the assent of the participant with agreement of carer.
- Consent of carer.

Exclusion criteria

- Cardio-respiratory condition, neurological or musculo-skeletal condition of a degree that prevents participation to even the modified exercise regime unsafe or not possible.
- Three or more falls in the previous year ('frequent fallers') assessed by FRAT or high falls risk defined by TUSS.
- Uncontrolled medical problems, which the GP considers would exclude participants from undertaking the exercise programme; for example, acute systemic illness' such as pneumonia, poorly controlled angina, acute rheumatoid arthritis, unstable or acute heart failure.
- Sensory impairment to an extent that prevents dyad facilitated exercise.
- Participant or carer dissent to engage in the exercise programme.
- Acute confusional state assessed by The Confusion Assessment Method (CAM).

Informed consent

All participants and their carers will provide written informed consent. The Informed Consent Form (appendix 2 & 3) will be signed and dated by both the patient and carer before they enter the trial. The research worker (RW) will explain the details of the trial and provide a Participant Information Sheet, then allow the patient and carer a minimum of 72 hours to consider whether they would like to be involved in

the trial. The research worker will encourage the patient/carer to ask any questions that might help them make a decision on their potential involvement in the trial.

Informed consent will be collected from each participant before they undergo any interventions (including history taking) related to the study. One copy of the Informed Consent Form will be kept by the participant, one will be kept by the research worker, and a third will be retained in the participant's general practice records.

Where a participant who appeared to be eligible and signed a consent form is subsequently found not to be eligible (e.g. the GP considers they fulfil one of the exclusion criteria) they will not be considered to have entered the study.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended consent form which will be signed by the participant.

Compliance

Compliance will be defined as continuation with the exercise programme. This will be recorded through diarised entries, blood pressure and heart rate monitoring from carers and participants (see *Section 4.7.2*).

Randomisation

Patient/carer dyads will be randomly allocated to receive treatment as usual (TAU) or exercise therapy in addition to treatment as usual (ET). The randomisation ratio for the two groups will be 1 : 1 (ET : TAU). A computer algorithm will be used to perform the randomisation centrally by an Independent Researcher after the initial interview, who will communicate the results to the participant and carer, and to the exercise therapist; but not the research worker or IR.

Concealment and blinding

In order to maintain blinding, randomisation will be performed independently of the research worker (RW) following baseline evaluation. The exercise programme will be initiated and supervised by an 'Exercise Therapist' (ETh). Baseline and subsequent evaluations will be undertaken by RW. An independent researcher (IR) will collect the primary outcome data (NPI) at weeks 6 and 12, which will be completed by telephone with the aim of minimising the risk of un-blinding participants.

Outcome assessment

Assessments will be conducted according to *Table 103*. Participants will be visited in either their own homes, or a mutually acceptable convenient location (e.g. GP's surgery), by a trained research worker (RW) masked to arm allocation. All possible measures will be taken to ensure that blinding will be uncompromised and the efficacy of this will be assessed at each time point using a 5 point Likert Scale. Both the IR and RW will complete the scale indicating to which arm they believe each individual dyad is randomised to. The scale will be polarised by the two arms and include a 'not sure' level as the centre rating. However, there remains a risk that the dyad will divulge information about the group they have been allocated to. The IR will collect the primary outcome measure (NPI) by telephone. This strategy has been adopted so as to minimise the risk of conversation with the dyad that might un-blind the randomisation.

Baseline assessment

In addition to the protocol, socio-demographic data and illness characteristics, including medication, will be sought at recruitment (see *Table 103*). Confirmation of clinical diagnosis of dementia will be ascertained at the beginning of recruitment into the trial using the ICD-10 criteria, using the DCR manual.

All participant-carer dyads will be provided with diaries to record the level of their physical activity i.e. walking and any difficulties they encountered when walking (see appendix 2.4.1 & 2.4.2). Diaries for the intervention group will differ slightly from the control group. Thus, the dyad on intervention group will also

TABLE 103 Assessment Schedule: delineation of responsibility

	Exercise therapist (ET)	Research worker (RW)	Independent researcher 1 (IR1)	Independent researcher 2 (IR2)
	Exercise group only	All participants	All participants	All participants
Baseline		Screens for eligibility; Obtains consent; Outcomes assessed; BP & HR at rest assessed		
T -1				Randomisation & mails diaries and phone contact to provide instruction about diary completion
Week 1	RPE, walk, support to complete diary RPE, walk, support to complete diary RPE, walk, support to complete diary			
Week 2	Telephone contact			
Week 4	Telephone contact			
Week 6	RPE, walk, support to complete diary	Visits: outcomes; Adverse events; BP & HR at rest assessed	Telephone to complete NPI, remind diary completion	
Week 12	RPE, walk, support to complete diary	Visits: outcomes; Adverse events; BP & HR at rest assessed	Telephone to complete NPI, remind diary completion	
Week 13		Collects sealed diaries		
Week 16		Qualitative interviews		
Week 26		Telephone contact: CSRI Change in domicile? Still exercising? Mortality assessment		

BP, blood pressure; HR, heart rate.

be asked to complete a visual analogue scale (Rating of Perceived Exertion)⁸³ to which they will be trained by the exercise therapist.

Follow-up assessments

The primary outcome assessments include change of behavioural and psychological functioning measured using the NPI.⁶² This tool can also be used to derive a score which pertains to the distress caused by each behavioural domain). We can not think of any plausible mechanism by which our intervention might effect psychotic behavioural domains and so we will exclude the domains of delusions and hallucinations from our analysis.

An assessment of caregiver-rated quality of life (DEMQOL-Proxy);⁸⁶ assessment of general health (GHQ)⁸⁴ and a caregiver assessment of the burden of caring (short version of the ZBI)⁹⁴ will also be administered. Participants general level of fitness will also be assessed as heart rate at rest and blood pressure readings.

At week 6 and 12 the NPI, GHQ, DEMQOL-Proxy, ZBI and measurement of vital signs will be repeated in both groups.

In carrying out the NPI assessment we will focus on eight of the ten domains. We will measure the difference between the treatment and control groups in agitation/aggression, dysphoria, anxiety, euphoria, apathy, disinhibition, irritability/ability and aberrant motor behaviour. We do not expect physical exercise to impact on hallucinations and delusions. The summative mean of the 8 sub-scales is 8.08 (if hallucinations and delusions are included the figure is 8.25). In studies where NPI was measured in the placebo group a mean reduction of 2.2 was observed.³³⁹

The phenomenology of participants' and cares' perspectives of exercise and barriers to treatment will be examined with open-ended, in-depth interviews. The interviews will be carried out by the research worker after the quantitative data has been analysed and the randomisation code has been breached. Theoretical sampling will be used to ensure that an initial sample is drawn to include as many as possible of the factors that might affect variability of behaviour. It is anticipated that saturation will be reached after 15–20 interviews.

TABLE 104 Administration of outcome measures

Day	Administrator	Assessment schedule			
		Exercise dyad group		Treatment as usual group	
		Measure	Subject	Measure	Subject
0	<i>Researcher</i>	ICD-10	Participant+ Carer	ICD-10	Participant+ Carer
		MMSE		MMSE	
		NPI	Participant	NPI	Participant
		Demographics	Participant	Demographics	Participant
		CSRI	Carer	CSRI	Carer
		DEMQOL-Proxy	Carer	DEMQOL-Proxy	Carer
		GHQ		GHQ	
		ZBI	Participant+ Carer	ZBI	Participant+ Carer
		Medication	Carer	Medication	Carer
		Vital signs (BP&HR)	Participant	Vital signs (BP&HR)	Participant
			Participant+ Carer		Participant+ Carer
0	<i>Independent Researcher 2</i>	RANDOMISATION and SEND DIARIES TO ALL			
1–2	<i>Exercise therapist</i>	RPE	Participant+ Carer		
		Timed walk			
		Diary			
3–4	<i>Exercise therapist</i>	RPE	Participant+ Carer		
		Timed walk			
		Diary	Participant+ Carer		
6–8	<i>Exercise therapist</i>	RPE	Participant+ Carer		
		Timed walk			
		Diary			
40–46	<i>Independent Researcher 1</i>	NPI	Carer	NPI	Carer
	<i>(telephone contact)</i>	Remind completion of diaries	Participant+ Carer	Remind completion of diaries	Participant+ Carer
40–46	<i>Researcher</i>	DEMQOL-Proxy	Carer	DEMQOL-Proxy	Carer
		GHQ	Participant+ Carer	GHQ	Participant+ Carer
		ZBI		ZBI	
		Medication	Carer	Medication	Carer
		Adverse events	Participant	Adverse events	Participant
		Vital signs (BP&HR)	Participant+ Carer	Vital signs (BP&HR)	Participant+ Carer
			Participant+ Carer		Participant+ Carer

continued

TABLE 104 Administration of outcome measures (continued)

Day	Administrator	Assessment schedule			
		Exercise dyad group		Treatment as usual group	
		Measure	Subject	Measure	Subject
40–46	<i>Exercise therapist</i>	RPE Timed walk Diary	Participant+ Carer		
80–88	<i>Independent Researcher 1</i> <i>(telephone contact)</i>	NPI Remind completion of diaries	Participant Participant+ Carer	NPI Remind completion of diaries	Carer Participant+ Carer
80–88	<i>Researcher</i>	DEMQOL-Proxy GHQ ZBI Medication Adverse events Vital signs (BP&HR)	Carer Participant+ Carer Carer Participant Participant+ Carer	DEMQOL-Proxy GHQ ZBI Medication Adverse events Vital signs (BP&HR)	Carer Participant+ Carer Carer Participant Participant+ Carer
80–88	<i>Exercise therapist</i>	RPE Timed walk Diary	Participant+ Carer		
90–98	<i>Researcher</i>	Collection of diaries	Participant+ Carer	Collection of diaries	Participant+ Carer
112–120	<i>Researcher</i>	Qualitative interviews	Participant+ Carer		
182–196	<i>Researcher</i>	Telephone contact: CSRI Change in domicile? (hospitalisation) Still exercising? Mortality assessment	Participant+ Carer	Telephone contact: CSRI Change in domicile? (hospitalisation) Still exercising? Mortality assessment	Participant+ Carer

Statistical methods

Sample size

Based on observing a meaningful clinical difference between the groups (0.3) on the primary outcome measure (NPI), using a statistical cut off of $p < 0.05$ with a two tailed test, a sample size of 146 participants will give 90% power to detect this difference. (calculated by URL: <http://www.stat.ubc.ca/~rollin/stats/ssize/b2.html>)

Intervention	Difference	N (including compensation for 20% attrition)
0.4	0.4	70 (88)
0.5	0.3	116 (145)
0.6	0.2	238 (298)

Therefore, we aim to recruit 146 persons with dementia and their carers in this trial, 73 dyads on each arm.

Data entry

Double entry of data provided in paper form will be undertaken using automated consistency and logical checks. Data will be stored encrypted and password-protected on local drive with weekly backup. The central database will be maintained at CNWL NHS Foundation Trust head quarters. A log will be kept of data amendments. A research diary will be maintained by the researchers, which will be counter-signed monthly by the Principal Investigator.

Data protection

We will be fully compliant with the provisions of the Data Protection Act.⁵⁰ All records will be kept in a locked filing cabinet at the study centre. Confidentiality of electronic records will be ensured by password protection. The databases will be designed so that participant names are not shown on screen. Participant names and contact addresses will be deleted from the database at the earliest opportunity (for example, if a participant withdraws from the trial).

Data analysis

Baseline demographic and outcome data will be compared between the two randomisation groups. Categorical data will be analysed using the chi-square test. Continuous data will be analysed using the *t*-test or, if the data is found to be non-normally distributed, the Wilcoxon Rank-Sum test.

Outcomes at 6 and 12 weeks will be compared between randomisation groups using ANCOVA for continuous data. The relevant baseline scores will be included as the co-variate in order to adjust for any potential baseline differences in the respective outcome. Categorical outcomes will be compared using the chi-square test.

All data will be analysed on an intention-to-treat basis. Where appropriate imputation of missing data will be implemented. Under the assumption that data are missing at random (MAR) multiple imputation will be used.

All analyses will be completed using the statistics package STATA before the breaking of the randomisation key and the blinded analyses will be sent to a third party.

Qualitative data will be simultaneously collected and analysed. In order to enhance reliability, the analysis and coding will be carried out independently and simultaneously by two independent researchers. The analysis will be aided by the use of the NVivo™ computer software package. Line-by-line initial descriptive open coding will be carried out. Low-level categories will emerge from the data, which will be integrated into meaningful units to form higher-level categories, which will be grounded in the data. A coding

paradigm will be applied to link categories with one another and create themes. The process of data collection and analysis will continue until theoretical saturation has been achieved.

Adverse events and risk management

Attrition will be carefully monitored to determine its effects on the power of the study. If a dyad withdraw from the exercise component of the trial permission would be sought to continue monitoring outcomes.

Definitions

An adverse event is any unfavourable and unintended sign, symptom, syndrome or illness that develops or worsens during the period of observation in the trial.

An AE does include a/an:

1. exacerbation of a pre-existing illness
2. increase in frequency or intensity of a pre-existing episodic event or condition
3. condition detected or diagnosed after intervention even though it may have been present prior to the start of the trial
4. continuous persistent disease or symptoms present at baseline that worsen following the start of the trial.

An AE does not include a/an:

1. medical or surgical procedure (e.g. surgery, endoscopy, tooth extraction, transfusion); but the condition that leads to the procedure is an AE
2. pre-existing disease or conditions present or detected at the start of the trial that did not worsen
3. situations where an untoward medical occurrence has not occurred (e.g. hospitalisations for cosmetic elective surgery, social and/or convenience admissions).

A Serious Adverse Event (SAE) is any adverse event occurring following study mandated procedures, having received exercise intervention or usual treatment that results in any of the following outcomes:

1. death
2. a life-threatening adverse event
3. inpatient hospitalisation for non elective procedures
4. sudden or rapidly progressive major disablement
5. an event that caused the participant to seek non-routine medical treatment.

Important medical events that may not result in death, be life-threatening, or require hospitalisation may be considered a serious adverse event when, based upon appropriate medical judgement, they may jeopardise the patient or participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

All adverse events will be assessed for seriousness, expectedness and causality.

A distinction is drawn between serious and severe AEs. Severity is a measure of intensity whereas seriousness is defined using the criteria above. Hence, a severe AE need not necessarily be serious.

Reporting of adverse events

All treatment related serious adverse events will be recorded and reported to the TSC and REC as part of the annual reports. Unexpected serious adverse events will be reported within the timeframes to the REC as stated below. The Principal Investigator shall be responsible for all adverse event reporting.

During the trial we will conduct monitoring of adverse events. Participants will be asked to contact the trial site immediately in the event of any serious adverse event. Adverse Events (AEs) will be brought to the attention of the study team by either:

- *Return of AE card* Participants will be instructed to complete a coded, Freepost postcard each time they experience an AE, which they have not previously reported to the study centre.
- *Telephone call to the study team* Participants will be encouraged to call the study team if they experience any adverse effects during the study.
- *Notification by GP* Participant's doctors will be encouraged to contact the study team of any AEs they are made aware of.
- *Notification by carer* The participant's carer will be encouraged to contact the study team, either by returning the AE postcard or by telephoning the study team, if they observe any AEs in the participant or themselves.

On notification of an AE at the study centre, the Principal Investigator will call the subject and carer for further information. The Principal Investigator shall determine seriousness and causality in conjunction with any treating medical practitioners.

All adverse events will be recorded and closely monitored until resolution, stabilisation, or it has been demonstrated that the study treatment is not the cause.

Risk management

To ensure the safety of the researchers the GP will be asked if there is a history of violence with any participants to be interviewed. In case of participants recruited from residential or nursing homes, staff will be approached for history of violence. Where participants are recruited from secondary care, similar information will be obtained from the secondary care team or CMHT. Falls risk will be minimised by assessment prior to randomisation

Risk issues:

- inadvertent disclosure of dementia [disclosure of diagnosis rests with lead clinician (GP)]
- carer suffering from undiagnosed dementia
- falls (exclude high falls risk; exercise therapist to monitor; adverse event reporting)
- cardiovascular events (exclude high risk, exercise therapist to monitor; adverse event reporting)
- worsening of BPSD (exercise therapist to monitor; adverse event reporting)
- accidents – exercise therapist to assess road sense and undertake location risk assessment (for exercise location) (e.g. traffic density, kerb height, risk of mugging/assault), ability of carer to manage the person with dementia safely in the streets.

Trial intervention related SAEs

A serious adverse event that is deemed directly related to or suspected to be related to the trial intervention shall be reported to the TSC and ethics committee. The reporting form for SAEs is shown in the *Appendix 4*.

The event shall be reported immediately of knowledge of its occurrence to the Principal Investigator.

The Principal Investigator will:

- Assess the event for seriousness, expectedness and relatedness to the trial treatment.
- Take appropriate medical action, which may include halting the trial and inform the sponsor of such action.
- If the event is deemed related to the trial treatment, shall inform the REC using the reporting form found on the NRES web page within 7 days of knowledge of the event.
- Within a further 8 days send any follow-up information and reports to the REC.
- Make any amendments as required to the trial protocol and inform the REC as required.

Removal of participants from interventions, assessments or the trial

Participants may be withdrawn from the trial either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care.

The research team will advise discontinuation of exercise intervention or withdrawal from the trial if the exercise intervention poses a hazard to the safety of a participant, or if the participant poses a hazard to the safety of his carer or someone else.

Those who withdraw from the trial or follow-up will not be replaced. Participants should not be accepted as lost to follow-up unless 2 phone calls, letters or visits to the participant and carer have been fruitless.

Feasibility

The design allows for a total recruitment period of 24 months. We have obtained funds to recruit and employ one researcher who is based at CNWL FT HQ. Taking into account leave, sickness we expect 44 working weeks per year from the researcher. On this basis, there are 440 days for recruitment and follow-up. We believe it is possible to undertake an average of two participant contacts per day depending on location and complexity (in addition to other duties such as data entry). We estimate a maximum of 435 face-to-face participant contacts by the researcher in this trial. There will be a maximum of 725 visits by the exercise therapist.

Stopping rule

The stopping rule will be as follows: once all participants have been randomised any recruitment interviews that have been arranged will be honoured. Participants yet to be contacted, as well as those subsequently expressing an interest in the trial, will be sent a letter thanking for their interest but explaining that recruitment for the trial is now closed.

End of trial notifications

Once the trial is completed a summary of the results will be sent to the participants and to their GPs.

Ethical and regulatory aspects

Full ethical approval for the study will be sought from IRAS.

This research will be conducted in accordance with the Declaration of Helsinki.³⁴² Informed consent will be sought from all participants. However, due to the nature of this study, we anticipate some participants will be unable to give real consent. In the case of subjects who are not able to give informed consent, guidance from the Mental Capacity Act will be followed, and consent sought from the responsible carer. Specifically, as in all biomedical research involving human subjects, the investigators will need to obtain the informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the proxy agreement of a representative, having given due consideration to advance decisions. This is also in accord with internationally accepted guidelines on research involving human subjects with dementia.

The participants' GPs will have clinical responsibility for the participant throughout the trial. Study personnel will inform the GP of any adverse events and any significant clinical problems that are brought to the investigators' attention.

All study records will be securely stored for 10 years after the completion of the study.

We will make every effort to maintain confidentiality of data supplied by participants. Participants will be free to withdraw from the study at any time and will be reassured that doing so will not affect their medical care.

Informed consent and participant information

The process for obtaining participant informed consent will be in accordance with the REC guidance, and GCP and any other regulatory requirements that might be introduced. The researcher and the participant or other legally authorised representative shall both sign and date the Informed Consent Form before the participant can participate in the trial.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Trial Master File. A second copy will be filed in the participant's medical notes and a signed and dated note made in the notes that informed consent was obtained for the trial.

The decision regarding participation in the study is entirely voluntary. The research worker shall emphasise to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No trial-specific interventions will be done before informed consent has been obtained.

The research worker will inform the participant of any relevant information that becomes available during the course of the trial, and will discuss with them, whether they wish to continue with the trial. If applicable they will be asked to sign revised consent forms.

If the Informed Consent Form is amended during the trial, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for ongoing participants).

Records

Case report forms

Each participant will be assigned a unique Participant Identification Number for use on CRFs, other trial documents and the electronic database. CRFs will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate Trial Recruitment Log (TRL) to record confidential participant information including, name, date of birth and Participant Identification Number. This permits identification of all participants enrolled in the trial, in case additional follow-up is required.

CRFs shall be restricted to those personnel approved by the Principal Investigator and recorded on the 'Trial Delegation Log.'

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.

The Principal Investigator shall sign a declaration ensuring accuracy of data recorded in the CRF.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to consent forms and questionnaires. A CRF may also completely serve as its own source data. Only trial staff as listed on the Delegation Log shall have access to trial documentation other than the regulatory requirements listed below.

Direct access to source data/documents

The CRF and all source documents shall be made available at all times for review by the Principal Investigator, and inspection by the sponsor [Central and North West London NHS Foundation Trust] and relevant regulatory authorities, including the R&D departments.

Ethical issues

It is possible some participants have not been formally diagnosed with dementia or have been diagnosed but have not been told, or have forgotten the diagnosis.

Quality assurance and audit

Research staff training

The researcher conducting the recruitment and outcome interviews will undergo training in administering the relevant questionnaires. In addition researcher will be trained in participant risk assessment.

Monitoring and audit

The Principal Investigator will conduct an internal audit at the study centre every 3 months to ensure: confidentiality and integrity of databases; effectiveness of database backup systems; confidentiality and integrity of paper records; reconciliation of enquiries with enquiry outcome; data entry procedures; numbers allocated to each treatment group; comparison of paper records and electronic records. Each month, the Principal Investigator, together with the study team will review the progress of recruitment by recording number of letters sent, number of enquiries received, number of calls made, number of participants entered, number of participants randomised.

The study team will comply fully with any request for external audit by the sponsors or funding body.

Indemnity arrangements

This project will be indemnified through Central North West London NHS Foundation Trust. This covers participants in the event of negligent or non-negligent harm. Standard NHS indemnities apply.

User and public involvement

User representatives will be involved in the development, implementation and interpretation of the study. This involvement will include: advice on recruiting patients, invitation letters, the design of information leaflets, and research instruments, piloting assessments, helping to assess progress, and contributing to the evaluation of the project, the interpretation of findings and the dissemination of results. User representatives will be invited to trial steering committee meetings and also provide assistance to the study.

Trial Steering Committee

The Trial Steering Committee (TSC) will provide a critical overview of the trial, and will meet at the beginning of the trial and then 6-monthly, unless the Principal Investigator needs to seek its advice on risk management, in which case a special meeting will be convened. The TSC will include the Principal Investigator (JW), the project lead (DL), researchers (RB and AP), independent representatives of relevant voluntary organisations, individuals with expertise in exercise promotion and falls prevention, a statistician, and nominees of the funding body. It will be chaired by an independent investigator with expertise in

exercise promotion. Because no medicinal products are being tested and the risks of the kind of exercise that are being promoted are low, a separate data management and ethics committee will not be convened, but responsibility for overview of the risks of the trial will rest with the TSC.

Independent members

Chair – Dr Craig Ritchie, Senior Lecturer, Imperial College

Vice Chair – Clare Leonard, Physiotherapist

- James Lee, Exercise Therapist
- Sue Ricketts, Carer
- Timothy Shore, Assistant Clinical Psychologist
- Lyn Strother, Carer and EVIDEM advisory group member
- Fiona Walters, OT
- Lay representative

EVIDEM members

- Dr Rahul Bhattacharya, SpR Charing Cross Psychiatric Training Scheme
- Sandra Brookes, Lead of the Old Age Directorate in CNWL FT
- Prof Steve Iliffe, Professor of Primary Care for Older People at UCL, and co-director of the Centre for Ageing Population Studies in the Research Department of Primary Care
- Mark Griffin, Lecturer Medical Statistical Department, UCL
- Dr David Lowery, EVIDEM Research Programme Manager, CNWL NHS FT
- Dr James Warner, Consultant Psychiatrist CNWL NHS FT and Senior Lecturer Imperial College School of Medicine
- Arlinda Cerga-Pashoja, Research Worker

Non-participant observers

- Jane Wilcock, Senior Research Fellow and EVIDEM Research Programme Manager UCL

The steering group will meet 6-monthly (or more often if necessary).

Methods for disseminating and implementing research results

The systematic review will be forwarded to The Cochrane Library, as will the write-up of the trial for inclusion in their clinical trials register.

The trial will be published in a peer-reviewed medical journal.

Abstracts will be submitted to identified relevant conferences to inform other researchers of the work.

The support of the National Institute for Health Research (NIHR) will be credited in all publications that arise from this project in accordance with the acknowledgment and disclaimer agreed between NIHR and the EVIDEM Consortium.

Project timetable

Year	Month	General administrative tasks	Milestones	Participant management tasks	Target recruitment (cumulative)	
2009	March	Steering Group	Researcher starts, ethics submissions			
	April					
	May					
	June					
	July		Ethics and R&D approvals			
	August		Recruitment begins		0	
	September	Steering Group			8	
	October				16	
	November		Final follow-up begins		24	
	December				30	
	2010	January				38
		February				46
March		Steering Group			54	
April					62	
May					70	
June					78	
July					86	
August					92	
September		Steering Group			100	
October					108	
November					116	
December					124	
2011	January				132	
	February		Recruitment ends		146	
	March					
	April	Steering Group				
	May		Final follow-up ends			
	June		Analysis and writing up			
	July					
	August					
	September					
	October					
	November					
	December					
2012	January	Steering Group				
	February		Final report/publications			

Appendix 9 Chapter 2: Consenting protocol – standard operating procedures

It is important to establish if the potential participant and their carer have the capacity to provide informed consent at each interview. It is vital that the carer can provide informed consent. If the potential participant does not have the capacity to provide informed consent, they must still provide their assent (agree to participate) alongside the informed consent of their carer.

Assessment of capacity is based on current case law applicable in England. To determine if the individual is capable of providing informed consent, it is important to test whether pertinent information about the trial and the alternative (i.e. no trial) can be *understood*; if it can be *retained* for a sufficient amount of time to *weigh in the balance* and reach a decision about participation; and that the person can *communicate their decision* to participate free from coercion. The process for doing this is as follows:

1. *Understanding the trial* As well as providing written information sheets, the main points of the trial and the alternative (i.e. no trial) should be provided (and discussed) verbally *in a way that the potential participant can understand*. These points are:
 - i. Dementia causes problems with memory and thinking as well as changes in mood and behaviour.
 - ii. Problems with mood and behaviour are usually treated with drugs, which can sometimes have a negative impact on the person taking them.
 - iii. There is some evidence that exercising may be a safe, alternative treatment to BPSD.
 - iv. Walking is a safe way of exercising.
 - v. Participants will be randomly allocated into two groups: to receive either exercise therapy or care as usual for 12 weeks. There is an equal chance (50 : 50) of receiving either of these two allocations. This is because we do not know for sure if exercise works.
 - vi. A few participants and their carers will be allocated to one further follow-up, at which they will be asked questions about their experiences of the trial. This interview will be audio-recorded.
 - vii. A final telephone contact will occur at week 26, where all participants from the exercise therapy group will be asked a few questions about their current activity levels.
 - viii. Participation is for 12–26 weeks but participants can withdraw at any time without having to give a reason.
 - ix. Participants at risk of falling or who have other physical health problems that may unable them to carry out a walking programme will not be included in the study.
 - x. An exercise therapist will visit participants at home and establish a programme of walking outside for the participant–carer dyad.
 - xi. The walking programme will be at a pace and distance to suit both the participant and his/her carer.
 - xii. The exercise therapist will visit participants on five occasions. Each visit will last approximately 1–2 hours and will take place in the home of either the participant or their carer.
 - xiii. A RW will visit participants on three or four occasions. At each visit, we will complete various questionnaires.
 - xiv. All information held about them will be strictly confidential and it will not be possible to identify them from published project data.
 - xv. They do not have to take part and if they do not, the medical care they receive will in no way be altered. They can withdraw at any time.

2. *Retain and weigh in the balance of the information* The length of time they need to retain this information for depends on the individual. If they are happy to give a decision immediately then they need to retain only the information for that amount of time. Similarly, if they ask to think about it and say that they will decide the next day then they need to retain the information until the next day. The best way to test belief and retention of information is to ask the participant to repeat back the relevant information.

3. *Communicate a decision free from coercion* The individual needs to communicate their decision on participation without any pressure from the carer (if applicable) or the researcher attempting to obtain informed consent.

Once this procedure is followed, the researcher can then assess whether or not she/he feels that the individual has the capacity to give informed consent. If it is decided that they are not so capable then the potential participant may be able to participate but still needs to give their assent to the study (confirmation that they are happy to participate in the absence of full capacity). Therefore, an Assent Form will be completed. Three copies of the Assent Form are then made: one to go to the participant's GP; one to go to the carer; and one to be kept at the study centre.

Participants with established capacity to consent will complete the Participant's Consent Form. One copy of the form will go to the participant's GP; one to the participant; and one to be kept at the study centre.

The carer will complete a Participant–Carer Consent Form, at all occasions. One copy will be kept by the carer and one will be kept at the study centre.

Appendix 10 Chapter 2: Standard operating procedure for monitoring of adverse events

Classification of event

All adverse events will be classified by the Principal Investigator as either:

- *Adverse event (AE)* Any unfavourable and unintended sign, symptom or disease temporarily associated with the use of an investigational product, whether or not considered related to the investigational product.
- *Serious adverse event (SAE)* An AE that results in death, or is life threatening, or required in-participant hospitalisation, or results in persistent or significant disability or incapacity.

Classification of intensity

Regardless of the classification of AEs as serious/non-serious, the *maximal intensity* of the event is to be evaluated by the responsible clinician, after consultation with the participant, carer and participant's GP:

- *Mild* no impairment of normal daily activities
- *Moderate* impairment of normal daily activities
- *Severe* unable to perform normal daily activities.

Classification of causal relationship

Each AE must be classified on the basis of the available data with regard to the presumed *causal relationship* to one of the following categories:

1 = *probable*

- Rational relationship to the time of intake of the investigational medication.
- AE is already known to be a side effect of the investigational medication or may be expected.
- Regression or disappearance of the AE after discontinuation of investigational medication or dose reduction.
- Reappearance of the AE after repeated exposure.
- AE cannot be explained in a reasonable manner by the clinical state of the participant.

2 = *possible*

- Rational relationship to the time of intake of the investigational medication.
- AE is already known as a side effect of the investigational medication or may be expected.
- AE could be explained by numerous other factors.

3 = improbable

- Rational relationship to the time of intake of the investigational medication.
- AE has not been reported so far as a side effect of the investigational medication or cannot be expected.
- AE persists after discontinuation of the investigational medication or dose reduction.
- Repeated exposure does not lead to reappearance of the AE.
- AE could be explained by numerous other factors.

4 = no relationship

- No rational relationship to the time of intake of the investigational medication.
- AE is evidently caused by other factors, for example symptom of a concomitant disease.

5 = unable to evaluate

- Amount and content of data do not permit a judgement of the relationship to the investigational medication.

Appendix 11 Chapter 2: Risk assessment and management tool

INCIDENT REPORT FORM

Name :	
Date of Incident :	Member of Staff Incident reported to :
Details of the Incident	
Action Taken	
<u>Witness Name and Role in Trial</u>	
<u>Outcome</u>	
Name of Member of Staff	Witness Signature
Signed	Dated

Appendix 12 Chapter 2: Serious adverse event reporting form

Patient ID: _ _ _	Patient Initials: _ _ _
Patient Date of Birth: _ / _ / _	Allocation Group: Intervention/Control
Date form completed: _ / _ / _	

Death (any cause):	Yes <input type="checkbox"/> No <input type="checkbox"/>
Description:	_____

Date of occurrence	_ / _ / _

Hospital Admission:	Yes <input type="checkbox"/> No <input type="checkbox"/>
Description:	_____

Was the admission as a result of a fall?	Yes <input type="checkbox"/> No <input type="checkbox"/>

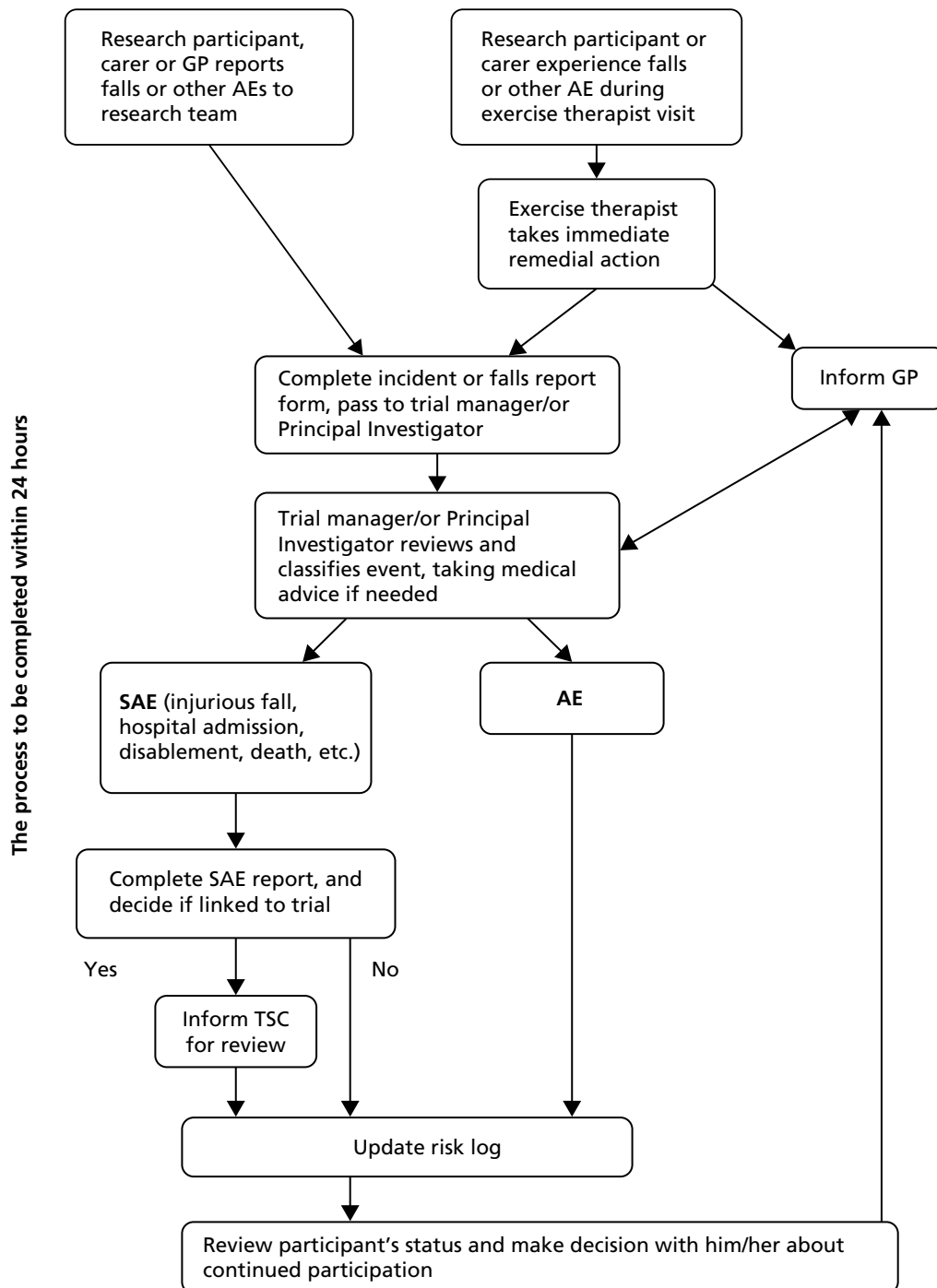
Injurious fall without Admission:	Yes <input type="checkbox"/> No <input type="checkbox"/>
Description:	_____

Fall During the exercise sessions:
Did a fall or medical event occur during an actual exercise session, requiring medical attention?
Yes <input type="checkbox"/> No <input type="checkbox"/>

Form completed by:	
_____ (Print name)	Date _ / _ / _____ (Signature)
Form reviewed by	
_____ (Print name)	Date _ / _ / _____ (Signature)

For Principal Investigator	
Is this event an SAE relating to patient safety in the trial?	
<input type="checkbox"/> Yes – inform TSC, convene meeting to discuss trial safety	
<input type="checkbox"/> No – no further action required	
Signed by Chair of TSC	Date

Appendix 13 Chapter 2: Risk management pathway



Appendix 14 Chapter 2: Diary – intervention group, example page

Date	Did you go out for a walk today? Yes/No	How many times?	How long was each of your walks? (in minutes) [e.g. walk1=10mins; walk2=20mins, etc]
What RPE did you achieve? Rating of Perceived Exertion (Please circle below) ___ 6 ___ 7 ___ 8 ___ 9 ___ 10 ___ 11 ___ 12 ___ 13 ___ 14 ___ 15 ___ 16 ___ 17 ___ 18 ___ 19 ___ 20 ___ no exertion very light light somewhat hard hard very hard extremely hard maximal exertion			
What did you enjoy about your walk/s?	What did you NOT enjoy about walk/s?	Did you complete the course set by the exercise therapist? Yes/No	
If you did NOT go out, why not? Please circle below Didn't feel like it / Something stopped me (i.e. pain, agitation, weather conditions)/ Carer unavailable/ Other (please describe below)			

Appendix 15 Chapter 2: Diary – control group, example page

Week 1			
Date	Did you go out for a walk today? Yes/No	How many times?	How long was each of your walks? (in minutes) [e.g. walk1=10mins; walk2=20mins, etc]
What did you enjoy about your walk/s?		What did you NOT enjoy about walk/s?	
If you did NOT go out, why not? Please circle below Didn't feel like it / Something stopped me (i.e. pain, agitation, weather conditions)/ Carer unavailable/ Other (please describe below).			

Appendix 16 Chapter 2: Intervention protocol

Within 5 working days of randomisation, the consultant is to visit the participant in the participant's own home at a time that is convenient to the participant and carer (Visit 1):

- explain the exercise regime to carer and patient
- explain diary including the use of a visual analogue scale for Rating of Perceived Exertion (RPE) (Borg)⁸³
- carry out local risk assessment for Carer–Patient dyad performing walking independently of study personnel
 - where risk is identified, the consultant agrees to record and report such risks to the Trial Manager within 24 hours
- join Carer–Patient dyad on walk of approximately 20–30 minutes (depending on ability) and record time and distance
- assess RPE and extend exercise to 60–70%, or 12–14 on 20-point scale
- support completion of diary and facilitate participant completion of RPE
- inform the Randomisation Officer when the first visit has been completed.

At Visits 2 (must be between 3 and 5 days of first visit) and 3 (must be within 8–10 days of first visit) – the consultant will:

- inquire and document the dyads' compliance with the exercise regime, and re-explain the regime/diary/RPE where required
- identify any barriers to adherence and suggest solutions where possible
- give general encouragement to maintain the exercise regime.

Up to 28 days from the first visit the consultant will respond to the participant–carer dyad by telephone on an 'as needs basis' for information about the exercise programme only.

- Where participants' requests extend beyond the exercise regime or the 28-day time period, the consultant will provide them with the contact details of the Trial Manager and log the contact with the Trial Manager within 48 hours.
- The Consultant will respond to any carer/patient telephone call within 48 hours.

At Visits 4 (must be within 41–45 days of first visit) and 5 (must be within 82–86 days of first visit) – the consultant will:

- join carer–participant dyad on walk of approximately 20–30 minutes (depending on ability) and record time and distance
- support completion of diary and facilitate participant's completion of RPE.

Appendix 17 Chapter 3: Overall EVIDEM-C protocol 2007

Introduction

Urinary and faecal incontinence in people with dementia is a major challenge for carers and professionals in supporting a person with dementia in their own home and a common trigger for admission to long-term care. Continence research and evidence-based guidance either explicitly excludes people with dementia (see for example NICE 2006)¹²² or addresses those in care home settings (see for example Ouslander *et al.* 2005).³⁴³ Current evidence-based guidelines on primary care management of dementia does not address incontinence management or its contribution to carer burden.³⁴⁴ This study is part of a wider programme of research and has the ultimate goal of developing and field testing evidence-based tool kit for the management of urinary and faecal incontinence with carers, community nurses, social care workers and home care staff. The elements within this study include: an investigation into the prevalence of incontinence problems in people with dementia living at home, the identification and testing of feasible and acceptable interventions for continence management in the home, and the development of educational packages tailored to informal carers and different groups of specialist and generalist health and social care professionals.

Background and rationale

Dementia affects over 4% of the people over 60, increasing to 13% for those over the age of 80 in Western Europe with significant projected increases in the next 20 years.³⁴⁵ Dementia has enormous impact not only for the individual and their family but also for the health and social care system.³⁴⁶ The median length of survival from diagnosis to death is 8 years, with a trajectory of progressive deterioration in cognition, abilities and physical functioning. In the later stages of the condition, people with dementia can present with complex and challenging problems including aggressive behaviour, restlessness and 'wandering', eating problems, incontinence, delusions and hallucinations, and mobility difficulties. Urinary and faecal incontinence are frequent symptoms as the disease progresses. Incontinence is the involuntary leakage of urine or stool or both.^{347,348}

The prevalence of any type of urinary incontinence in all older adults is between 6% and 10%, with increasing rates associated with old age.³⁴⁹ It is estimated that 2–5% of adults experience faecal incontinence.³⁵⁰ Incontinence lowers quality of life and impacts negatively on mental health^{351,352} as well as creates significant practical and financial problems. There is evidence that incontinence contributes significantly to other major health issues for older people such as falls.³⁵³ Incontinence has been identified by professional and older people as an issue of unmet need in primary care.^{354–356}

A United Kingdom (UK) population-based study of 15,000 home-dwelling people aged over 75 identified that 18.3% had cognitive impairment and of these 31% had urinary incontinence problems.¹³⁵ A national general practice audit of 999 older patients with faecal incontinence identified that 27% had a diagnosis of dementia.³⁵⁷ Estimates suggest that about 60% of people with cognitive impairment live in their own homes.³⁵⁸ For this group, there are no data on the prevalence over time of faecal incontinence or urinary incontinence problems to aid in service planning for the support of continence management or estimating cost consequences for households or primary care organisations.

Incontinence problems have been identified as a significant factor in increasing informal carer burden and triggering the admission of people with dementias to care homes.^{110,134,356} There is little literature that explores the nature and impact of managing bladder and bowel problems in people with dementia at home by informal carers. Two small scale qualitative investigations into informal carers views ($n = 12$) on managing frail spouses' incontinence suggested individual problem solving strategies^{359,360} that contributed further to carer stress such as decreasing their outside social contact. There is an absence of information that identifies both those aspects of incontinence problems and also the carer and service contexts that contribute to the admission to care homes. Anecdotal evidence suggests that faecal incontinence is the tipping point as far as carers are concerned whether they are able to continue supporting the person with dementia.³⁶¹ Evidence from care home settings suggest that carers had difficulty interpreting what the person with dementia wanted and therefore how best to manage their continence e.g. repeated requests to be taken to the toilet and refusal of medication to ease constipation.³⁶²

Assisting older people remain in their own homes, improving continence care and addressing carer burden are priorities for the health and social care improvement and service frameworks.^{363–365} People with dementia receive services from both generalist primary care services and specialist mental health care of older people. They may also receive support from social workers (generalist or specialist) and publicly funded social care assistance. Incontinence is a clinical issue that often has low priority in generalist primary care services and specialist mental health care services. Specialist continence services are not currently available in all areas of the UK.^{366,367} However, there is no current evidence-based guidance for addressing problems of incontinence in people with dementia living at home. Evidence-based guidance in continence management has been developed by a number of agencies^{111,122,156,365,368} however, these either point to the evidence gaps in treatment and management for frail older people (e.g. SIGN 2004)¹²¹ or exclude people with cognitive impairment (e.g. NICE 2006).¹²² Current evidence-based guidelines on primary care management of dementia does not address incontinence management or its contribution to carer burden.³⁴⁴

Aims and research questions

The aims of this study are to:

1. identify the prevalence of different types of incontinence problems experienced by people with dementia and the associated cost consequences over a 3-year period
2. identify and test feasible and acceptable interventions for continence management in the home.

The specific research questions are:

1. What is the prevalence of different types of incontinence problems experienced by people with dementia, living at home, and their carers, over a 3-year period?
2. What is the evidence for different strategies and interventions in managing incontinence in people with dementia living at home?
3. What are the perceived factors that support or detract from the use of different interventions (identified in question 2) from the perspective of informal carers, generalist and specialist health-care staff, social workers and social care?
4. Are the interventions (identified in questions 2 and 3) feasible, acceptable, effective and appropriate in the home setting from the perspective of the person, their carer(s), professionals and public service delivery?

Method

The overall research approach is one of critical realism³⁶⁹ which allows an integration of both subjective and objective research approaches and makes explicit the interrelationships between context, process, interventions (mechanisms) and outcomes.³⁷⁰ In taking this approach, the multifaceted nature of the issues and problems in managing incontinence in the home, as well as the perspectives of multiple and diverse stakeholders can be examined in the light of the evidence of effectiveness. This research approach allows the study to acknowledge the complexity of the issues. The study therefore draws on more than one methodology for generating evidence and knowledge. There are three elements leading to the fourth element of producing and field testing educational packages tailored to informal and formal carers and different groups of specialist and generalist health and social care professionals. The three elements are:

Element 1 The establishment of period prevalence of different types of incontinence problems in a community-dwelling cohort through interview survey at three points during the 5-year programme span. This data will be obtained as part of the broader set of enquiries on 'transitions' undertaken with a sample of people and their carers enrolled in the parent cohort study.

Element 2 The development of feasible and acceptable interventions for incontinence management through:

1. A systematic review of the evidence, which integrates evidence from both quantitative and qualitative, approaches (Dixon-Woods *et al.* 2004).³⁷¹
2. Qualitative exploration of people with dementia, carers and professionals views of problems and potential interventions through:
 - i. Up to 25 (or until saturation is reached) semi-structured individual interviews and four group interviews with informal care givers using adapted structured focus group techniques¹³⁴ to explore perceptions of the problems and acceptability or consequences of different types of interventions.
 - ii. Up to 10 exploratory discussions (rather than semi-structured interviews) with people with dementia regarding their perceptions of problems with going to the toilet or lack of control.
 - iii. Up to eight group interviews with health and social care professionals employing adapted structured focus group techniques¹²⁵ on their perceptions of the problems and acceptability or consequences of different types of interventions.

Element 3 The testing of the identified interventions for feasibility, acceptability and cost consequences³⁷² with up to 40 people with dementia (the exact number to be determined following the evidence revealed by one and their carers over 12 months). The detailed methods for element 3 are dependent on results from element 2. A subsequent protocol will be developed for this.

Element 1 method

This element addresses research question 1. The research design for this element is a repeated descriptive survey. It is a nested study within the broader cohort 'longitudinal study of transitions', which addresses a broader range of health and social topics. The survey questions are repeated annually over 3 years. The rationale for embedding this element in a broader study is that most adults find discussion of bowel and bladder problems deeply embarrassing and often shameful. Adults are unlikely to volunteer to participate in a study that focuses on this issue in isolation; however, they are likely to be more willing to discuss it in the wider contexts of their daily life.

The sample

The sample will be people with cognitive impairment, living at home, and their carers within the cohort who have agreed to participate in the 'longitudinal study of transitions'. The recruitment for this longitudinal study will be recruited via health, social work and social care professionals. Recruitment and consent processes are in line with the overall EVIDEM programme principles.

The data collection and tools

There are no data collection tools on incontinence specifically validated for a population of cognitively impaired people. The study advisory group and user group will provide expert opinion on drawing together the most appropriate and acceptable validated tools (e.g. Leicester Urinary Symptom Questionnaire)³⁷³ plus additional questions to describe symptoms, severity, impact, causes and contributing factors e.g. motor/mobility deficits, behavioural problems, management strategies and associated costs. While population-based surveys of incontinence problems have found that postal methods are acceptable (Perry *et al.* 2002³⁵⁰) it is unlikely to be feasible with this group of people and their carers. It is anticipated that this will be an interviewer delivered survey and that the interviewer will proceed with the interview in conversational ways rather than as a checklist set of questions which are more likely to distress and agitate people with dementia. The survey questions on this topic will be piloted as part of the wider longitudinal survey and amended as necessary. The survey interviews will be undertaken at three points in time over 3 years. The feasibility of carer completed diaries of continence related problems will also be explored as these have been used successfully in some other studies. It is possible that after the first survey, some carer informants may prefer and be willing to complete a postal survey.

Data analysis

The data will be entered on to a SPSS™ software programme and analysed descriptively in the first instance and subsequently for correlates between types of incontinence, management strategies and demographic and mental and physical condition factors.

Timetable

	Year 1	Year 2	Year 3	Year 4
Advisory group and user group	X	X	X	X
Developing data collection tools	X			
Ethics and research governance (linked to broader study)	X			
Recruitment and piloting (linked to broader study)	X			
Recruitment and data collection and analysis time period 1	X			
Data collection and analysis time period 2		X		
Data collection and analysis time period 3			X	
Overall data analysis and report writing				X

Element 2 method

This element addresses research questions 2 and 3.

The systematic literature search

A systematic review of the published and unpublished literature on continence management community-dwelling older people with dementia and their carers will be undertaken using methods developed by the Cochrane Collaboration³⁷⁴ and the Social Care Institute for Excellence,³⁷⁵ incorporating both qualitative and quantitative evidence. The scope of the review will include:

- studies that offer continence care, management and educational-based interventions with people with dementia and their carers in primary care settings including patients' own home
- studies that consider services operated within developed health economies and focus on research undertaken in the UK, Europe, Australasia and North America where there is a similarity in the age distribution of the populations and comparable methods of health-care delivery.

Excluded from the review will be:

- Studies that are hospital based and nursing home based. It is not within the scope of this review to include foreign language papers.

The review will then proceed in stages:

1. Search the literature across a wide range of health and social care electronic databases including MEDLINE, EMBASE, CINAHL, PsycINFO BNI, CAREDATA, Cochrane Library (including DARE, NTIS, SIGLE), Social Science Citation index, Age Info, National Research register, Papers First (conference presentations) and the specialised register of the Cochrane Effective Practice and Organisation of Care Group (EPOC), Dissertation Abstracts, Department of Health and similar websites. Preliminary searching will begin with a strategy based on keyword/index (MeSH) terms. The two main themes will be dementia and incontinence. In addition 'lateral searching' techniques will be used such as checking reference lists of relevant papers, and using the 'Cited by' option on WoS, Google Scholar and Scopus, and the 'Related articles' option on PubMed and WoS, as recommended in searching for studies of complex interventions.¹²⁶ In addition, leading researchers and expert practitioners in the field will be contacted to help identify unpublished research. Key publications linked to dementia care and incontinence management that are not indexed on databases will be hand searched.
2. Abstracts and brief records from databases will be screened by two researchers for relevance to the research questions 2 and 3 and filed in a bibliographic management package (RefMan 10).
3. A common data extraction sheet will be developed for study quality appraisal and evidence relevant to research questions 2 and 3 (above). Each retrieved study will be assessed by two researchers independently. The initial aim will be to identify and classify interventions to incontinence care for community-dwelling older people with dementia.
4. The evidence will be synthesised and a report produced.

The findings from the review will inform the second element of this phase.

Method: the exploration of perceptions of feasible and acceptable interventions for continence management (the qualitative interview studies)

This stage uses qualitative methods to explore perceptions of feasibility and acceptability of different types of strategies for incontinence management from the perspectives of the three groups of key stakeholders: the people with dementia, the informal carers of people with dementia and professionals (generalist and specialists) providing services to people with dementia in their own home. Three data collection methodologies will be used by:

1. up to 25 (or until saturation is reached) semi-structured individual interviews and four group interviews with informal care givers using adapted structured focus group techniques¹²⁵ to explore perceptions of the problems and acceptability or consequences of different types of interventions
2. up to 10 exploratory discussions (rather than semi-structured interviews) with people with dementia regarding their perceptions of problems with going to the toilet or lack of control
3. up to eight group interviews with health and social care professionals' employing adapted structured focus group techniques¹²⁵ on their perceptions of the problems and acceptability or consequences of different types of interventions.

Sample recruitment

The study user advisory group will be consulted on suitable wording for recruitment materials and data collection tools. Recruitment for carers and people with dementia will take place via local Alzheimer's Society branches. Recruitment of professionals will take place through local service generalist and specialist services. Each structured focus group will have between 8 and 12 participants.

Data collection and analysis

The structured focus group interviews will be led by an experienced researcher, with another researcher present to take research field notes.³⁷⁶ The lead researcher will record the key issues and views on flip chart, using some of the techniques of nominal group technique (NGT)⁴³ to focus the discussions on the key research questions. With permission the group discussion will be taped as an aide to the record of the group which will be typed up from the flip charts and the filed notes. The record of the groups interviews will be analysed in NVivo™ software using a template methodology,³⁷⁷ derived from a priori theories derived from the literature review but also allowing new themes and issues to be identified. The semi-structured interviews will be guided by an aide-memoire¹²⁵ developed from the literature in the first phase. Interviews will be recorded with permission, transcribed (tapes destroyed) and analysed with the same template framework as used for the NGT groups using NVivo™ software. The exploratory discussions with people with dementia are forms of semi-structured interviews that are much more flexible in their approach, using conversational techniques rather than lists of questions,³⁷⁸ to assist participation by people with dementia. The exploratory discussions will focus around views and feelings related to bladder, bowel and toilet problems rather than questions that require detailed recall.³⁷⁹ With permission the discussions will be recorded, transcribed (recording destroyed) into the NVivo™ software package and analysed as described above. The findings between the different stakeholders will be compared and contrasted and the evidence used with that of the findings from the systematic review to design element 3.

Ethical considerations

Participants' information sheets will be developed in consultation with the research advisory and study user reference group. Participants will be recruited having been provided with full information about the study, its processes and data uses. The consenting process for people with dementia will conform to that agreed for the EVIDEM research programme and for all participants researchers will make it clear that individuals will be free to withdraw at any point in the research process. The Individuals in interview process will be assured confidentiality and anonymity in data processing (through assignment of a study identification number) and subsequent reporting. Participants in group interviews will be known to each other and each interview will start with group agreements on the level of confidentiality those participants feel

comfortable with. Quotations from participants may be used but in a way that will not reveal identities. All data will be kept on password protected computers and locked filing cabinets. Each participant will be made aware that the researchers have a duty of care should any information be revealed that suggests a vulnerable adult is being neglected or abused in any way.

Timescale

	Year 1	Year 2	Year 3	Year 4
Advisory group and user group	X	X	X	X
Systematic literature review	X			
Ethics and research governance for element 2b	X			
Data collection 2b interviews and focus groups	X			
Data analysis and report writing	X	X		
Development of protocols for element 3	X	X		

Establishment of research and user advisory group

It is anticipated that a group of professionals with interests in the care of people with dementia and incontinence and service users/carers will be formed to advise on the conduct of this work stream. It is anticipated that there will be an initial and annual meeting but most work will be undertaken by e-communication.

Dissemination

The dissemination strategy is part of the overall EVIDEM strategy to submit material for lay and professional audiences, participate in Central and North West London NHS Foundation Trust research events and submit to present orally in relevant conferences.

Appendix 18 Chapter 3: Protocol – exploring issues and solutions in promoting continence and managing incontinence with people with memory problems living at home and their carers, 2008

Introduction

Urinary or faecal incontinence are distressing symptoms for any adult that impact on many facets of an individual's health and quality of life. Professional knowledge and public awareness is increasing the availability of an evidence base in treatment and best practice.^{121,362,380} However, people with memory problems and dementia living at home are one group for whom there is little guidance on promoting continence or managing incontinence. Incontinence problems are a common element in the decisions to move into a care home.^{134,356} Continence research and evidence-based guidance either explicitly excludes people with dementia (see for example National Institute of Clinical Excellence 2006)¹²² or more commonly includes only those people living in care home settings (see for example Ostaszkievicz *et al.* 2004).³⁶⁸ Evidence-based guidelines produced in 1998 for primary care staff on supporting people with dementia and their carers did not address incontinence management.¹²³ The recent NICE–SCIE guideline on supporting people with dementia and their carers¹²⁴ does not review evidence in relation to continence promotion but offers the view that combined interventions are more likely to support and maintain independence in the person with dementia.

EVIDEM C is a part of the NIHR funded programme of research (Principal Investigator Professor Steve Iliffe, University College London). It has the ultimate goal of developing and field testing an evidence-based resource for the promotion of continence and management of urinary and faecal incontinence with carers, community nurses, and social care staff.

Background and rationale

Dementia affects over 4% of the people over 60, increasing to 13% for those over the age of 80 in Western Europe with significant projected increases in the next 20 years.³⁴⁵ Dementia has enormous impact not only for the individual and their family but also for the health and social care system.^{119,296,346} The median length of time from diagnosis to death is 10 years for those under 65 at diagnosis and 4 years for those over 80 years.¹⁷³ The clinical syndrome of dementia has a trajectory of progressive deterioration in cognition, abilities, and physical functioning. The impairment experienced by the individual is often compounded by extrinsic factors such as attitudes of 'therapeutic nihilism'¹¹⁵ in professionals, unadapted environments, and social exclusion. As the condition progresses problems may arise in maintaining independence in going to the toilet, in avoiding constipation, and in managing incontinence problems that cannot be resolved. Estimates suggest that there are 500,000 people with dementia in England and two-thirds live at home.¹¹⁹

Incontinence is the involuntary leakage of urine or stool or both.^{347,349} The prevalence of any type of urinary incontinence in all older adults is between 6% and 10%, with increasing rates associated with old age.³⁴⁹ It is estimated that 2–5% of adults experience faecal incontinence.³⁵⁰ Incontinence lowers quality of life and impacts negatively on mental health^{351,352} as well as creates significant practical and financial problems. There is evidence that incontinence contributes significantly to other major health issues for older people such as falls.³⁵³ Incontinence has been identified by professionals and older people as an issue of unmet need in primary care.^{354,355,366}

A UK population-based study of 15,000 home-dwelling people aged over 75 identified that 18.3% had cognitive impairment and of these 31% had urinary incontinence problems.¹³⁵ A national general practice audit of 999 older patients with faecal incontinence identified that 27% had a diagnosis of dementia.³⁸¹ Estimates suggest that about 60% of people with cognitive impairment live in their own homes.³⁵⁸

For this group, there are no data on the changes over time in continence status to aid in service planning for the support of continence management or estimating cost consequences for households or primary care organisations.

Incontinence problems have been identified as a significant factor in increasing informal carer burden and triggering the admission of people with dementias to care homes.^{110,134,356} There is little literature that explores the nature and impact of managing bladder and bowel problems in people with dementia at home by informal carers. Two small scale qualitative investigations into informal carers views (total $n = 12$) on managing frail spouses' incontinence^{359,360} suggested that individual problem solving strategies might contribute further to carer stress through decreasing their outside social contact. There is an absence of information that identifies both those aspects of incontinence problems and also the carer and service contexts that contribute to the admission to care homes. Anecdotal evidence suggests that faecal incontinence is the tipping point as far as carers are concerned whether they are able to continue supporting the person with dementia.³⁶¹ Evidence from care home settings suggest that formal carers had difficulty interpreting what the person with dementia wanted and therefore how best to manage their continence, e.g. repeated requests to be taken to the toilet and refusal of medication to ease constipation.³⁶²

Assisting older people to remain in their own homes, improving continence care and addressing carer burden are priorities for the health and social care improvement and service frameworks (DOH 1998, 2000, 2001).³⁶³⁻³⁶⁵ People with dementia receive services from both generalist primary care services and specialist mental health care of older people. They may also receive support from social workers (generalist or specialist) and publicly funded social care assistance. Incontinence is a clinical issue that often has low priority in generalist primary care services and specialist mental health care services. Specialist continence services are not currently available in all areas of the UK.³⁵⁶ Evidence-based practice guidance is not currently available to assist professionals and staff in generalist services in their support of people with dementia living at home and their carers.

Study aim and research approach

This study draws on the Medical Research Council (MRC 2000)⁵⁶ Framework for developing complex interventions in using stepwise phases. The study has a number of linked phases commencing with an integrative review of the literature,³⁶⁷ which is currently in progress. The research approach is one of critical realism³⁶⁹ which allows an integration of both subjective and objective research approaches and makes explicit the interrelationships between context, process, interventions (mechanisms) and outcomes.³⁷⁰ In taking this approach, the multifaceted nature of the issues and problems in promoting continence and managing incontinence in the home, as well as the perspectives of multiple and diverse stakeholders can be examined in the light of the evidence of effectiveness. This research approach allows the study to acknowledge the complexity of the issues.

The research questions for this phase of the study are:

1. What is the evidence for different strategies and interventions in promoting continence and managing incontinence in people with dementia living at home? (Addressed by the integrative review of the literature.)
2. What is the experience and perceptions of people with dementia and their close carers regarding the problems and successful strategies for promoting continence and managing incontinence at home?

The results from this phase will then be used to develop feasibility studies of potential interventions, which will be submitted for peer and ethical review.

The development of this protocol has been informed by the EVIDEM and EVIDEM-C advisory group, which involves service users and carers.

Method

The methodology is qualitative, in the interpretive tradition, using individual and group interviews.

The sample and recruitment

Informal carers and people with dementia (up to 55 people) will be recruited through (a) invitation letters in local North London Alzheimer's Society branch newsletters and (b) invitation letters being distributed to service users with memory problems and their carers, who might be interested in participating, by professional staff in the day and community services for older people with mental health problems (primarily those provided by Central and North West London NHS Trust). It is anticipated that people with dementia likely to be willing to participate would be at the mild to moderate stage of the disease progression.

Those individuals willing to participate will make contact with the researcher who will send them the participant information leaflet and arrange a time to meet at their home or another community service venue convenient for them. At the meeting the research will be explained and consent sought to participate (see section below on detailed ethical considerations and mental capacity).

Data collection and analysis

Data will be gathered through:

- Up to 25 (or until saturation is reached) semi-structured individual interviews with close care givers to explore perceptions of the problems, their criteria for success in promoting continence and managing incontinence, and their experience of successful strategies in promoting continence and managing incontinence. These will be face to face or by telephone as the person chooses.
- Up to four group interviews (approximately five per group) with close care givers using adapted structured focus group techniques³⁶⁹ to gain their views on the feasibility and acceptability of different types of strategies/interventions identified from the literature. From the data gathered, individual interviews will be undertaken with carers and professionals. If group interviews are not feasible logistically or in terms of numbers then individual interviews (face to face or by telephone as the person chooses) will be conducted.
- Up to 10 exploratory discussions¹⁶⁴ with people with mild to moderate dementia regarding their feelings and experience of problems with going to the toilet and different types of help.

Semi-structured interviews with individuals will use an aide memoire to ensure key themes are explored. Interviews will be taped, with permission, transcribed and the tapes deleted. Each transcription will only be known by an identifying number not the person's name and all items that might identify the informant, such as names, will be made anonymous. The transcriptions will be entered into a software programme, NVivo™, to aid data management. Content analysis³⁷⁰ will be undertaken by two researchers, independently and compared, to aid validation of the analysis.

Small group interviews will be conducted by two researchers. One will lead the discussion using the same topics as in the aide memoire and the other will take notes. The group's discussion points will be summarised on flip chart to aid verification from the group of the issues raised and views expressed. The notes and flip chart will be transcribed into word documents and entered into NVivo™ for cross comparison and analysis between groups and themes from individual interviews.

Exploratory discussions with individuals with dementia will be much more conversational and centre on two questions:

- What sort of problems do you have with going to the toilet? *and*
- What helps you when you have these problems?

It is anticipated that the conversation is likely to be in the presence of the person's spouse/close carer if they have one. The emphasis in the exploratory discussion will be on experiences and feelings not 'facts'. Exploration on views of different types of help will only be explored if the person is comfortable with the discussion and willing to continue. The conversation will be taped, with permission. If permission is not given, permission for taking notes will be sought. The tapes or notes will then be treated in the same way as the transcriptions of the semi-structured interview as above.

Ethical considerations

The research questions under consideration are directly relevant to people who have dementia and it is important to incorporate views of those people experiencing the problems not just the professional views or their family members.³⁸² People who have dementia may lack capacity to consent. Only those people with dementia with the capacity to make the decision to participate in the research will be included. The procedure for establishing the ability to make the decision will proceed in accordance with the guidance for the Mental Capacity Act 2005. People with dementia will only be approached after their close family carer or a professional who knows them well enough to judge their ability to consent to participation in the study, has discussed the research first and asked whether they would be willing to meet the researcher. This person will explain about the research and the exploratory discussion process using the information leaflet which has been adapted to provide key points in straight forward language. After consent to approach the person has been gained, the researcher will arrange to meet them with their carer or supporting person of their choice. She will repeat the explanations, using the leaflet and check the person is able to consent at that point in time. Key elements in checking will be: whether the person has general understanding of what they are consenting to and why they are being asked to make it, whether the person understands what will happen if they agree to participate in the study, whether they are they able to understand the verbal and/or written information relevant to making a decision whether to participate in the study. A consent form for signing will be offered, although if the informant is unwilling to sign (writing may be difficult) this will not be pursued and verbal consent will be noted. Any sign (verbally or in body language) that the individual is not happy about taking part or continuing to take part in the research will be interpreted as withholding consent, or a desire to withdraw. The researcher will end the conversation, thanking the person for their time and involvement. The researcher will check throughout the discussion that the informant is willing to continue and cease if the person indicates they wish the discussion to end.

Urinary or faecal incontinence are distressing symptoms that are embarrassing to discuss for any adult. Undertaking intimate care associated with incontinence for an adult spouse, relative or loved one is a sensitive issue. All interviews will be conducted by researchers aware of the potential socially problematic nature of the issues that are being discussed. Interviewers will use language understandable and acceptable to the interviewee and make all efforts to lessen any discomfort in discussing the issues. Should an individual become distressed then the interviewer will pause, be sympathetic, and check whether the person wishes to discontinue the interview. The researcher will encourage informants to share their problems and distress with their key health professional, or family doctor as appropriate. All researchers will have contact information on key support agencies to leave with informants.

All informants will be assured of anonymity and confidentiality in the transcription, analysis and reporting of their interview. Any direct quotations used in the report will be non-attributable. At the start of the group interviews, informants will be asked to respect that views and opinions expressed in the interview are held confidential to the group.

Informants will be made aware that if any information is shared that suggests that a vulnerable older adult is suffering neglect or abuse then the researcher has a responsibility to share that information with the service manager (in case of abuse or neglect from a service provider) or in the case of individuals gain their consent to share that information with the named Local Authority Officer for vulnerable adults.

Data protection considerations

All participants will be assigned a code number and this with their contact details will be kept separately and securely from any data collected in the process of the research. This file will be registered with the University data manager. All research data will be identifiable by code number alone. Audiotapes will be transcribed and deleted. The transcribed interviews will be entered stored on a password protected computer, accessible only to the researchers in locked offices the University. Hard copies of data will be stored in locked filing cabinets in the same offices. Research data will be archived for 5 years and then destroyed.

Timescale

Interviews – July and August 2008

Analysis – August and September 2008

Report writing – September 2008

Feedback to participants – end of September 2008

Reports and dissemination

The findings will be written up as a brief report for circulation to participants. A full report will be used as the basis for papers and articles to be submitted to a professional journal and local and national voluntary organisation's newsletters. An abstract will be submitted for presentation at a service users and professional conference, such as Dementia Congress.

Appendix 19 Chapter 3: Protocol – professional views of current issues and solutions in promoting continence and managing incontinence with people with memory and cognition problems living at home

This protocol concerns the investigation of the views of health and social care professionals and staff of current issues and solutions in promoting continence and managing incontinence with people with memory and cognition problems, and their carers, living at home. (NB. The views of people with these problems and their carers are also being investigated under a separate study protocol.)

Introduction

Urinary or faecal incontinence are distressing symptoms for any adult that impact on many facets of an individual's health and quality of life. Professional knowledge and public awareness is increasing the availability of an evidence base in treatment and best practice.^{119,124,362} However, people with memory problems and dementia living at home are one group for whom there is little guidance on promoting continence or managing incontinence. Incontinence problems are a common element in the decisions to move into a care home.^{343,356} Continence research and evidence-based guidance either explicitly excludes people with dementia (see for example National Institute of Clinical Excellence 2006)¹²² or more commonly includes only those people living in care home settings (see for example Ostaszkievicz *et al.* 2004).³⁶⁸ Evidence-based guidelines produced in 1998 for primary care staff on supporting people with dementia and their carers did not address incontinence management.¹²³ The recent NICE–SCIE guideline on supporting people with dementia and their carers³⁸⁰ does not review evidence in relation to continence promotion but offers the view that combined interventions are more likely to support and maintain independence in the person with dementia.

This investigation of professional views is part of a larger study (EVIDEM-C) which has the ultimate goal of developing and field testing an evidence-based resource for the promotion of continence and management of urinary and faecal incontinence with carers, community nurses and social care staff. EVIDEM-C is a part of the NIHR funded programme of research (Principal Investigator Professor Steve Iliffe, University College London website: www.evidem.org.uk).

Background and rationale

Dementia affects over 4% of the people over 60, increasing to 13% for those over the age of 80 in Western Europe with significant projected increases in the next 20 years.³⁴⁵ Dementia has enormous impact not only for the individual and their family but also for the health and social care system.^{119,296,346} The median length of time from diagnosis to death is 10 years for those under 65 at diagnosis and 4 years for those over 80 years.¹⁷³ The clinical syndrome of dementia has a trajectory of progressive deterioration in cognition, abilities, and physical functioning. The impairment experienced by the individual is often compounded by extrinsic factors such as attitudes of 'therapeutic nihilism'¹¹⁵ in professionals, un-adapted environments, and social exclusion. As the condition progresses problems may arise in maintaining independence in going to the toilet, in avoiding constipation, and in managing incontinence problems that cannot be resolved. Estimates suggest that there are 500,000 people with dementia in England and two-thirds live at home.¹¹⁹

Incontinence is the involuntary leakage of urine or stool or both.^{347,349} The prevalence of any type of urinary incontinence in all older adults is between 6% and 10%, with increasing rates associated with old age.³⁴⁹ It is estimated that 2–5% of adults experience faecal incontinence. Incontinence lowers quality of life and impacts negatively on mental health^{351,352} as well as creates significant practical and financial problems. There is evidence that incontinence contributes significantly to other major health issues for older people such as falls.³⁵³ Incontinence has been identified by professionals and older people as an issue of unmet need in primary care.^{354,355,381}

A UK population-based study of 15,000 home-dwelling people aged over 75 identified that 18.3% had cognitive impairment and of these 31% had urinary incontinence problems.¹³⁵ A national general practice audit of 999 older patients with faecal incontinence identified that 27% had a diagnosis of dementia.³⁶⁷ Estimates suggest that about 60% of people with cognitive impairment live in their own homes.³⁵⁶ For this group, there are no data on the changes over time in continence status to aid in service planning for the support of continence management or estimating cost consequences for households or primary care organisations.

Incontinence problems have been identified as a significant factor in increasing informal carer burden and triggering the admission of people with dementias to care homes.^{110,134} There is little literature that explores the nature and impact of managing bladder and bowel problems in people with dementia at home by informal carers. Two small-scale qualitative investigations into informal carers views (total $n = 12$) on managing frail spouses' incontinence^{359,360} suggested that individual problem solving strategies might contribute further to carer stress through decreasing their outside social contact. There is an absence of information that identifies both those aspects of incontinence problems and also the carer and service contexts that contribute to the admission to care homes. Anecdotal evidence suggests that faecal incontinence is the tipping point as far as carers are concerned whether they are able to continue supporting the person with dementia.³⁶¹ Evidence from care home settings suggest that formal carers had difficulty interpreting what the person with dementia wanted and therefore how best to manage their continence, e.g. repeated requests to be taken to the toilet and refusal of medication to ease constipation.³⁶²

Assisting older people to remain in their own homes, improving continence care and addressing carer burden are priorities for the health and social care improvement and service frameworks (DOH 1998,³⁶³ 2000,³⁶⁵ 2001³⁶⁴). People with dementia receive services from both generalist primary care services and specialist mental health care of older people. They may also receive support from social workers (generalist or specialist) and publicly funded social care assistance. Incontinence is a clinical issue that often has low priority in generalist primary care services and specialist mental health care services. Specialist continence services are not currently available in all areas of the UK.³⁶⁷ Evidence-based practice guidance is not currently available to assist professionals and staff in generalist services in their support of people with dementia living at home and their carers.

Aims

This investigation is part of a larger study (EVIDEM-C), which has the ultimate goal of developing and field testing evidence-based resources for the promotion of continence and management of urinary and faecal incontinence with people with dementia, close carers, primary care professionals, social care and home care staff. EVIDEM-C draws on the Medical Research Council (MRC 2000)⁵⁶ Framework for developing complex interventions in using stepwise phases. The research approach is one of critical realism³⁶⁹ which allows an integration of both subjective and objective research approaches and makes explicit the interrelationships between context, interventions (mechanisms) and outcomes.³⁷⁰ In taking this approach, the multifaceted nature of the issues and problems in promoting continence and managing incontinence in the home, as well as the perspectives of diverse stakeholders can be explored.

This investigation asks the questions:

- What are the views of health and social care professionals and staff of (a) current issues and (b) currently employed solutions in promoting continence and managing incontinence with people with memory and cognition problems, and their carers, living at home?
- From professional and clinical experience, are there strategies/advice/interventions/aids/support/technology that appear to be more acceptable and effective in supporting people living at home?
- From professional and clinical experience, are there gaps in the knowledge and/or provision to appropriately support people and their carers in dealing with these issues?

The results from this investigation will be both fed to local participating services and used to develop feasibility studies of potential interventions, which will be submitted for peer and ethical review.

The development of this protocol has been informed by the EVIDEM-C advisory group, which involves service users and carers.

Methods

The methodology is qualitative, in the interpretative tradition, using small group and individual interviews. The sample is purposive to capture views from a diverse range of professional and staff groups across health and social care services in different inner urban and urban areas within the North Thames DeNDRoN research network area (URL: http://www.dendron.org.uk/rn/north_thames.html).

Professional groups include:

- staff in older people mental health services providing day, outreach, and domiciliary services (likely staff groups include community mental health nurses, social workers, occupational therapists, admiral nurses)
- staff in Primary Care Trust Provider Services providing domiciliary services to older people (likely staff groups include district nursing, community nursing, physiotherapists) and continence/bowel and bladder services
- staff in independent service providers of home care and day centres for older people (likely staff groups include home care organisers, day centre managers)
- staff in Local Authority Adult Service Departments (likely staff groups include social workers, in house home care managers and carers)
- general practitioners and practice nurses (approached via the Greater London Primary Care Research Network).

The initial approach will be to a senior manager of the organisation to explain the investigation and seek permission to approach staff to volunteer. Requests for volunteers and participation information sheets will be circulated to staff. If it is not possible to organise small groups in convenient work locations then face-to-face or telephone interviews will be conducted as preferred.

Data will be gathered through:

- Group interviews (approximately 5–8 per group) using adapted structured focus group techniques (Robson 2004)³⁶⁹ based on the research questions outlined above or
- Individual semi-structured interviews based on the research questions outlined above. These will be face to face or by telephone as the person chooses.

Small group interviews will be conducted by two researchers. One will lead the discussion using the same topics as in the aide memoire and the other will take notes. The group's discussion points will be summarised on flip chart to aid verification from the group of the issues raised and views expressed. The notes and flip chart will be transcribed into word documents and entered into NVivo™ for cross comparison and analysis between groups and themes from individual interviews. Semi-structured interviews with individuals will be recorded in field notes to be comparable with the data gathered in the group interviews. These will be entered into MS Word documents and treated as above. Content analysis³⁷⁰ will be undertaken by two researchers, independently, and compared to aid validation of the analysis.

Ethical and data protection considerations

All informants will be assured of anonymity and confidentiality in the transcription, analysis and reporting of their interview. Any direct quotations used in the report will be non-attributable. At the start of the group interviews, informants will be asked to respect that views and opinions expressed in the interview are held confidential to the group.

Informants will be made aware that if any information is shared that suggests that a vulnerable older adult is suffering abuse from a service provider then the researcher has a responsibility to share that information with the service manager.

All participants will be assigned a code number and this with their contact details will be kept separately and securely from any data collected in the process of the research. All data will be identifiable by code number alone. Data collected in group interviews will not have any identifying information on it. Data will be stored on a password protected computer, accessible only to the researchers in locked offices of the University. Hard copies of data will be stored in locked filing cabinets in the same offices and destroyed after the investigation is completed.

This protocol is deemed as service evaluation by the NHS Research Ethics Service and does not require an NHS ethics committee review. The protocol complies with the ethical review procedures of the host University.

Reports and dissemination

The findings will be written up as a brief report for circulation to participants. A full report will be used as the basis for papers and articles to be submitted to professional and service orientated journals. The findings will be used to develop feasibility studies of possible interventions/services and develop an evidence-based resource for the promotion of continence and management of urinary and faecal incontinence with people with dementia, close carers, primary care professionals, social care and home care staff.

Appendix 20 Chapter 3: Protocol – investigating the experience of managing continence problems over time, version 2, 2010

This study protocol originally had greater emphasis on quantitative elements of a cohort study. Unfortunately the difficulties in recruiting people into the study led to an amendment with greater emphasis on the qualitative elements.

Introduction

Urinary or faecal incontinence are distressing symptoms for any adult that impact on many facets of an individual's health and quality of life. It is estimated that up to a third of people with memory problems living at home have incontinence problems. Incontinence is known to be a significant factor in the decision for people with memory problems and dementias to take up residence in a care home. This is an aspect of the health and well-being of people with memory loss that is poorly described both in its trajectory and the factors that promote the maintenance of continence and the management of incontinence at home. This lack of detailed knowledge of the issues and effective management strategies is reflected in the lack of guidance for people with dementia, their carers and health and social care professionals to address these problems.

This study aims to prospectively follow a group of people with dementia with continence problems and their carers for up to 3 years to describe the type of problems, the management strategies, the lived experience of the family carers and the person with dementia and the impact and cost of managing these problems.

This is one study in a group of studies known as EVIDEM-C which has the ultimate goal of developing and field testing an evidence-based resource for the promotion of continence and management of urinary and faecal incontinence with people with dementia, close carers, community nurses, social care workers and home care staff. In addition data from this study will assist in the planning of future studies which test interventions to help manage incontinence. EVIDEM-C is a part of the NIHR funded programme of research 'Changing practice in dementia care in the community: developing and testing evidence-based interventions, from timely diagnosis to end of life'. The chief investigator is Professor Steve Iliffe, University College London.

Background and rationale

Dementia affects over 4% of the people over 60, increasing to 13% for those over the age of 80 in Western Europe with significant projected increases in the next 20 years.³⁴⁵ Dementia has enormous impact not only for the individual and their family but also for the health and social care system.^{119,296,346} The median length of time from diagnosis to death is 10 years for those under 65 at diagnosis and 4 years for those over 80 years.¹⁷³ The clinical syndrome of dementia has a trajectory of progressive deterioration in cognition, abilities, and physical functioning. The impairment experienced by the individual is often compounded by extrinsic factors such as attitudes of 'therapeutic nihilism'¹¹⁵ in professionals, unadapted environments, and social exclusion. As the condition progresses problems may arise in maintaining independence in going to the toilet, in avoiding constipation, and in managing incontinence problems that cannot be resolved. In addition, there can be behavioural and psychological problems such as disinhibition, apathy, and faecal smearing. Estimates suggest that there are 500,000 people with dementia in England and two-thirds live at home.¹¹⁹

Incontinence is the involuntary leakage of urine or stool or both.^{347,349} The prevalence of any type of urinary incontinence in all older adults is between 6% and 10%, with increasing rates associated with old age.³⁴⁹ It is estimated that 2–5% of adults experience faecal incontinence. Incontinence lowers quality of life and impacts negatively on mental health^{351,352} as well as creates significant practical and financial problems. There is evidence that incontinence contributes significantly to other major health issues for older people such as falls.³⁵³ Incontinence has been identified by professionals and older people as an issue of unmet need in primary care.^{354,355,381}

A UK population-based study of 15,000 home-dwelling people aged over 75 identified that 18.3% had cognitive impairment and of these 31% had urinary incontinence problems.¹³⁵ A national general practice audit of 999 older patients with faecal incontinence identified that 27% had a diagnosis of dementia.³⁶⁷ Evidence on prevalence of problems is invariably provided at a single time point. However, for a progressive degenerative disorder such as the dementia syndromes the experience from the affected person and their family is one of ongoing changes and adaptations. There are no studies that describe changes over time. As a consequence there are no data on the changes over time in continence status and associated issues to aid in service planning for the support of incontinence management or estimating cost consequences for households or primary care organisations.

Incontinence problems have been identified as a significant factor in increasing informal carer burden and triggering the admission of people with dementias to care homes.^{110,134} There is little literature that explores the nature and impact of managing bladder and bowel problems in people with dementia at home by informal carers. Two small scale qualitative investigations into informal carers views (total $n = 12$) on managing frail spouses' incontinence^{359,360} suggested that individual problem solving strategies might contribute further to carer stress through decreasing their outside social contact. There is an absence of information that identifies both those aspects of incontinence problems and also the carer and service contexts that contribute to the admission to care homes. Anecdotal evidence suggests that faecal incontinence is the tipping point as far as carers are concerned whether they are able to continue supporting the person with dementia.³⁶¹ Evidence from care home settings suggest that formal carers had difficulty interpreting what the person with dementia wanted and therefore how best to manage their continence e.g. repeated requests to be taken to the toilet and refusal of medication to ease constipation.³⁶²

Assisting older people to remain in their own homes, improving continence care and addressing carer burden are priorities for the health and social care improvement and service frameworks (DOH 1998,³⁶³ 2000,³⁶⁵ 2001³⁶⁴). People with dementia receive services from both generalist primary care services and specialist mental health care of older people. They may also receive support from social workers (generalist or specialist) and publicly funded social care assistance. Incontinence is a clinical issue that often has low priority in generalist primary care services and specialist mental health care services. Specialist continence services are not currently available in all areas of the UK.³⁶⁷ Evidence-based practice guidance is not currently available to assist professionals and staff in generalist services in their support of people with dementia living at home and their carers.

Professional knowledge and public awareness is increasing the availability of an evidence base in treatment and best practice.^{121,380,383} However, people with memory problems and dementia living at home are one group for whom there is little guidance on promoting continence or managing incontinence. Continence research and evidence-based guidance either explicitly excludes people with dementia (see for example National Institute of Clinical Excellence 2006)¹²² or more commonly includes only those people living in care home settings (see for example Ostaszkievicz *et al.* 2004).³⁶⁹ A recent review of a sample of English Primary Care Trust continence assessment and management policies for primary care nurses¹⁶² demonstrated that little guidance was available for this group of patients beyond offering a general leaflet (Continence Foundation undated). Evidence-based guidelines produced in 1998 for primary care staff on supporting people with dementia and their carers did not address incontinence management.¹²³ The recent NICE–SCIE guideline on supporting people with dementia and their carers¹²⁴ does not review evidence in relation to continence promotion but offers the view that combined interventions are more likely to

support and maintain independence in the person with dementia. International experts in incontinence have reviewed the research evidence concerned with frail elderly people and concluded that there is a paucity of research that specifically consider frail elderly people, including those with cognitive impairment. They recommended that further research is required that considers the prevalence and natural history of urinary incontinence and faecal incontinence, the management and cost consequences.³⁸⁴

Our earlier study interviewing people with dementia, family carers and health and social care professionals as to effective continence management strategies³⁸⁵ suggested a number of social and contextual factors that may be significant in the experience over time. These factors include access to health and social care services, access to finance to pay for additional continence aids, the gender of the family carer in relation to the gender of the person with dementia as well as the type of relationships e.g. spousal or child. Some of these factors reflect the broader literature on the nature and impact of informal care giving.^{56,386–390}

Our review of evidence³⁹¹ has found no studies that explore the experience or impact of managing toileting and incontinence problems in people with dementia living at home and their family carers over time. This study aims to investigate aspects of these questions specifically in a community-dwelling sample of people with dementia and their family carers.

Study aim and research approach

This study aims to prospectively investigate and describe the experience of people with memory loss and continence problems living at home and their family carers over a time period of up to 3 years. The purpose is to inform the development of an education resource, inform the planning of future intervention studies and inform the commissioning and provision of services for people with dementia and their carers at home. The research questions it addresses are:

- What types of continence promotion problems and incontinence problems are experienced by people with memory loss and dementia living at home over time?
- What is the range of continence promotion and incontinence management strategies?
- Which strategies are viewed as most effective?
- What is the impact and cost consequences of incontinence management for the individuals, their carers and services supporting them? In particular what is the lived experience of managing intimate care involving excreta and what factors influences the ability of the family carer(s) to offer care in these circumstances or decide that alternative caring options must be found?
- What is the sequence of continence related events that contribute to decisions to seek residential placement for the person with dementia?

The overall EVIDEM-C study draws on the Medical Research Council^{56,392} Framework for developing complex interventions in using stepwise phases. The study has a number of linked phases commencing with an integrative review of the literature,³⁶⁷ which is currently in progress. The research approach is one of critical realism³⁶⁹ which allows an integration of both subjective and objective research approaches and makes explicit the interrelationships between context, process, interventions (mechanisms) and outcomes.³⁷⁰ In taking this approach, the multifaceted nature of the issues and problems in promoting continence and managing incontinence in the home, as well as the perspectives of multiple and diverse stakeholders can be examined in the light of the evidence of effectiveness. This research approach allows the study to acknowledge the complexity of the issues.

The EVIDEM research group have assisted in the development of this protocol. This includes:

Professor Steve Iliffe (UCL, primary care)

Dr James Warner (Imperial College, old age psychiatry)

Professor Claire Goodman (University of Hertfordshire, health services research)

Professor Jill Manthorpe (King's College London, social work and social care)

Dr Greta Rait (UCL, primary care)

Professor Martin Knapp (LSE, economics)

Dr Mark Griffin (UCL, statistics)

Kalpa Kharicha (UCL, health service research and primary care)

David Lowery (CNWL NHS Trust, research management)

Members of the EVIDEM-C advisory group, which involves service users and carers, have also assisted in the development of the protocol.

Methods

This is a prospective longitudinal, descriptive study investigating the experience of up to 30 people with dementia with continence problems, living at home and their carers through qualitative serial interviews.^{175,393} The use of qualitative, serial interviews allows the in-depth exploration of the patient with dementia and the family carer experience as it changes over time rather than as a snapshot at one point in time. The relationship and trust between the participant(s) and researcher builds over time, allowing the time for sensitive or complex information to be disclosed in depth. Serial qualitative interviewing yields a detailed and contextualised account of the experience of change and decline in chronic illness, relationships between the cared for and the family carers as they develop strategies to manage distressing and stigmatising symptoms and the response and impact of health and social care services and professionals as the disease progresses and the symptoms change. Longitudinal qualitative studies allow for the exploration of transitions, adaptations and trajectories.³⁹⁴

The study will be through face-to-face and telephone interviews, repeated at 4-monthly intervals. The initial interview and those at yearly intervals will gather data that characterises the participants using validated tools. At the first interviews carers will be asked to provide retrospective information for the preceding year.

The sample and recruitment

Sample size in qualitative longitudinal research is influenced by the research questions, the population under consideration, the theoretical framing and available resources.^{395,396} Examples can be found of studies with samples of 12 or less³⁹⁷ to those with cohorts of 500.³⁹⁸ The Department of Health funded Bangor Longitudinal study of ageing included a qualitative study of a sub set of 30 people visited 2–4 times a year over 3 years.³⁹⁹ The sample size in this study has been based on a number of factors. These are (a) the theoretical framing and findings revealed in the earlier study (referred to above), (b) the resources and timescales of the broader EVIDEM-C study and c) experience of the difficulties of trying to recruit participants, who are often already burdened by coping with their day-to-day lives, to a study investigating sensitive, embarrassing and often felt to be stigmatising aspects of their condition.

The aim is to have a sample of up to 30 men and women with dementia and continence problems living at home and their family carers to try and capture diversity in dementia conditions, socio-demographic characteristics, and health and social care service contexts. The sample is intended to be purposive, with a sampling framework informed by theory and earlier research findings, to ensure the greatest diversity in experience. The sample is intended to be selected to include both men and women, people in a range of

age bands (age 65–74, 75–84, 85 and over), people from majority and minority ethnic groups, people from a range of socio-economic circumstances (i.e. those on income support and those not) and from a range of service and contextual factors (from deprived inner city areas to wealthier suburban areas). The experience to date is that the sample is one of convenience in that it includes those that volunteer rather than those selected for specific characteristics. In the sample recruited to date (August 2010) there are male and female participants with dementia, in age bands 75–84, and 85 and over, from majority and minority ethnic groups, people from a range of socio-economic circumstances (i.e. those on income support and those not) and from a range of service and contextual factors (from deprived inner city areas to wealthier suburban areas). Participants are living alone, living with spouses and living with daughters as their main family carers.

Inclusion criteria

The person has mild to moderate memory problems and cognition problems (not all people have formal dementia diagnosis) and problems with managing the toilet, remaining continent or incontinence problems.

The person and/or their carer are able to communicate in English.

Exclusion criteria

Neither the person nor their carer can communicate in English.

Recruitment

People with dementia (up to 30 people) and their carers living at home, will be recruited through the following multiple routes:

- through initial approaches from their general practice (in the London PCTs of Westminster, Kensington & Chelsea, Brent and Harrow, Hounslow, Hillingdon, Hammersmith and Fulham)
- through initial approaches from their specialist secondary services in Central and North West London NHS Trust older people services e.g. memory clinics, and community mental health teams and services such as Admiral Nurses
- through the individuals volunteering, having seen the wider EVIDEM publicity or joined the wider EVIDEM cohort of people willing to consider involvement in community-based research studies and the North Thames DemReg
- through specialist dementia social care services such as Housing 21 in North West London
- through advertisements and contacts in local Alzheimer's Associations, Age Concern and Carer groups in North London.

The clinical support officers from the Greater London Primary Care Research Network and the North Thames Dementias & Neurodegenerative Diseases Research Network will assist in general practice and in secondary care services in identifying patients with dementia and continence problems to be approached. Individuals will either be asked in the first instance by their clinician at the end of a consultation whether they would be willing to be approached to learn more about the study or their clinician will write to them asking whether they are willing to be approached to learn more about the study.

It is anticipated that people with dementia likely to be willing to participate would be at the mild to moderate stage of the disease progression. Those individuals willing to participate will make contact with the researcher who will send them the participant information leaflet and arrange a time to meet. At the meeting the research will be explained and consent sought to participate (see section on detailed ethical considerations and mental capacity).

After the first interview, the family carer will be asked if they would be willing to be interviewed again in 4 months time to discuss their experience in the intervening period. If they decline then they will be asked if they are willing to continue in the study by brief telephone contact at 4 and 8 months, followed by being asked to undertake a full interview at 12 months, repeated the following year. Participants are able

to decline and drop out of the study at any point without needing to give a reason. Those happy to continue in the qualitative element will be interviewed at 4 and 8 and 12 months of each year they are in the study. After the first interview, the interview can be with the carer alone if the person with dementia decides not to continue or their condition is such that their communication abilities preclude an interview. If an individual moves to a care home then a final interview will be undertaken with the carer and if appropriate, consent sought for a final interview with the affected person.

The data collection and tools

The interviewer will proceed with the interview in conversational ways rather than as a checklist set of questions which are more likely to distress people with dementia. If the interview is proving too long for the individual, the interviewer will arrange, with permission, to return at another time to complete the interview.

Data collection for the person with dementia and as appropriate their carer will include:

- demographic data
- medical information, including current other medical conditions, number of births for women, weight and medications
- characterisation of their mental condition and levels of ability (Mini-Mental State Examination,⁵² Disability Assessment for Dementia,¹⁷⁶ Neuropsychiatric Inventory Questionnaire,⁶² Cornell Scale for depression in dementia²²⁰)
- characterisation of their continence promotion activities and incontinence problems (ICIQ short form ICIQ-Nocturia,¹⁷⁷ additional questions regarding bowel symptoms and management)
- characterisation of their home and its adaptation to any impairments (adapted Home Environment Assessment Protocol⁴⁰⁰)
- characterisation of their quality of Life (DEMQOL, Smith *et al.* 2005)⁸⁶
- characterisation of service use and cost consequences (Client Service Receipt Inventory part 1).⁴⁰¹

Data collection for the qualitative element with the person with dementia descriptive will be by guided conversation as to any views on what helps in dealing with continence problems.

For the carer alone:

- demographic data
- characterisation of their level of support to their family member, service use and cost consequences (Client Service Receipt Inventory part 2, Howard *et al.* 2007)⁴⁰¹
- characterisation of the impact of caring and their quality of life, (caregivers burden scale,⁴⁰² health-related quality of life EQ-5D, EuroQol 2008)
- perceptions of the effectiveness of strategies that are most helpful with current problems.

The qualitative element included at the annual and 4-monthly interviews will be undertaken using an aide memoire. This will cover the following topics, explored through open ended, semi-structured questions.

- The experience of living with someone with toileting problems and incontinence due to dementia.
- The experiencing of developing strategies in managing the current toileting problems and incontinence problems, including sources of information, advice and practical help.
- The experience of developing a caring role in providing intimate care that involves managing excreta.
- Any critical or significant events related to incontinence that have occurred since the last interview and the impact of those events e.g. hospital admission.
- The extent to which providing intimate care involving excreta influences their view of their ability to continue in a caring role or whether alternatives are being sought.

Data analysis

Descriptive techniques will be used to characterise the participants, summarising information collected through the validated tools.

The analysis of longitudinal qualitative data requires specific techniques to ensure that the temporal nature at the individual and group level is captured.⁴⁰³ This analysis will be based on methods suggested by Pettigrew (1990)³⁹⁴ Saldana (2003)³⁹⁶ and Lewis (2005)⁴⁰⁴ and previous experience as part of a NIHR Service Delivery and Organisation study of older adults experience of nurse case management overtime.⁴⁰⁵ Data will be entered onto the NVivo™ software package and the organisation of the cases and multiple interviews undertaken as recommended by Saldana (2003).³⁹⁶ In addition a schematic representation of the individual case narrative overtime will be prepared as recommended by Pettigrew (1990)³⁹⁴ and Lewis (2005)⁴⁰⁴ and undertaken in a previous study.⁴⁰⁵ The analysis will be undertaken at five different levels as described by Lewis (2005)⁴⁰⁴ and framed by the research questions above:

- Individual case narratives to capture the trajectory over time, i.e. the course of events, the adaptations, transitions as well any re-interpretations of events and decisions over time.
- Cross-sectional analysis between cases at specific time points.
- Identification of themes using the constant comparative method⁴⁰⁶ and analysis of linkages between themes and participant characteristics over time.
- Cross-case comparisons of narratives and themes.
- Between-group comparisons for example by sub groups defined by gender.

Final interpretations will address the research questions as well as generalise the findings at a theoretical level.

Ethical considerations

The research questions under consideration are directly relevant to people who have dementia and it is important to incorporate views of those people experiencing the problems not just the professional views or their family members.³⁸² People who have dementia may lack capacity to consent. Only those people with dementia with the capacity to make the decision to participate in the research will be included at the first point. The procedure for establishing the ability to make the decision will proceed in accordance with the guidance for the Mental Capacity Act 2005. People with dementia will only be approached after their close family carer or a professional who knows them well enough to judge their ability to consent to participation in the study, has discussed the research first and asked whether they would be willing to meet the researcher. This person will explain about the research and the exploratory discussion process using the information leaflet which has been adapted to provide key points in straight forward language. After consent to approach the person has been gained, the researcher will arrange to meet them with their carer or supporting person of their choice. She will repeat the explanations, using the leaflet and check the person is able to consent at that point in time. Key elements in checking will be: whether the person has general understanding of what they are consenting to and why they are being asked to make it, whether the person understands what will happen if they agree to participate in the study, whether they are they able to understand the verbal and/or written information relevant to making a decision whether to participate in the study. A consent form for signing will be offered, although if the informant is unwilling to sign (writing may be difficult) this will not be pursued and verbal consent will be noted. Any sign (verbally or in body language) that the individual is not happy about taking part or continuing to take part in the research will be interpreted as withholding consent, or a desire to withdraw. The research will end the conversation, thanking the person for their time and involvement. The researcher will check throughout the discussion that the informant is willing to continue and cease if the person indicates they wish the discussion to end.

As this is a study over time the consent process will be repeated before each subsequent contact. Consent will be at subsequent contacts over the 3 years, the person with dementia may have lost the capacity to make a decision to consent, i.e. understand information about the decision to be made, retain that information in their mind, use or weigh that information as part of the decision-making process, or communicate their decision (by talking, using sign language or any other means). In these instances the researcher will consult the family carer (the consultee) in accordance with the code of practice of the Mental Capacity Act 2005 whether the person would want to take part in this further stage of the research. With their agreement in writing, the interviewer would continue. However, the interviewer would stop at any sign that the person wishes to withdraw, as described as above. The interviews in this study offer minimal risk to the person and minimal intrusion (see next paragraph) or interference to their rights.

Urinary or faecal incontinence are distressing symptoms that are embarrassing to discuss for any adult. Undertaking intimate care associated with incontinence for an adult spouse, relative or loved one is a sensitive issue. All interviews will be conducted by researchers aware of the potential socially problematic nature of the issues that are being discussed. Interviewers will use language understandable and acceptable to the interviewee and make all efforts to lessen any discomfort in discussing the issues. Should an individual become distressed then the interviewer will pause, be sympathetic, and check whether the person wishes to discontinue the interview. The researcher will encourage informants to share their problems and distress with their key health professional, or family doctor as appropriate. All researchers will have contact information on key support agencies to leave with informants.

All informants will be assured of anonymity and confidentiality in the transcription, analysis and reporting of their interview. Any direct quotations used in the report will be non-attributable.

Informants will be made aware that if any information is shared that suggests that a vulnerable older adult is suffering neglect or abuse then the researcher has a responsibility to share that information with the service manager (in case of abuse or neglect from a service provider) or in the case of individuals gain their consent to share that information with the named Local Authority Officer for vulnerable adults.

Data protection considerations

All participants will be assigned a code number and this with their contact details will be kept separately and securely from any data collected in the process of the research. All research data will be identifiable by code number alone. The interview data will be entered and stored on a password protected computer, accessible only to the researchers in locked offices of the University. Hard copies of data will be stored in locked filing cabinets in the same offices. Research data will be archived for 5 years and then destroyed.

Timescale

Recruitment will commence in October 2008 and end in December 2010.

Data analysis will be ongoing and completed by January 2012.

A final report will be made in 2012.

Reports and dissemination

The findings will be written up as a brief report for circulation to participants. The full report will be used as the basis for papers and articles to be submitted to a professional journal and local and national voluntary organisation's newsletters. An abstract will be submitted for presentation at a service users and professional conference, such as Dementia Congress.

Appendix 21 Chapter 3: Protocol – incidence and management of incontinence in general practice patients with dementia: an analysis of THIN data, 2011

Incontinence problems have been identified as a significant factor in increasing carer ‘burden’ and triggering the entry of people with dementias to care homes.^{110,134,356} Supporting people with dementia to live at home is a major policy objective. There are currently no primary care-based data available in the UK or elsewhere to provide clinicians or commissioners services with data on the incidence and current management of people with dementia living at home who also have problems with urinary and/or faecal incontinence. This protocol addresses this absence of data through an analysis of general practice records held in the THIN database.

Background

Dementia affects over 4% of the people over 60, increasing to 13% for those over the age of 80 in Western Europe with significant projected increases in the next 20 years.³⁴⁵ Dementia has enormous impact not only for the individual and their family but also for the health and social care system.^{119,296,346} The median length of time from diagnosis to death is 10 years for those under 65 at diagnosis and 4 years for those over 80 years.¹⁷³ The clinical syndrome of dementia has a trajectory of progressive deterioration in cognition, abilities, and physical functioning. The impairment experienced by the individual is often compounded by extrinsic factors such as attitudes of ‘therapeutic nihilism’¹¹⁵ in professionals, un-adapted environments, and social exclusion. As the condition progresses problems may arise in maintaining independence in going to the toilet, in avoiding constipation, and in managing incontinence problems that cannot be resolved. Estimates suggest that there are 500,000 people with dementia in England and two-thirds live at home.¹¹⁹

Incontinence is the involuntary leakage of urine or stool or both.^{347,349} The prevalence of any type of urinary incontinence in all older adults is between 6% and 10%, with increasing rates associated with old age.³⁴⁹ It is estimated that 2–5% of adults experience faecal incontinence. Incontinence lowers quality of life and impacts negatively on mental health^{351,352} as well as creates significant practical and financial problems. There is evidence that incontinence contributes significantly to other major health issues for older people such as falls.³⁵³ Incontinence has been identified by professionals and older people as an issue of unmet need in primary care.^{354,355,381}

There are no population surveys that identify the incidence of people with dementia and continence problems living at home. However, there are some indications that they may be a substantial minority. A UK population-based study of 15,000 home-dwelling people aged over 75 identified that 18.3% had cognitive impairment and of these 31% had urinary incontinence problems.¹³⁵ A national general practice audit of 999 older patients with faecal incontinence identified that 27% had a diagnosis of dementia.³⁶⁷ There are some indications that people with dementia and incontinence symptoms are not investigated and managed proactively.⁴⁰⁷

There are currently no primary care-based data available in the UK or elsewhere to provide clinicians or commissioners services with data on incidence and the characteristics of people with dementia living at home who also have problems with urinary and/or faecal incontinence.

The experience of people with dementia and their family carers interviewed in a related ongoing study by the authors suggests that:

- Like the general population⁴⁰⁸ most delay consulting general practice or any health professional about incontinence problems as they feel embarrassed and humiliated.
- Family members report avoiding talking to their general practitioner about these issues as they seek to protect the person with dementia's dignity and public persona.³⁵⁴ However, as the dementia progresses this becomes unsustainable and the family carers insist on seeking help in order to cope with the wider burden of supporting their family member. This is sometimes reported as part of a crisis situation in which hospitalisation or temporary residence in a care home occurs.
- Family carers report a variety of responses from general practice when they do seek help: some indicate they get little assessment or help other than the referral for continence pads, others indicate a more detailed investigative approach to identify or discount possible treatable causes of these symptoms, such as urinary tract infections or prostate hypertrophy problems, and then more active management of the problems.

Purpose

This cohort study will describe current practice in continence care for people with dementia, and quantify the burden of disease. It will also examine whether this differs with demographics or health status, or between general practices in ways not explained by patient characteristics.

Hypotheses

The background described above suggests a number of hypotheses:

1. The general practice reported incidence of incontinence problems is higher in the dementia population than in the general population of similar age registered with a GP. This relationship may be confounded by other factors such as age or mobility.
2. The general practice response to people with dementia consulting for incontinence problems, compared to people of similar demographics without dementia, is more likely to be prescription of continence pads, and less likely to be investigation and referral for tractable problems, including surgery, or it may take longer to get referred.

Research questions

1. What is the incidence rate of urinary and/or faecal incontinence, stratified by age and sex, recorded in general practice patients aged over 60:
 - a. overall
 - b. with a diagnosis of dementia and
 - c. without a diagnosis of dementia?

Which covariates affect this relationship (co-morbidity, restricted mobility, Townsend deprivation score)?

2. What is the incidence of recorded treatments, management and referrals made for incontinence in patients with and without dementia, stratified by sex and age?

Which covariates affect this relationship (polypharmacy, restricted mobility, Townsend deprivation score)?

Methods

Study design

A cohort study

Data source

Data will be taken from THIN (URL: <http://www.epic-uk.org/thin.htm>) covering general practices in the United Kingdom (UK) providing data during the period 1 January 2000 – 31 December 2009. This electronic recording scheme is one of the largest UK sources of continuous primary care data on patients' consultations and prescribing data. It has been widely used for epidemiological studies, including a study of dementia and survival.¹³ Anonymised patient data are pre-collected from participating practices. Practices are broadly representative of UK general practices in terms of patients' age and sex, practice size and geographical distribution. GPs enter medical diagnoses and symptoms using Read codes, a hierarchical recording system used to record clinical summary information. The age, sex, medical diagnosis and symptom records, health promotion activity, referrals to secondary care, prescriptions and quintiles of Townsend deprivation score are recorded for each registered individual.

Inclusion/exclusion criteria

In order to examine the incidence of incontinence (research question 1) we will first identify an 'exposed cohort' of individuals aged 60 or above with data available for at least 6 months between 1 January 2000 and 31 December 2009. Any patients with Read codes indicating learning disabilities and specifically Down's syndrome will be excluded as this is a known risk factor for both dementia and incontinence. Based on the overall age and gender distribution in this cohort we will identify a comparison 'unexposed cohort' stratified by age, sex and practice, by randomly selecting from patients over the age of 60 without a record of dementia.

For all research questions, data will be taken from each practice after they have achieved an acceptable level of data quality as defined by the Acceptable Mortality Rate (AMR) date.⁴⁰⁹ We will use established methods to identify and exclude likely prevalent cases of incontinence or dementia recorded within 120 days of registration. This cut-off has been established by analysing THIN using the method of Lewis *et al.*, specifically for incontinence and dementia.⁴⁰³ Pre-existing incontinence and/or dementia will be identified from any time point in the patient's data, except for 'incontinence' codes prior to age 16.

Study variables

Dementia and incontinence will be identified from Read codes and drug codes, excluding single isolated drug codes and any codes flagged on THIN as having errors. Learning disabilities, Down's syndrome and restricted mobility will similarly be identified from Read codes. Lists of Read codes have been developed in order to identify patients with these conditions. Codes were identified by searching the code dictionary for relevant terms (e.g. continen*, faecal, urin*, dement*, alzheimer*, memor*), then adjacent codes were examined and searches run on other keywords which are suggested by the dictionary definitions. This process has been used on a number of studies using THIN data.⁴¹⁰ Drug/device codes were identified in the same way. All these lists were checked by two clinicians for relevance and completeness.

The first date against a code for dementia, incontinence and restricted mobility will be stored, allowing dementia and mobility to be modelled as time-varying predictors. The first date of each of various types of treatment/referral for incontinence will also be stored for use in research question 2.

We will use drugs prescribed as a proxy index for co-morbidity, calculated from the therapy records by counting the number of distinct BNF sections prescribed within the 6 months preceding the first incontinence code. For those without incontinence, a random date will be selected within their time at risk (uniformly distributed) and 6 months of prescriptions taken prior to that point. These calculations will apply to both exposed and unexposed cohorts.

Year of birth and sex will be extracted from the patient data files. Townsend deprivation scores (in quintiles) will be extracted from the postcode variable information (PVI) file for each practice.

Other variables to be extracted include:

- practice and patient ID
- indicator variables for the presence of dementia, incontinence (including pre-existing codes), and different types of treatments or referrals
- the AMR date for the practice
- year of birth, registration date, transfer date and death date.

Analysis

For research question 1 (incidence of incontinence in dementia compared to no dementia), incidence rates will be derived for incontinence in people with and without pre-existing dementia, and stratified by age, gender and deprivation. Epidemiological calculations of rate ratios will be used for the stratified analysis. Continuous covariates and inter-practice variation will be accounted for in a multilevel Poisson regression model. Incontinence will be the outcome, dementia the exposure, potential covariates are age, sex, deprivation, polypharmacy, and calendar period, and in a Poisson model time at risk will be an offset variable. This will allow us to find the adjusted relationships between dementia and incontinence and to consider whether the covariates interact (are effect modifiers) with dementia. We will account for variation between practices by modelling this as a random effect in the Poisson regression. Results will be compared with published statistics that are representative of current practice.¹¹⁶

For research question 2 (access to, and timeliness of, treatment for incontinence in dementia compared to no dementia), another multilevel regression model will be constructed with treatment options for incontinence as the outcomes, dementia as the exposure, and covariates defined as for question 1. A multilevel Poisson regression will be used and the offset and random effect will be defined as above. This will allow us to quantify any differences in access to treatment between those with and without dementia.

Limitations

The data are limited to consultations recorded in general practice and there may be differences in coding by different GPs, which we will investigate where possible. Because the data are drawn from GP consultations, there could be a Berkson's bias inflating associations between morbidities. This will be minimised by looking over long time periods and measuring the time to first recording (incidence) of a diagnosis or treatment.⁴¹¹ We also know that people with continence problems can delay seeking help, sometimes by years, so there may be a bias toward earlier recording of incident incontinence in patients with dementia. We will cross-check diagnostic codes against prescriptions and free-text comments for under-recording or delayed recording of diagnoses.

Appendix 22 Chapter 3: Protocol – investigating the acceptability, effectiveness and associated costs of different types of absorbent products used for incontinence by people with memory problems living at home, 2010

Aim

The aim of this study is:

- (a) to investigate the feasibility of the research methods to ascertain the acceptability, effectiveness and associated costs of different types of absorbent products used for incontinence by people with memory problems living at home
- (b) to provide preliminary data on the acceptability, effectiveness and associated costs of different types of absorbent products used for incontinence by people with memory problems living at home to inform both future research design and also service providers.

Background and rationale

Urinary or faecal incontinence are distressing symptoms for any adult. Incontinence lowers quality of life and impacts negatively on mental health^{351,352} as well as creates significant practical and financial problems. Incontinence can lead to social embarrassment, restriction of leisure activity, creation of extra laundry and replacement costs for clothing and bedding, and it can be a source of conflict between individuals and their family (Continence Foundation, undated).

There is no firm evidence of the numbers of people with memory problems living at home who have continence problems. Evidence suggests that up to a third of people with memory problems and dementia living at home experience incontinence problems.^{135,381} Dementia affects over 4% of the people over 60, increasing to 13% for those over the age of 80 in Western Europe with significant projected increases in the next 20 years.³⁴⁵ Dementia has enormous impact not only for the individual and their family but also for the health and social care system.^{119,296,346} The clinical syndrome of dementia has a trajectory of progressive deterioration in cognition, abilities, and physical functioning. As the condition progresses problems may arise in maintaining independence in going to the toilet, in avoiding constipation, and in managing incontinence problems that cannot be resolved. In addition, there can be behavioural and psychological problems such as disinhibition, apathy and faecal smearing.¹¹⁴ Estimates suggest that there are 500,000 people with dementia in England, two-thirds of whom live at home.¹¹⁹ Incontinence is known to be a significant factor in the decision for people with memory problems and dementias to take up residence in a care home.^{110,134,359} There is an absence of information exploring incontinence problems combined with the carer and service contexts that contribute to the admission to care homes.

Incontinence is the involuntary leakage of urine or stool or both.^{347,349} There are a number of internationally agreed algorithms for the assessing and treating incontinence symptoms, with the term 'functional' incontinence used to describe that which has no physiological basis.³⁴⁸ UK surveys suggest that even though individuals find their urinary symptoms bothersome and socially disabling, some older people consider them as an inevitable part of ageing and too humiliating to seek help,¹⁶⁶ while others view the treatments as cumbersome and too invasive.⁴¹² There is also evidence that health professionals have a nihilistic view of

incontinence in older adults, thinking that nothing can be done, and rather than thorough assessment and treatment of the underlying causes they resort to provision of containment devices e.g. pads, as the first option.⁴⁰⁷ The International Continence Society suggests that for frail, elderly people (which include people with moderate to severe dementia) the aim of professional input may be to have well contained incontinence.¹¹⁷

There are no UK estimates of the total public expenditure associated with treating or managing incontinence. There are some indications of the scale of the direct expenditure. It was estimated that the NHS spent £536 million at 1999/2000 prices in treating clinically significant urinary incontinence symptoms in community-dwelling adults.³⁵⁴ In 2007 nearly 1.5 million NHS prescriptions were filled for incontinence appliances in England at a cost of £33 million.⁴¹³ Absorbent incontinence products account for the majority of this spending.¹⁸¹ They come in a wide range of designs and absorbencies (see table below). Reviews of NHS provision of continence services^{357,365,382} have suggested that:

- There are significant geographical variations in eligibility criteria to receive NHS continence services, in access to specialist continence services, and in the range and quantities of treatment provided in primary and secondary care.
- In addition, a national survey found variations, inflexibility, and arbitrary ceilings on the NHS provision of continence aids e.g. disposable and washable pads, and bed pads.⁴¹⁴

Our recent research involving interviewing people with dementia living at home, their family carers and health and social care staff closely supporting them¹⁶² suggested that:

- (a) Carers and people with dementia often stated preferences for certain types of continence pad designs; this was often but not always for 'pull-up' pants.
- (b) Preferences might be affected by: different degrees of incapacity, different types of behavioural problems and ease of use at night or during the day in the home or ease of use outside the home.
- (c) Ineffective containment pads increased the financial costs and stress of supporting someone with these problems at home.

There are only currently studies looking at absorbent incontinence products and preferences, ease of use and effectiveness with people living at home who do not have dementias.¹⁶⁹ The following chart indicates the range of products available.

Types of absorbent pad designs

Designs of body-worn containment pads	Used for which type of incontinence	Design details
Inserts	Light/moderate/heavy	<p>Disposable inserts for light incontinence often held in place in underwear by an adhesive strip</p> <p>Other types held in place by close fitting underwear or stretch mesh briefs</p> <p>Sometimes have wetness indicator to signal the need for a pad change</p> <p>Sometimes have elasticised gathers of hydrophobic material which are intended to impede lateral leakage</p>
Nappies	Moderate/heavy	<p>Adult-sized versions of babies' nappies (nappies)</p> <p>Disposable nappies usually have elasticated waist and legs and self-adhesive tabs (usually resealable), and often a wetness indicator and standing gathers</p> <p>Washable nappies are fixed with Velcro or press-studs and usually elasticated at the waist and legs</p>

Designs of body-worn containment pads	Used for which type of incontinence	Design details
T-shaped nappies	Moderate/heavy	To enable users to apply the nappy while the person is standing Fastens round the waist before the pad is pulled through between the legs into position and secured
Pull-up disposable pants	Moderate/heavy	Similar in construction to trainer pants for toddlers Those for light incontinence are often known as pants with integral pad
Menstrual pads (W) (disposable only)	Light	Have an adhesive strip to adhere to underpants
Leaflets (M) and pouches (M)	Light	Leaflets designed to fit over the penis, pouches designed to fit over the scrotum also Worn with close-fitting underwear or stretch mesh briefs Disposables have an adhesive strip to adhere to underpants

(W) and (M) denote products specifically designed for women and men, respectively. All designs have disposable and washable variants.

Research questions

1. Do the research questionnaires capture all aspects of the acceptability, effectiveness, and associated costs of different types of absorbent products used for incontinence by people with memory problems living at home?
2. Is there evidence from this pilot study of the extent to which different types of absorbent products used for incontinence by people with memory problems living at home are acceptable, and effective in dealing with different types of continence in different social situations?
3. Are people with memory problems, their family carers and/or their paid carers willing to participate in this type of research and try different types of absorbent incontinence products?
4. Is it feasible to ask people with memory problems, their family carers and/or paid carers to collect this amount of data?

Method

This pilot study design is informed by the Medical Research Council recommendations for assessing feasibility in developing and testing complex interventions.⁵⁶ The design aims to examine key uncertainties as outlined in the questions above and may be refined for future studies. This is a pilot study using primarily quantitative methods but also capturing participants' views with qualitative methods.

We aim to recruit up to 40 family carers of people with memory problems living at home and using absorbent incontinence products. We also aim to recruit the person with memory problems if they have capacity to consent. We aim for the sample to have a wide variation of demographic characteristics, co-morbidities and health status as a result of recruiting through a NHS continence services and voluntary organisations across London. Interested NHS continence services will be identified through presentations at the London Association of Continence Advisors and then permissions sought with the employing NHS organisation as required under NHS research governance requirements.

The sample

The sample will be a purposive sample of up to 40 family carers, who are supporting their family member in managing continence problems with absorbent pads. In addition those people with memory problems who have capacity to consent will be recruited. The purposive sample will include family carers of people with memory problems who have been using pads for different amounts of time and people who had incontinence problems that pre-dated symptoms of dementia.

Inclusion criteria:

- The person is a family carer who is supporting their family member with memory problems in managing incontinence with absorbent pads.
- They are able to communicate in English.
- The person using the absorbent pads has capacity to give consent.

Exclusion criteria:

- The family carer cannot communicate in English.
- The person with memory problems does not have capacity to consent.

Recruitment

Participants will be recruited using several approaches as it is anticipated people will be slow to come forward due to the sensitive nature of the topic. We will ask local (in up to four different areas of London Strategic Health Authority) community service and primary care staff such as district nurses, continence nurses and GPs to identify and initially approach family carers of people with dementia living at home with incontinence and in receipt of absorbent pads from local NHS services. In addition we will place information in local Alzheimer's Society branch newsletters and in the Dementia Research Network Registry (DemReg) asking people to contact us directly who might be interested in participating. Those individuals willing to participate will make contact with the researchers who will send them the participant information leaflet and arrange a time to meet them in their home. At the meeting the research will be explained and consent sought to participate (see below on detailed ethical considerations and mental capacity).

Data collection

Participants (family carers and people with memory problems) will be seen in their own home and information collected at two points:

- *Time point 1*: initial meeting in the person's home.
- *Time point 2*: 8–10 days after time point 1 as suits the participant.

Data collection at time point 1

The following data will be collected using these tools. If the person with dementia has consented then the data will be collected in an interview supported by the family carer. If the person with dementia is unable to consent then the information will be collected from the family carer alone.

- demographic data about the person with dementia
- medical information about the person with dementia, including current other medical conditions, weight and medications
- Disability Assessment for Dementia¹⁷⁶

- characterisation of continence promotion activities and incontinence problems (ICIQ short form ICIQ-Nocturia,¹⁷⁷ additional questions regarding bowel symptoms and management)
- characterisation of service receipt and cost consequences (Client Service Receipt Inventory part 1 section C)⁴⁰¹
- characterisation of mental condition and levels of ability (Mini-Mental State Examination)⁵² only used if the person with dementia is able to consent.

For the family carer alone:

- demographic data about the family carer
- characterisation of the impact of caring and their quality of life (caregivers burden scale)⁹⁴
- NPI (Neuropsychiatric Inventory).⁶²

The researcher will also:

- introduce the pilot study diaries and recording tools (Pad and leakage diary sheet, and opinion sheet) to be kept for the next seven days (including for night-time); these have been adapted with permission from the research tools used by Dr M Fader *et al.*¹⁸¹ for the NIHR Health Technology funded project.
- enquire whether the family carer would be willing to try pad weighing scales and record the weight (indicates the volume of contents); for those willing, scales will be left alongside the study diaries.

Data collection at time point 2

The researcher will collect the study diaries and recording sheets. The researcher will also ask about the acceptability, ease of completion, level of completion and any other relevant views regarding the study data collection tools (topic guide for evaluation of study research methods).

Flow chart of the study

Professionals identify and approach suitable participants. Those that agree are put in touch with the researchers who arrange to visit and explain the study in more detail and arrange a future contact to consent and proceed



Interview: time point 1

Interview in the home in two parts:

- i) Structured interview measures to characterise the person with dementia, the family carer, the incontinence, its management and the impact
- ii) Introduce the diary sheets and opinion sheet, leaving pad weighing scales if agreeable



Interview: time point 2

(between 1 week to 2 weeks' later, as convenient)

- Collection of diary sheets and opinion sheet
- Semi-structured interviews on views about the data collection tools and completing them

Data analysis

Quantitative data will be managed through SPSS™ and analysed descriptively to address the research questions. Qualitative data from the second interview will be managed and thematically analysed through a software system such as NVivo™.

Ethical considerations

There are ethical issues related to capacity to consent, distress, confidentiality and safeguarding vulnerable adults.

The research questions under consideration are directly relevant to people who have memory problems and it is important to incorporate views of those people experiencing the problems if possible (Department of Health 2005).⁴¹⁵ People who have memory problems may lack capacity to consent. Only those people with memory problems with the capacity to make the decision to participate in the research will be included.

The procedure for establishing the ability to make the decision will proceed in accordance with the guidance for the Mental Capacity Act 2005. People with memory problems will only be approached after their close family carer or a professional who knows them well enough to judge their ability to consent to participation in the study, has discussed the research first and asked whether they would be willing to meet the researcher. This person will explain about the research and the exploratory discussion process using the information leaflet which has been adapted to provide key points in straight forward language. After consent to approach the person has been gained, the researcher will arrange to meet them with their carer or supporting person of their choice. She will repeat the explanations, using the leaflet and check the person is able to consent at that point in time. Key elements in checking will be: whether the person has general understanding of what they are consenting to and why they are being asked to give it, whether the person understands what will happen if they agree to participate in the study, whether they are they able to understand the verbal and/or written information relevant to making a decision whether to participate in the study. A consent form for signing will be offered, although if the informant is unwilling to sign (writing may be difficult) this will not be pursued and verbal consent will be noted. Any sign (verbally or in body language) that the individual is not happy about taking part or continuing to take part in the research will be interpreted as withholding consent, or a desire to withdraw. The research will end the conversation, thanking the person for their time and involvement. The researcher will check throughout the discussion that the informant is willing to continue and cease if the person indicates they wish the discussion to end.

The interviews in this study offer minimal risk to the person and minimal intrusion (see next paragraph) or interference to their rights. Urinary or faecal incontinence are distressing symptoms that are embarrassing to discuss for any adult. Undertaking intimate care associated with incontinence for an adult spouse, relative or loved one is a sensitive issue. All interviews will be conducted by researchers aware of the potential socially problematic nature of the issues that are being discussed. Interviewers will use language understandable and acceptable to the interviewee and make all efforts to lessen any discomfort in discussing the issues. Should an individual become distressed then the interviewer will pause, be sympathetic, and check whether the person wishes to discontinue the interview. The researcher will encourage informants to share their problems and distress with their key health professional, or family doctor as appropriate. All researchers will have information on key support agencies to leave with informants.

All informants will be assured of anonymity and confidentiality in the transcription, analysis and reporting of their interview. Any direct quotations used in the report will be non-attributable.

Informants will be made aware that if any information is shared that suggests that a vulnerable older adult is suffering neglect or abuse then the researcher has a responsibility to share that information with the service manager (in case of abuse or neglect from a service provider) or in the case of individuals gain their consent to share that information with the named Local Authority Officer for adult safeguarding.

Data protection considerations

All participants will be assigned a code number and this with their contact details will be kept separately and securely from any data collected in the process of the research. All research data will be identifiable by code number alone. The data will be entered and stored on a password protected computer, accessible only to the researchers in locked offices of the University. Hard copies of data will be stored in locked filing cabinets in the same offices. Research data will be archived for 5 years and then destroyed.

Timescale

The timescale for the project is 1 year. Recruitment will commence in June/July 2010 (determined by ethical review and governance procedures). Our experience to date suggests that recruitment will be slow for such a sensitive subject and we anticipate that it may take up to 6 months to recruit. A final report will be written in 2012.

Reports and dissemination

The findings will be written up as a brief report for circulation to participants and in the EVIDEM final report. Papers and articles to be submitted to a professional journal and local and national voluntary organisation's newsletters. An abstract will be submitted for presentation at a service users and professional conference, such as Dementia Congress.

Appendix 23 Chapter 3: Protocol – a modified Delphi consultation to develop a dementia-focused continence assessment tool for use with people with dementia living at home, 2010

This protocol describes the process for developing and establishing the face and content validity of the EVIDEM-C continence assessment tool to be used with people with dementia living at home and their family carers. (NB. It draws on the background from previous protocols and does not repeat it here.)

Background

EVIDEM-C is a research study investigating issues of continence promotion and incontinence management for people with dementia living at home and their family carers with the ultimate aim of developing resources to assist those working in primary care. Our earlier studies revealed that:

- people with dementia and their family carers often only sought professional help in toileting and incontinence problems at points for crisis¹⁶⁹
- people with dementia and their family carers often reported difficulties with health professionals recognising and advising on their problems¹⁷⁰
- local NHS continence policies and assessment tools, primarily used by primary care nurses, rarely directly explored the problems of people with dementia in toileting and incontinence or outlined appropriate care pathways.¹⁶²

Aim

The aim is to develop and test the face and content validity of a prototype dementia specific assessment tool to be used in tandem with locally agreed continence assessment tools.

Method

To undertake a three-stage adapted Delphi consultation.¹⁸²

Stage one will bring together a group of experts in a facilitated series of group activities to review current examples of local continence assessment tools and agree the range of principles to be incorporated in a dementia specific continence assessment tool.

Stage two will consult those in stage one and a wider group of experts by post (or e-mail) on a prototype dementia specific tool for views on whether it addresses the principles and issues identified in stage one plus views on any omitted items.

Stage three will undertake a postal consultation of family carers and professional experts to address the following questions:

- Is this additional assessment tool likely to improve primary care professionals' recognition of the toileting and incontinence problems experienced by people with dementia and their family carers? (face validity)

- Have all the important items associated with toileting problems and incontinence experienced by people with dementia and their family carers, been included? And are there any items which are not important and should not be included? (content validity)

Stage three

The diversity of the sample is important rather than its size to capture the widest variation in views.¹⁸³ The aim is for at least five participants in each of eight categories as listed described below:

Stage three proposed participants

Expert group	No.	Route to approach
Family carers	5–10	EVIDEM-C family carer e-network
Voluntary organisations with knowledge and expertise in bladder and bowel problems and dementia carers supporting people with dementia	5–10	Members of EVIDEM steering group from these organisations plus direct approaches to Bladder and Bowel Foundation
General practitioners	5–10	Identified as either published about an aspect of dementia or incontinence
Psychogeriatricians	5–10	Identified as having published about an aspect incontinence
Nurses in the community	5–10	Identified as either published about aspects of dementia or incontinence. Also through the e-network of the Queens Nursing Institute
Continence nurse specialists	5–10	Identified through the Association of Continence Advisors local branches in London and the North West of England
Community mental health nurses and Admiral Nurses	5–10	Identified through Community Psychiatric Nursing Association, For Dementia and also publishing on aspects of care for people with dementia living at home
Others with specific e.g. occupational therapists, Disable Living Advice Centres, PromoCon social workers, social care providers	5–10	EVIDEM–C network of advisers and contacts

Individual experts will be identified through publications in this field, from the advice of the wider EVIDEM team, the EVIDEM-C advisory group and events held in the host NHS Trust. Each identified person will be sent the draft assessment tool and a data collection form. Analysis will be by descriptive statistics for the quantitative elements. Thematic analysis¹⁶⁵ of any text received in the comments section.

Ethics

NHS research ethics query service advised that this is not within the domain of the NHS ethics committee. University requirements will be followed. Anonymity and confidentiality of participants will be kept by the use of participant identifying numbers. Data will be kept in locked filing cabinets and on password protected University computers.

Timescale

Stage one will commence in the Autumn 2010.

Stage two, early Winter 2010.

Stage three, Spring 2011.

Reports and dissemination

The findings will be written up as a brief report for circulation to participants and in the EVIDEM final report. Papers and articles to be submitted to a professional journal and local and national voluntary organisation's newsletters. An abstract will be submitted for presentation at professional conferences.

Appendix 24 Chapter 3: Adoption by research networks and research permissions

The EVIDEM-C study was adopted onto the portfolio of the UK Clinical Research Network (UKCRN) and by the associated research networks for primary care and dementia and neurodegenerative diseases. Individual study elements required permissions from each organisation through which participants were approached. In addition, application and agreement for payment of NHS support to research costs to GPs was required for some elements. This is summarised below in *Table 105*. Most of these processes required completion of forms specific to that organisation and then correspondence, monitoring returns (from monthly to completions of data collection to annual) and often reports on study completion. Throughout the period of the EVIDEM-C study the research governance processes and the organisations responsible for them repeatedly altered.

TABLE 105 Research network adoption, research governance, NHS service support costs to research and access permissions

Study element	Research network adoption	UKCRN Portfolio ID	Body/bodies agreeing research access permissions	Body/bodies agreeing NHS service support costs
Qualitative interviews study	UKCRN	4938 (EVIDEM-C-1)	West London Mental Health Research & Development Consortium	
	DeNDRoN		Brent PCT for 6 North West London PCTs Westminster PCT	Brent PCT for North West London PCTs
	NIHR PCRN		London Borough of Westminster Social Care Services Housing 21 For Dementia Age Concern (Westminster) Four local branches of Alzheimer's Society	
Longitudinal study	UKCRN	8928 (EVIDEM-C-2)	West London Mental Health Research & Development Consortium	
	PCRN– Greater London as above		Brent PCT for 6 North West London PCTs Hounslow PCT Westminster PCT London Borough of Westminster Social Care Services Housing 21 For Dementia Age Concern (Westminster) Four local branches of Alzheimer's Society	Brent PCT for North West London PCTs

continued

TABLE 105 Research network adoption, research governance, NHS service support costs to research and access permissions (*continued*)

Study element	Research network adoption	UKCRN Portfolio ID	Body/bodies agreeing research access permissions	Body/bodies agreeing NHS service support costs
Absorbent pads study	UKCRN	10058 (EVIDEM-C-3)		
	DeNDRoN as above			
	PCRN-Greater London as above		South East London NHS Research & Development Centre	South East London NHS R&D Centre
			South West London Primary & Community Care	South West London Primary & Community Care
			West London Mental Health Trust	
			CNWL NHS Foundation Trust	
			Age Concern (Westminster)	
			Eight local branches of the Alzheimer's Society	

UKCRN, UK Clinical Research Network.

Appendix 25 Chapter 3: EVIDEM-CL1 March 2011 – briefing for Local Authority Adult Services managers and social workers

Meeting the needs of frail and cognitively impaired older people with incontinence in order to maintain independence and minimise the consequences for the person, their family and health and social care services.

Prepared by Vari Drennan, Jill Manthorpe and Steve Iliffe.

Background

Incontinence is leakage of urine or faeces or both. It is a symptom of a bladder or bowel problem. The prevalence of incontinence rises with age, with estimates of up to 15% of older women and 2–11% for older men experiencing daily urinary incontinence (UI).¹¹⁶ Among people living in care settings the rates are even higher. The risk of women having UI increases with factors such as having three or more children (although this diminishes with increasing age), obesity, diabetes and moderate to severe dementia.¹¹⁶ We know less about factors that predispose men to UI but these include urinary tract infections, disability and cognitive impairment, brain disorders and prostate problems. Among people aged over 60, rates of faecal incontinence are 5.1% in men and 6.2% in women¹¹⁶ and these increase with age. It can be caused by problems in the gastrointestinal or nervous systems as well as food intolerances, infections and the interplay between loss of mobility and cognition.⁴¹⁶ For some people with physical and/or cognitive impairments incontinence is the result of a lack of aids, unadapted environments, or a lack of timely assistance rather than a bladder or bowel problem.

Incontinence lowers a person's quality of life and adversely affects mental health.³⁵¹ It can be socially embarrassing, restricts social activity, creates extra work, such as laundry, and can mean much money has to be spent on replacement clothing and bedding. It can cause conflict between individuals and their family⁴¹⁷ and can make caring harder. Other health problems may get even worse, and it can lead to events such as falls.³⁵³

There are no UK estimates of the total public expenditure associated with treating or managing incontinence. There are some indications of the scale of the direct health service expenditure. It was estimated that the NHS spent £536 million at 1999/2000 prices in treating clinically significant urinary incontinence symptoms in community-dwelling adults.⁴¹⁸ In 2007 nearly 1.5 million NHS prescriptions were filled for incontinence appliances in England at a cost of £33 million.⁴¹³ Absorbent products for incontinence account for the majority of this spending.¹⁸¹

This briefing highlights the key actions in six areas that Local Authority staff and funded services can take in helping to promote continence and manage incontinence to minimise the consequences for the service user, the family carers and the health and social care services. Each action point is elaborated by a brief explanation and followed by a range of questions raising key points for adult service managers and social workers to consider.

Key action points

Assessment before assumptions

In many cases incontinence can be treated and the symptoms stop or lessen but treatment can only start if the person seeks help, usually from their GP or community nurse, who should conduct a thorough assessment. Assumptions that these symptoms should just be managed by absorbent products i.e. incontinence pads, are demoralising for the person and costly to them, their families and any health and social care services.

Key points for social care: many bowel and bladder problems can be treated or the consequences reduced

Are care planners and social care staff actively encouraging and helping service users to consult their GP or community nurse for an assessment if they have these bladder or bowel symptoms or the symptoms change? Do they encourage family carers to seek help? Is this information available to personal assistants? Do the local authority and NHS publish information about this? Is this information given to people in frontline, information, signposting and other community-facing roles? Do social care workers, older people and families have confidence that these problems are addressed by GPs and not seen as ones where nothing can be done because of a person's age? How are the experiences of those making referrals audited or collated? What is done with any concerns?

Are positive stories about the point of consulting NHS professionals available to social care staff? Are these promoted among staff who may not encounter many professionals or who are worried of being seen as interfering? Are such messages as 'requests for assessment are welcome' promoted among families, volunteers and housing support staff?

Promoting continence

The likelihood of bladder and bowel problems increases with age and having other medical problems. Simple steps can help avoid some bladder and bowel problems and associated incontinence.

These include:

- a balanced diet, with sufficient fibre, e.g. five portions of fruit and vegetables a day, 6–8 glasses of fluids a day (approximately 1.2 litres or 2–3 pints) – more in hot weather.
- general exercise of up to 30 minutes five times a week (adapted exercise for those with disabilities)
- a toilet routine that allows privacy, dignity and adequate time for their bowels to open; and
- in the case of those with impaired mobility or dexterity (skill in using hands), adaptations, aids or assistance (such as raised toilet seats, grab rails, elastic waist trousers rather than zips, etc.).

Key points for social care: there are basic steps to promote continence and prevent incontinence

Are basic prevention factors understood, in place in support plans, and promoted in social care contacts with users of services, particularly older people?

Are these subjects covered in reviews? What evidence is available that they are covered in self- or facilitated assessments, support planning and reviews? Would an audit of support plans show that these subjects are being addressed? What outcomes are recorded in this area?

Needing the help of other people with managing toileting

Many older people with health problems and disabilities have limited mobility and reduced dexterity. They may need support in acquiring the best adaptations, aids or assistance to maintain independence in toileting. For some people this will mean that they can only remain continent if they are supported by other people.¹¹⁷ This has implications for family and other carers and social care supporters. Extensive help will very likely be needed if a person becomes seriously cognitively impaired, for example with Alzheimer's disease.

Key points for social care: some people will only remain continent with aids, adaptations and assistance

Is publicly funded social care focused on maintaining continence rather than just relying on the premature use of continence pads which lower self esteem and are costly? Can re-ablement and other prevention services be called upon and what are the referral routes? What importance does the Resource Allocation System (RAS) give to these outcomes and what sums are allocated? What information is given about sources of equipment to people paying for all their social care as well as those receiving some support through personal budgets or help with paying care home fees?

Do carers and social care providers have access to training and support to enable them to help people remain continent? What is the access point for carers and social care workers if they have questions? What are the training opportunities for carers and care workers around subjects such as 'prompted voiding' (the reminding or helping someone to use the toilet regularly of a person with dementia)? Are these training opportunities available to personal assistants and to carers?

What is the local source of advice for care managers and care staff on aids and adaptations and what is provided through publicly funded joint (NHS and local government) equipment stores? How are such services audited in terms of access and acceptability? Are local older people engaged in activities such as 'mystery shopping' to see if such services are accessible and informative? Are charges and payments systems clear and fair?

Are frontline staff well equipped to inform people about sources of information and advice, particularly those not meeting publicly funded social care eligibility criteria? Are information, brokerage and navigation services audited to ensure that they are giving the best support?

Do care managers, brokers, dementia advisers and others supporting people with dementia and their carers consider specifically what assistance with continence might be needed and who is responsible for this? How and where is this recorded?

Do planners and providers consider the needs of people with dementia in the design of day centres and care homes, e.g. toilet signage, adequate lighting, contrasting colours for toilet seats? Are aspects of good design part of neighbourhood and community planning and regeneration?

Managing incontinence

Some people's incontinence cannot be treated or the underlying condition means they are unable to regain continence e.g. teaching pelvic floor exercises may not work for a person with dementia. The aim then is to manage and contain incontinence and minimise distress to all concerned. It may be possible to manage urinary incontinence and maintain bowel continence by assisting the person to sit on the toilet or commode after a meal (often breakfast), or at the time they usually open their bowels.

Key points for social care: many people who have urinary incontinence contained by pads are able to sit on a toilet or commode to open their bowels

Has the extent of support or aids required to assist someone to open their bowels on a toilet or commode been considered by those supporting people with assessments and in support planning? Is this part of desired outcomes for people affected, including carers? Are the costs of meeting these outcomes included in the Resource Allocation System (RAS)? Is information about help with equipment such as dryers and washing machines from the Social Fund or the voluntary sector clearly signposted to older people, carers and advice sources?

Absorbent products

The aim for the person, their family carers and for health and social care staff is to ensure that the use of incontinence pads leads to the best possible outcomes. Points to consider include ensuring that they:

- adequately contain the urine and/or faeces without leakage (both during the day and at night)
- are changed in ways to preserve dignity and as required to avoid skin damage
- are a design that is acceptable to, and manageable by, the person who is changing the pads
- are used according to the manufacturers' instructions
- are disposed of safely.

Chair and mattress protection may help meet outcomes such as promoting hygiene, in the context other issues such difficulty in pad design or in the case of a person with cognitive impairment who may be unwilling to use pads (dry or wet) or who may disturb or take them off.

The Department of Health has stated that the NHS supplies absorbent continence products according to clinical need³⁶⁴ and has developed standards and criteria for continence services.³⁶⁵ Social care services managers may wish to consult these if there are disagreements about responsibilities. The Royal College of Physicians' national audits show great variation in provision and policies.¹⁵⁸

Key points for social care: incontinence products

Are care managers and social care managers aware of local community health services/NHS policies on the provision of NHS-funded continence pads including any eligibility criteria? Has there been discussion of how these are operationalised at a local level, e.g. at Health and Wellbeing Boards or Overview and Scrutiny Committees? Do social care services staff in all sectors know how to refer people for an assessment for these products? Are care managers and care providers aware of other sources of information about these products such as the web-based PromoCon (part of the Disabled Living Foundation), the Disabled Living Foundation and the Bladder and Bowel Foundation Charity? Is information about these readily accessible on the internet and other public information services?

Are care managers and social care providers aware of the local contacts for altering or stopping deliveries of NHS funded pads when the need changes, or the person moves or dies?

How are people given choice and control over the products that are supplied by the NHS?

Do social care staff receive education and training in the correct use of different designs of pads and how to maintain modesty and dignity while changing pads? Do they receive training in hygienic practices and correct disposal? How is this audited? How do complaints about this lead to improvement? How are NHS services informed by local feedback on the quality of the service as well as the quality of the product?

Challenging behaviour and 'matter' out of place

Assistance in toileting and intimate, personal care can seem particularly insulting or threatening for someone with dementia and may be a flash point for the person to resist help or become aggressive. Other challenges for carers and staff may include faecal smearing, and lack of hygiene. Visitors may misinterpret care practices and the issue may lead to conflict between carers and care staff. Both older people and care workers may have cultural preferences that need to be considered. The Mental Capacity Act 2005 provides a framework for acting legally and in a person's best interests in this area of making decisions, as it does in others when a person lacks capacity to make decisions. Some situations may give rise to concerns about safeguarding and advice should be sought on these from safeguarding staff in accordance with local policy and procedures.

Key points for social care: challenging behaviour in toileting and intimate personal care

Have social care providers received training in working with people with dementia and are they knowledgeable about communicating with people with dementia to reduce fear, anxiety and resistance? What support is available to staff and carers in written but also face-to-face learning? Are there opportunities for staff to discuss intimate care in group or personal supervision? How well are interventions, information and support meeting the needs of diverse groups of older people, carers and care workers? Is care informed by the principles and guidance of the Mental Capacity Act when carers and care workers are making decisions about supporting people lacking capacity when they are acting in their best interests, e.g. carrying out care when a person is refusing this?

Are social care staff aware of behavioural management techniques that may help to identify potential causes of challenging behaviours? Are social care staff aware of who to either refer the person to, or encourage the person and their family to approach for assessment and strategies to manage or lessen behavioural and psychological disturbances? What is the referral pathway in the locality and is there evidence that it leads to positive outcomes? Are there any examples that can be used to assure care staff and carers that this is worth the trouble?

Incontinence is humiliating, distressing and embarrassing for any adult. Denial and concealing this problem from others is a common response. In people with dementia this can sometimes mean inappropriate activities, e.g. hiding soiled clothing and forgetting it, wrapping up faeces and hiding them. As the dementia progresses, identifying the correct place to urinate or defecate can also become a problem, as can apathy, and both can result in urine or faeces spillage. Attempts to clear up leakage and 'matter' out of place can also be ineffective or make matters worse from a carer's or care worker's point of view. If a person has faeces on their hands and tries to remove them (also known as faecal smearing) this can cause great distress. This can occur when the person can no longer manage personal hygiene after defecating or the person has tried to manipulate the pelvic floor or rectum to help defecation, or in severe dementia as an innate response of curiosity to the sensation of faeces exiting the body. These types of behaviours can place additional stress and distress on family carers and care workers, as well as visitors and others living in close proximity.

Key points for social care: when urine and faeces is out of place

Are care managers and care providers aware of contact points for obtaining assessment and advice in preventing and managing these situations? Is access to advice timely and useful? Are people who are not eligible for publicly funded social care services fully included in information and advice resources?

Are carers and social care workers provided with accessible and realistic information on managing spillage and leakage hygienically? Who is responsible for ensuring this information is useful and how is it audited? What is the involvement of carers and frontline staff in the construction of referral pathways and in the production of information? What records are kept to ensure that care practices are lawful and that staff are protected from unfair allegations that they are acting unlawfully? Are risk assessments used to support good practice and decision-making? Are safeguarding staff able to access expertise when responding to referrals or enquiries in this area?

Questions to address in the overall commissioning and provision

What do older people say about local information and services? What information is available to carers and to direct care workers, and is this accurate, sufficient and accessible?

How are local responsibilities for information, equipment, advice and professional interventions divided or managed jointly?

What should be the responses to an actual or future audit of assessments, support plans and reviews covering continence and incontinence?

If managing continence and incontinence is to be part of the outcomes framework in local commissioning, what needs to happen locally for this to be successful?

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Research instruments and tools

These appendices provide examples of the research instruments and tools used in the different EVIDEM-C studies.

Appendix 26 Chapter 3: Aide-memoire for guided conversations with the person with dementia

Instructions to researcher

Repeat rationale for the study and the process of this data collection. Confirm confidentiality and anonymity in reporting. Confirm that they are willing to carry on with the discussion. Confirm permission to record or not. Confirm that the exploratory discussion can be stopped at any time.

The discussion will start with general enquires of health and well-being to start establishing a non-threatening rapport and set the tone for the conversation about the more sensitive issues.

Discussion should centre around these themes:

1. Some people like you sometimes experience problems with not being able to get to the toilet in time, do you ever have those sort of problems?
 - i. Conversational probes for types of problems – urge/stress urinary incontinence, nocturia, finding the toilet, managing clothes, etc.
2. What helps you when you have that . . . INSERT . . . problems? How do you manage?
 - i. Conversational probes for types of strategies for addressing those problems and preferences, e.g. containment pads/pants, commode/urinal by bed, manageable clothes.
 - ii. Conversational probes on preferences and feelings about different strategies. How do you feel about managing in that way?
3. Some people like you sometimes experience problems with their bowels, getting constipated and then sometimes very loose motions, do you ever have those sorts of problems?
 - i. Conversational probes for types of problems with bowels.
4. What helps you when you have those sorts of problems?
 - i. Conversational probes for types of strategies and preferences.
5. Some people discuss these sorts of problems with their family doctor or with a district or continence nurse? Have you discussed these problems with your doctor or any other professional?

Probes for any views on experience of discussing or receiving help for these problems.

Confirm demographic information:

- age band, e.g. sixties, seventies, etc.
- living arrangements, e.g. living with family or alone.

Check whether uses any other health and social care services not mentioned above.

Closure by thanking for their contribution and confirm arrangements for summary of all research findings to be shared.

Appendix 27 Chapter 3: Aide-memoire in the qualitative interview study with family carers

Instructions for researcher

Repeat rationale for the study and the process of this data collection. Confirm confidentiality and anonymity in reporting. Confirm permission to record or not. Repeat that the interview can stop at any time.

The interview will start with general enquires of health and well-being of the close carer and the types of support and help they give to the person with dementia they care for. The interview then moves to the more sensitive issues.

1. Can you describe any problems your (insert – husband/wife, partner, parent, etc.) has with going to the toilet or being incontinent? Probes into:
 - i. urinary and faecal
 - ii. origin of problems
 - iii. impact of different types of incontinence
2. What types of interventions/strategies/support help you in helping support your loved one (a) stay continent and (b) manage their incontinence? Probe:
 - i. explore strategies for different problems, for day and night-time or for changing circumstances
 - ii. explore whether strategies ideas worked out alone or from suggestions/help from professionals/ other carers
3. Are there problems/situations that are more difficult to cope with than others? Probe:
 - i. emotional issues in relation to dealing with adult urine/faeces, intimate tasks
 - ii. successful strategies but with other consequences like restricting outside activities
4. Have you discussed these sorts of problems with your family doctor or with continence nurse or any other professional?
5. Are you currently using services/aids/equipment to help manage these problems? If yes what sort, how acquired and what has that experience been like?
6. Confirm demographic information
 - i. age band, e.g. sixties, seventies
 - ii. record gender
 - iii. ask whether has had a carer's assessment of need by social services
 - iv. ask whether in receipt of additional financial benefits, e.g. attendance allowance.

Closure by thanking for their contribution and confirm arrangements for summary for findings to be shared.

Appendix 28 Chapter 3: Interview tools to characterise the person with dementia and the carer in the longitudinal study and absorbent pads study

ID number:
Date: / /

Carer details

(also on CSRI)

We would like to know some things about you. Please tick as appropriate.

What is your year of birth?

Are you....? Male Female

Is the person with memory problems your....?

Spouse/Partner Parent
 Sibling Other family member
 Friend/Neighbour

Is English your 1st language? Yes No

If no, please state first language: _____

Interpreter required? Yes No

Current Medical Conditions

Are you currently seeing your GP for treatment for a medical (physical) condition? Yes No

Are you currently seeing your GP for treatment for a mental health problem?
 Yes No

Are you currently seeing hospital specialists for a medical (physical) condition?
 Yes No

Are you currently seeing hospital specialists for a mental health problem?
 Yes No

Decline

ID number: Date: //

Carer Ethnicity Categories

What ethnic background are you? (Categories are taken from the Census)

White

British

Irish

Any other White background

Mixed

White and Black Caribbean

White and Black African

White and Asian

Any other Mixed background

Asian or Asian British	<input type="checkbox"/>
Indian	
Pakistani	
Bangladeshi	
Any other Asian background	
Black or Black British	<input type="checkbox"/>
Caribbean	
African	
Any other Black background	
Chinese or other ethnic group	<input type="checkbox"/>
Chinese	
Any other background	
Decline	<input type="checkbox"/>

ID number:

Date: / / **PWD Demographic details** (also on CSRI)

Year of birth	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	----------------------	----------------------

Gender	Male <input type="checkbox"/>	Female <input type="checkbox"/>
---------------	-------------------------------	---------------------------------

Carers relationship			
Spouse/Partner	<input type="checkbox"/>		
Daughter/son	<input type="checkbox"/>	Sibling	<input type="checkbox"/>
Other family member	<input type="checkbox"/>	Friend/Neighbour	<input type="checkbox"/>

English 1st language?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If no, please state first language: _____		
Interpreter required?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Medical information

GP Details

Name: _____

Surgery: _____

Address: _____

Telephone number: _____

Current Medical Conditions

Please give details:

1) _____

2) _____

3) _____

4) _____

5) _____

6) _____

Height (estimated)

feet and

inches

OR

centimetres

Weight (estimated)	<input type="text"/> <input type="text"/>	stone and	<input type="text"/> <input type="text"/>	pounds	BMI (calculated later)	<input type="text"/>
<input type="text"/>						
	OR	<input type="text"/> <input type="text"/> <input type="text"/>		kilos		

Number of births (women only)

1 2 3 4 5 6+

Past surgical procedures? (NB probe for surgery related to gynae. and urinary system)

No Yes

If yes, please give details: _____

ID number: Date: //**PWD Ethnicity Categories: Census**

(Self assigned at end of interview)

White

British

Irish

Any other White background

Mixed

White and Black Caribbean

White and Black African

White and Asian

Any other Mixed background

Asian or Asian British	<input type="checkbox"/>
Indian	
Pakistani	
Bangladeshi	
Any other Asian background	
Black or Black British	<input type="checkbox"/>
Caribbean	
African	
Any other Black background	
Chinese or other ethnic group	<input type="checkbox"/>
Chinese	
Any other background	
Decline	<input type="checkbox"/>

Appendix 29 Chapter 3: Validated tools used in the longitudinal study and the absorbent pads study

Measures	References	Permissions
Neuropsychiatric Inventory (NPI)	Cummings JL, Mega M, Grey K, Rosenberg-Thompson S, Carusi DA, Gornbein J. The Neuropsychiatric Inventory: comprehensive assessment of psychopathology in dementia. <i>Neurology</i> 1994; 44 :2308–14	Permission obtained
Health-related quality of life for people with dementia (DEMQOL)	Smith SC, Lamping DL, Banerjee S, Harwood R, Foley B, <i>et al.</i> Measurement of health-related quality of life for people with dementia: development of a new instrument (DEMQOL) and an evaluation of current methodology. <i>Health Technol Assess</i> 2005; 9 (10). URL: www.iop.kcl.ac.uk/departments/?locator=330&context=773	Publicly available
Mini Mental State Examination (MMSE)	Folstein MF, Folstein SE, McHugh PR. Mini-Mental State. A practical method for grading the cognitive state of patients for the clinician. <i>J Psychiatr Res</i> 1975; 12 :189–98	Publicly available
International Consultation on Incontinence Questionnaire: Urinary Incontinence (ICIQ-UI) and Nocturia (ICIQ-N)	Avery K, Donovan J, Peters T, Shaw C, Gotoh M, Abrams P. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. <i>Neurourol Urodyn</i> 2004; 23 :322–30.	Permissions obtained
Disability Assessment for Dementia (DAD)	Gelinas I, Gauthier L, McIntyre M. Development of a functional measure for persons with Alzheimer's disease: the Disability Assessment for Dementia. <i>Am J Occupat Ther</i> 1999; 53 :471–81	Permissions obtained
International Statistical Classification of Diseases and Related Health Problems: dementia (ICD-10)	URL: www.who.int/classifications/icd/en/	Publicly available
Health outcomes/quality of life (EQ-5D)	URL: www.euroqol.org/	Permission obtained
Zarit Burden Inventory (ZBI)	Zarit SH, Reever KE, Bach-Peterson J. Relatives of the impaired elderly: correlates of feelings of burden. <i>Gerontologist</i> 1980; 20 :649–55	Permission obtained
Census ethnicity categories	Office for National Statistics (ONS)	Publicly available
Client Service Receipt Inventory (CSRI)	Reference for CALM study: Howard RJ, Juszcak E, Ballard CG, Bentham P, Brown RG, Bullock R, <i>et al.</i> Donepezil for the Treatment of Agitation in Alzheimer's Disease. <i>N Engl J Med</i> 2007; 357 :1382–92 Schneider J, Murray J, Banerjee S, Mann A. EURO CARE: A cross-national study of co-resident spouse carers for people with Alzheimer's Disease: I factors associated with carer burden. <i>Int J Geriatr Psychiatry</i> 1999; 14 :651–61	Permission obtained

Appendix 30 *Chapter 3: Toileting difficulties and incontinence questions used in addition to the ICIQ-UI and ICIQ-N, for the longitudinal study and the absorbent pads study*

Answered by: PWD / Carer

ID number:

(Please delete as appropriate)

Date: /

/

1. Problems with going to the toilet

a) Toileting difficulties? (e.g. finding the toilet)

Yes (go to Q.2) No

b) Any problems with your bladder / passing water?

Yes (do to Q.3) No

c) Any problems with your bowels?

Yes (go to Q.4) No

d) Any problems with both bladder and bowels?

Yes (go to Q.3 AND Q4) No

2) Toileting difficulties

a) What happens?

Can't find the toilet	<input type="checkbox"/>	Uses inappropriate receptacle / place	<input type="checkbox"/>
Finds the toilet but can't use it	<input type="checkbox"/>	Can't manage clothing	<input type="checkbox"/>
Hides evidence of accidents	<input type="checkbox"/>	Faecal smearing	<input type="checkbox"/>
Won't sit on the toilet	<input type="checkbox"/>	Not recognising the urge or desire to act on it	<input type="checkbox"/>
Screaming	<input type="checkbox"/>	Other (please give details): _____	

b) How frequently?

- | | | | |
|---------------------|--------------------------|---------------------------------|--------------------------|
| All the time | <input type="checkbox"/> | Two or three times a week | <input type="checkbox"/> |
| Several times a day | <input type="checkbox"/> | About once a week or less often | <input type="checkbox"/> |
| About once a day | <input type="checkbox"/> | Never | <input type="checkbox"/> |

c) How much does this bother you (PWD)?

(Please ring a number between 0 (not at all) and 10 (a great deal))

- | | | | | | | | | | | |
|------------|---|---|---|---|---|---|---|---|--------------|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| not at all | | | | | | | | | a great deal | |

d) Overall, how much do the toileting difficulties that you (PWD) experience interfere with your (PWD) everyday life? Please ring a number between 0 (not at all) and 10 (a great deal)

- | | | | | | | | | | | |
|------------|---|---|---|---|---|---|---|---|--------------|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| not at all | | | | | | | | | a great deal | |

e) What helps you to deal with that?

- Active – doing something before Passive – after (e.g. pads)

Please explain: _____

f) Are the strategies bothersome?

(Please ring a number between 0 (not at all) and 10 (a great deal))

- | | | | | | | | | | | |
|------------|---|---|---|---|---|---|---|---|--------------|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| not at all | | | | | | | | | a great deal | |

g) Have you sought advice or help on this from any professional?

- Yes (e.g. continence nurse) No

i) Who? _____

ii) What help was offered/ did you gain? _____

3) Problems with your bladder / passing water

3) ICIQ-UI

a) How often do you leak urine? (Tick one box)

- | | | | |
|---------------------|--------------------------|---------------------------------|--------------------------|
| All the time | <input type="checkbox"/> | Two or three times a week | <input type="checkbox"/> |
| Several times a day | <input type="checkbox"/> | About once a week or less often | <input type="checkbox"/> |
| About once a day | <input type="checkbox"/> | Never | <input type="checkbox"/> |

b) We would like to know how much urine you think leaks.

How much urine do you usually leak (whether you wear protection or not)? (Tick one box)

- | | | | |
|-------------------|--------------------------|----------------|--------------------------|
| A large amount | <input type="checkbox"/> | A small amount | <input type="checkbox"/> |
| A moderate amount | <input type="checkbox"/> | None | <input type="checkbox"/> |

c) Overall, how much does leaking urine interfere with your everyday life?

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

not at all

a great deal

d) When does urine leak? (Please tick all that apply to you / PWD)

- | | |
|--|--------------------------|
| Leaks all the time | <input type="checkbox"/> |
| Leaks when you are asleep | <input type="checkbox"/> |
| Leak for no obvious reason | <input type="checkbox"/> |
| Leaks when you cough or sneeze | <input type="checkbox"/> |
| Leaks when you have finished urinating & are dressed | <input type="checkbox"/> |
| Leaks before you can get to the toilet | <input type="checkbox"/> |
| Leaks when you are physically active/exercising | <input type="checkbox"/> |
| Never – urine does not leak | <input type="checkbox"/> |

ICIQ-N

e) How often do you pass urine during the day?

13 times or more 11 to 12 times 9 to 10 times 7 to 8 times 1 to 6 times

i) How much does this bother you?

(Please ring a number between 0 (not at all) and 10 (a great deal))

0 1 2 3 4 5 6 7 8 9 10

not at all

a great deal

f) During the night, how many times do you have to get up to urinate, on average?

Four or more Three Two One None

i) How much does this bother you?

(Please ring a number between 0 (not at all) and 10 (a great deal))

0 1 2 3 4 5 6 7 8 9 10

not at all

a great deal

Additional

g) Overall, how much does leaking urine interfere with your everyday life?

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

not at all

a great deal

h) What helps you to deal with that?

Active – doing something before Passive - after (e.g. pads)

Please explain: _____

i) Are the strategies bothersome?

(Please ring a number between 0 (not at all) and 10 (a great deal))

0 1 2 3 4 5 6 7 8 9 10

not at all

a great deal

j) Have you sought advice or help on this from any professional?

Yes (e.g. continence nurse) No

i) Who? _____

ii) What help was offered/ did you gain? _____

4) Problems with your bowel

a) Do you have problems with your bowels?

Yes (please go to Q.4b) No

b) What type of problem?

i) Constipation

Yes (please go to Q.5) No

ii) Leakage / incontinence

Yes (please go to Q.6) No

iii) Both

Yes (please go to Q.5 then Q.6) No

iv) Other e.g. uncontrollable wind (flatus):

Yes (please give details below) No

Details:

5) Constipation

a) How often do you feel constipated?

All the time Two or three times a week

Several times a day About once a week or less often

About once a day Never

b) How much does this bother you?

(Please ring a number between 0 (not at all) and 10 (a great deal))

0 1 2 3 4 5 6 7 8 9 10
 not at all a great deal

c) Overall, how much does constipation interfere with your everyday life?

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10
 not at all a great deal

d) What helps you to deal with that?

Active – doing something before

Please explain: _____

e) Are the strategies bothersome?

(Please ring a number between 0 (not at all) and 10 (a great deal))

0 1 2 3 4 5 6 7 8 9 10
 not at all a great deal

f) Have you sought advice or help on this from any professional? Yes (e.g. continence nurse) No

i) Who? _____

ii) What help was offered/ did you gain? _____

6) Leakage / incontinence of faeces

a) How often are you incontinent of faeces?

- | | | | |
|---------------------|--------------------------|---------------------------------|--------------------------|
| All the time | <input type="checkbox"/> | Two or three times a week | <input type="checkbox"/> |
| Several times a day | <input type="checkbox"/> | About once a week or less often | <input type="checkbox"/> |
| About once a day | <input type="checkbox"/> | Never | <input type="checkbox"/> |

b) What type of stool is it? Liquid Solid `Other (please give details below)

Details: _____

c) When does it happen?

Small amounts leaking all the time

Occurs when you are asleep

Occurs when you are passive, just sitting

Occurs before you can get to the toilet

Occurs at particular points e.g. after meals (please give details):

c) How much does this bother you?

(Please ring a number between 0 (not at all) and 10 (a great deal))

0 1 2 3 4 5 6 7 8 9 10

not at all

a great deal

d) Overall, how much does faecal incontinence interfere with your everyday life?

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

not at all

a great deal

e) What helps you to deal with that?

Active – ding something before

Passive - after (e.g. pads)

Please explain: _____

f) Are the strategies bothersome?

(Please ring a number between 0 (not at all) and 10 (a great deal))

0 1 2 3 4 5 6 7 8 9 10

not at all

a great deal

g) Have you sought advice or help on this from any professional? Yes (e.g. continence nurse) No

i) Who? _____

ii) What help was offered/ did you gain? _____

ID number:

Date:

7) Carer

a) How much does the person you care for's incontinence bother you?

(Please ring a number between 0 (not at all) and 10 (a great deal))

0 1 2 3 4 5 6 7 8 9 10

not at all

a great deal

b) Overall, how much does this interfere with your everyday life?

Please ring a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

not at all

a great deal

c) Are the strategies bothersome?

(Please ring a number between 0 (not at all) and 10 (a great deal))

0 1 2 3 4 5 6 7 8 9 10

not at all

a great deal

d) Have you sought advice or help on this from any professional?

Yes (e.g. admiral nurse) No

i) Who? _____

ii) What help was offered/ did you gain? _____

Appendix 31 Chapter 3: Further incontinence questions about pad usage for the longitudinal study

ADDITIONAL QUESTIONS - for person with dementia using pads

3) ICIQ-UI

a) How often do you leak urine (outside of the pad)? (Tick one box)

- | | | | |
|---------------------|--------------------------|---------------------------------|--------------------------|
| All the time | <input type="checkbox"/> | Two or three times a week | <input type="checkbox"/> |
| Several times a day | <input type="checkbox"/> | About once a week or less often | <input type="checkbox"/> |
| About once a day | <input type="checkbox"/> | Never | <input type="checkbox"/> |

b) We would like to know how much urine you think leaks (outside of the pad).

How much urine do you usually leak? (Tick one box)

- | | | | |
|-------------------|--------------------------|----------------|--------------------------|
| A large amount | <input type="checkbox"/> | A small amount | <input type="checkbox"/> |
| A moderate amount | <input type="checkbox"/> | None | <input type="checkbox"/> |

c) Overall, how much does leaking urine (outside of the pad) interfere with your everyday life?

(Please ring a number between 0 (not at all) and 10 (a great deal))

- | | | | | | | | | | | |
|------------|---|---|---|---|---|---|---|---|---|--------------|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| not at all | | | | | | | | | | a great deal |

d) When does urine leak (outside of the pad?) (Please tick all that apply to you / PWD)

- | | |
|--|--------------------------|
| Leaks all the time | <input type="checkbox"/> |
| Leaks when you are asleep | <input type="checkbox"/> |
| Leak for no obvious reason | <input type="checkbox"/> |
| Leaks when you cough or sneeze | <input type="checkbox"/> |
| Leaks when you have finished urinating & are dressed | <input type="checkbox"/> |
| Leaks before you can get to the toilet | <input type="checkbox"/> |
| Leaks when you are physically active/exercising | <input type="checkbox"/> |

Never – urine does not leak

Other

Please explain: _____

h) What helps you to deal with that?

Active – doing something before Passive - after (e.g. pads)

Please explain: _____

i) Are the strategies bothersome?

(Please ring a number between 0 (not at all) and 10 (a great deal))

0 1 2 3 4 5 6 7 8 9 10
 not at all a great deal

j) Have you sought advice or help on this from any professional?

Yes (e.g. continence nurse) No

i) Who? _____

ii) What help was offered/ did you gain? _____

ADDITIONAL QUESTIONS - for person with dementia wearing pads

ICIQ-N

f) During the night, how many times do you leak urine INTO the pad, on average?

Four or more Three Two One None

i) How much does this bother you?

(Please ring a number between 0 (not at all) and 10 (a great deal))

0	1	2	3	4	5	6	7	8	9	10
not at all										a great deal

Appendix 32 Chapter 3: Additional table in the Client Service Receipt Inventory (part 1) longitudinal and absorbent pads study

Adaptations, equipment and products	Tick <i>if yes</i>	Type of adaptation or equipment (<i>list all</i>)	Who supplied this?	Who/what organisation paid for this?
Changes to service user's home (e.g. putting in shower cubicle, stair lift)				
Special equipment (e.g. for mobility, bathing, etc.)				
Continence products (e.g. pads, pull-up pants)				
Aids to getting to and using the toilet or protecting bedding/furniture (e.g. grab rails, raised toilet, urinal bottles)				
Furniture, clothing, bedding or household goods replaced because of incontinence problems				

Appendix 33 Chapter 3: Data collection tools for examining feasibility and acceptability in the absorbent pads study

Topic guide for evaluation of study research methods

ID number:

--	--	--	--

Date:

--

One of the aims of this study was to help us test our research questionnaires and diaries to design a larger research study

The following questions are designed to help with this study. Please could you let us know how you found the experience of helping with our research?

1. Were the questions you were asked acceptable?
 - a. If the questions were not acceptable, which questions or topics were you not comfortable with?
2. How easy did you find it to complete the questionnaires?
3. Did you complete all the questions?
 - a. If you did not, which parts did you not complete?
 - b. Why did you not complete these sections?
4. Did you find it demanding being involved in this research?
5. Did you have any issues dealing with this sensitive topic?
6. Were you happy to weigh the incontinence pads?
 - a. If you were not happy to be involved in weighing the incontinence pads, what were your reasons?
7. Have you any suggestions of how you would change how this research was carried out?
8. Would you be happy to be involved in research in the future?

Evidem-C Investigating absorbent products Topic Guide Version 1 29032010

Opinion sheet for each absorbent product for incontinence (Fader 2008)

Please ring as appropriate and use a sheet for each type of incontinence product used

ID number:

--	--	--	--

 Date:

--	--	--	--

NAME of PRODUCT	(name)						
Ease of putting on – by day	Very good	Good	OK	Poor	Very poor		
Ease of putting on – by night	Very good	Good	OK	Poor	Very poor		
Contains leakage	Very good	Good	OK	Poor	Very poor		
Stays in place	Very good	Good	OK	Poor	Very poor		
Contains smell	Very good	Good	OK	Poor	Very poor		
Discreet	Very good	Good	OK	Poor	Very poor		
Dry comfort	Very good	Good	OK	Poor	Very poor		
Wet Comfort	Very good	Good	OK	Poor	Very poor		
Keeps skin dry	Very good	Good	OK	Poor	Very poor		
Overall opinion for DAY use	Very good	Good	OK	Poor	Very poor		
Overall opinion for NIGHT use	Very good	Good	OK	Poor	Very poor		

Thank you for taking the time to complete this sheet.

Evidem-C Investigating absorbent products Opinion of absorbent product Version 1 28032010

Appendix 34 Chapter 3: Additional table in the Client Service Receipt Inventory (part 1) for the absorbent pads study

Absorbent products

Brand	Size	Teardrops	Amount/frequency	Source, e.g. NHS/internet	Cost (if applicable)	Notes

Other continence products^a

Name	Source, e.g. NHS/internet	Cost (if applicable)	Notes

^a For example, disposable bed/chair sheets, disposable bags, gloves, sprays, etc.

EVIDEM C Investigating absorbent products CSRI Version 1 29032010

Appendix 35 Chapter 4: Phase 1 protocol

REC REF 08/H0502/74

Changing practice in dementia care in care homes: developing and testing evidence-based interventions at the end of life

PI: Professor Claire Goodman, University of Hertfordshire, c.goodman@herts.ac.uk

Background

How people with dementia die, and the type of end-of-life interventions they should receive, has been widely discussed and partially introduced across the NHS and care home sector.^{191–193} These discussions focus particularly on place of care and the adaptation of existing approaches to provide palliative care for people with dementia. There remains, however, a limited understanding of how this population experience the end of life and if the recognition of an end stage of life in dementia can improve service provision and influence place of care.

Older people with dementia have a limited life expectancy from the time they receive a diagnosis, and particularly on entry to a care home. Cox and Cook¹⁹⁰ identify three ways in which people with dementia can die:

- People who have a diagnosis of dementia at the end of life, but whose death is caused by another medical condition, for example, cancer, or heart disease.
- People who die due to a complex interplay of mental and physical problems, where the dementia has not impacted greatly on their functioning.
- People who are described as having end-stage dementia, where the associated consequences of the dementia impact upon all domains of their life and they ultimately die of the complications that go with progressive neurodegeneration.

Each of these different ways will directly influence the place and experience of death for an individual and his/her family members. Death for people with dementia is not a single trajectory, rather patients and carers live with dementia for years often with different trajectories of functional decline and needs.^{194,195}

Practitioners experience many difficulties in recognising and responding to older people's needs with dementia at the end of life. Practitioners of all disciplines lack confidence in discussing advance care planning with patients and their families, and find the recognition of when someone is dying, and identification of the kind of support needed, problematic.^{197,199} The range of health needs experienced at the end of life by people with dementia is many. Communication problems, confusion, functional loss, nutrition and complications, such as, infections and incontinence, can compound the distress of a person who is dying and challenge clinicians' knowledge and expertise.⁴¹⁹ Attempting to manage these challenges can result in inappropriate medical interventions and referral to acute care.¹⁹⁸

Few diagnostic and support tools have been developed for primary care, or take into account the range of community-based professionals and support workers that can be involved in caring for people with dementia in a care home. In the United Kingdom, over 13,000 care homes offer personal care and approximately 405,000 older people receive care in these settings. The average care home providing personal care has between 26 and 36 places depending on ownership.⁴²⁰ Twenty-three per cent of older people over 65 will die in a care home, the majority of whom will die with dementia. It is often assumed

that most people with dementia die in a care home with nursing care (a nursing home), but homes with personal care only (a residential home) care for a significant number of older people who have some degree of dementia, which may be unrecognised.¹⁹³ Care homes without on-site nursing provision are wholly reliant on primary care services for first contact, referral and access to health-care and end-of-life services. This makes end-of-life care an important issue for a wide, primary care-based workforce.

An integrative review of qualitative and quantitative research on palliative care interventions for community-dwelling older people with dementia (including older people in care homes), demonstrates that research on end-of-life care for people with dementia poses significant methodological challenges.²⁰⁰ The North American context of care heavily influences this literature where a focus on prognostication is linked to decisions about reimbursement for medical costs and use of more 'aggressive' interventions for people with advanced symptoms of dementia, for example, management of pneumonia with intravenous antibiotics. Moreover, the majority of research on end-of-life care for people with dementia tends to rely on proxy or retrospective accounts of particular symptoms and events in the illness. Few studies have addressed the environment and organisation of care, or the affect of different care decisions on patient outcomes.

It is important to recognise that the organisation and context of care home provision for people with dementia is highly variable and heterogeneous.^{202,203} This affects individuals' access to care and experience of support at the end of their lives. The care home sector is a mixed economy of care operating with different patterns of ownership (local authority, private, charitable and voluntary) and size of organisation (e.g. a single independent care home/a commercial chain). The cognitive ability and dependency of residents in care homes also varies by care home, and there is a considerable overlap in residents' needs between settings with on-site nursing and those without.²⁰⁵ Despite a requirement by the National Minimum Care Standards for Care Homes that 50% of care staff within a home are trained to NVQ level 2 by 2005,^{421,422} there is a wide variation in the levels of staff training that care homes offer and expect from their care staff. Many factors influence how care homes work with primary health-care services, and the degree a care home is likely to engage with end-of-life care for their residents. These include factors both within a care home, such as, ownership, care staff turnover, and qualifications held by a care home manager (e.g. a nursing qualification), and service provision to a care home, for example, GP attachment, the payment of a GP retainer, a locality's (LA/PCT) organisational history of innovation with care homes.^{198,199}

This study, the EVIDEM-end of life project, has two phases. This protocol addresses Phase 1 of the study. In Phase 1 we aim to establish the different possible pathways to death for older people with dementia living in a care home. The second phase will use these findings to develop and test dementia specific interventions that support health-care professionals, community workers and care home staff in palliative care for older people with dementia in care homes. The Phase 1 findings will directly inform Phase 2 that intends to develop a toolkit for providing end-of-life care for people with dementia resident in a care home.

Aim

To explore and document the need for support and end-of-life care of older people with dementia living in a care home environment.

Objectives

1. To describe the different characteristics of older people with dementia residing in a care home and their respective pathways to death.
2. To describe the care and support needs of older people with dementia living in a care home and their carers.

3. To establish how care staff, and NHS primary care practitioners define, assess and provide end-of-life care for older people with dementia resident in a care home.
4. To describe how different contexts and models of care in care home environments influence an older person with dementia's experience of end-of-life care.
5. To identify the treatments and interventions received, and services and resources used, leading up to an older person's death.
6. To establish if dementia specific educational support and assessment tools can improve experiences and outcomes for older people with dementia dying in care homes (this applies to Phase 2 of the study).

Definitions of end-of-life care

End-of-life care is a contested term⁴²³ and consequent inconsistencies in understanding can lead to different emphasis in care provision. End-of-life care as a type of service provision is closely related to the palliative care speciality. Palliative care focuses upon the support of people as they live and die with a life limiting illness. The World Health Organization (WHO) defines palliative care as:

*An approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.*⁴²⁰

This WHO stance on palliative care adopts a public health perspective with emphasis on early identification to prevent symptoms and ensure optimal disease management.⁴²⁰ There is a distinction between generalist and specialist palliative care services:^{424,425}

- *Generalist palliative care services* are provided by health and social care practitioners to individuals in whatever care setting they reside.
- *Specialist palliative care services* support these generalist services and provide care for people with unresolved symptoms, or complex psychosocial, end-of-life or bereavement issues. Specialist palliative care may be provided in dedicated settings such as hospices, but also in hospitals, people's homes, and long-term care facilities.

End-of-life care is a broader term than 'terminal care'. Terminal care is usually associated with the last few days and hours of life, and is based upon the knowledge that an individual is dying, while end-of-life care encompasses more than the terminal care phase. The term 'end of life' originates from North America and is particularly used in the context of the care of older people.

*End of life care for seniors requires an active, compassionate approach that treats, comforts and supports older individuals who are living with, or dying from, progressive or chronic life-threatening conditions. Such care is sensitive to personal, cultural and spiritual values, beliefs and practices and encompasses support for families and friends up to and including the period of bereavement.*⁴²⁶

Phase 1 study design

The project uses a two-phase prospective study design to explore and document needs for support and end-of-life care for people with dementia in care homes to develop care practices at the end of life. This proposal refers to Phase 1 only. Phase 1 intends to use documentary review and interviews to prospectively track care needs and service use for people with dementia in care homes over a 2-year period at

4-monthly intervals. The study will involve older people with dementia resident in care homes, care staff, NHS primary care practitioners and social service personnel. The Phase 1 findings will inform Phase 2, developing and evaluating care practices at the end of life for people with dementia in care homes. A separate NRES submission will be made for Phase 2.

Study settings

Six care homes in a range of possible sites within the North Thames DeNDRoN area (i.e. Camden, Barnet, Enfield, Haringey, Islington, Barking and Dagenham, City and Hackney, Havering, Newham, Redbridge, Tower Hamlets, Waltham Forrest, Brent, Hammersmith and Fulham, Ealing Kensington and Chelsea, Harrow, Hillingdon, Hounslow, Westminster, Hertfordshire, Bedfordshire and Essex) and registered with the Commission for Social Care and Inspection (CSCI) as offering personal care and specialist support in dementia care, with up to 50 beds (the median size of a care home in England offering personal care is 35 beds)⁴²⁷ and which, in recent inspections by CSCI, have been assessed as meeting National Minimum Standards.⁴²² To reflect the diversity of care home provision within England, and London in particular, requires the selection and identification of care homes that reflect a range of providers (e.g. private, voluntary/charitable and national chain), staffing expertise and history of working with NHS services (e.g. use of integrated care pathways, adoption of palliative care frameworks, etc.). The participating care home settings will therefore reflect a mix of ownership to include care homes that are part of a large commercial chain, private, voluntary, charitable and faith-based providers.

Recruitment

In the UK there are over 13,000 care homes that offer personal care and approximately 405,000 older people receiving care in residential settings.⁴²⁸ Older people in care homes with personal care represent the majority of residents in long-term care. For this population, access to health and palliative care services is mediated wholly through primary care services. This group are the focus of the study.

The care homes

The sensitivity of the focus of the study on end-of-life care for people with dementia, and the need to maintain a relationship with the care home staff over a 2-year period, requires that the recruitment of care homes and participants is undertaken in three stages, namely:

Stage 1: identification of possible care homes

The intrinsic heterogeneity (culture of care, population, staff turnover, income, ownership) of care homes makes identifying representative care homes problematic. The median size of a care home with personal care is 35 places.⁴²⁷ Using the CSCI Directory of Care Homes and Care services, we will identify eligible care homes from the range of possible sites in the North DeNDRoN area and Sussex on the basis that:

- The care home is for older people, offering personal care and specialist support in dementia care.
- The care home does not have on-site nursing care (care homes with mixed provision can be included in the study, we will recruit participants who have been assessed as not requiring nursing care).
- Has between 20 and 50 places.
- The most recent CSCI inspection report is favourable, with no ongoing problems or issues identified requiring action.
- The care homes' 'typicality' is comparable with findings from other national studies and similar to one another.
- Care home staff consider they have a good working relationship with their local primary care services.
- The final sample has a mix of ownership (e.g. charity, voluntary, private, corporate).

Stage 2: invitation to express an interest in participation

We will write to the managers of the identified care homes, introducing the study and asking if we can telephone to arrange a meeting at a mutually convenient time with the manager/senior management team to discuss the study's aim, and what participation will involve. Where several care homes are represented by one provider, we will first approach the owner organisation to gauge their interest and willingness for

their care homes to participate, and then write to the relevant care home managers. Managers and liaison staff within a Primary Care Trust (and Local Authority) where a care home has signalled an interest to participate will inform NHS professionals and social service personnel about the study taking place within their respective organisations.

Stage 3: discussion with older people, care staff, NHS and social service personnel

Having met with the care home manager, we will arrange meetings with the different participant groups to introduce ourselves and the study. This will include a care home's residents' forum, care home staff (preferably without the care home manager being present) and the relevant primary health care teams, and social service personnel. These will be informal meetings to gauge the different groups' level of interest and engagement with the study, and identify possible reasons for a care home or NHS staff not taking part (e.g. staff sickness, reorganisation within the care home). We will host coffee mornings/ afternoon tea events in interested care homes to encourage discussion and questions about the study.

Once it has been established which six care homes will participate in the study, we will provide all the potential participants (older people, care staff within a care home, and NHS and social service staff providing services to a care home) with information booklets about the study. We will ask to display a poster about the study in each care home to inform visitors that a research study is taking place. All participants will have a minimum of 48 hours to consider information provided about the study before further contact by the researcher to gauge interest or not in the study. To enable the older people (and/or their consultee) to discuss the older person's participation with family and trusted friends, we will allow a week for them to consider if they would like to take part. It will be made clear from the start that a decision whether to take part in the study or not is entirely voluntary and that their decision will not affect care or working in the care home or PCT in any way. At no stage will care home or NHS staff be involved in providing detailed information about the study to the older people, or in the consenting process.

Older people with dementia

A recent study found that the numbers of older people with a recorded diagnosis of dementia account for 46% of older people resident in care homes with no on-site nursing care.⁴²⁹ This is consistent with larger surveys of residents of care homes with personal care. The PSSRU report that 22% of residents' experience severe cognitive impairment⁴³⁰ and 48% mild/moderate impairment. Similarly, a secondary analysis of the Health Survey for England 2000 indicates 24% of residents experience severe impairment,⁴³¹ but 30% of residents were considered unable to complete a cognitive function test, indicating likely under reporting. In the PSSRU study, most individuals with severe impairment on admission had no documented diagnosis of dementia.²⁰⁶

To address objectives one, two and five, and capture the range of characteristics, episodes of ill health, care needs and service use experienced by older people with dementia, we will purposively recruit a minimum of 120, and up to 250, older people resident in 10 care homes with personal care and no on-site nursing. The older people approached to participate will either have a recorded diagnosis of dementia in their care notes, or following discussion with their care staff, be identified as having symptoms and behaviour that is consistent with a diagnosis of dementia. Older people will be recruited by project staff using a separate information and consent process, and in discussion with their consultee when a person with dementia lacks capacity to give (informed) consent. Respective inclusion and exclusion criteria comprise:

- **Inclusion criteria** Older people aged 65 years and over with a formal diagnosis of dementia (documented medical assessment) or informal diagnosis (considered by care home staff and/or in care notes as having dementia) and a validated measure of cognitive function impairment (undertaken by the researcher), resident in a care home registered to provide personal care only and specialist support in dementia care.

- *Exclusion criteria* People who do not speak English for whom an interpreter cannot be located, those whose care home manager considers it inappropriate to approach, and individuals who lack capacity to give an (informed) consent where a consultee cannot be identified to support (or not) the individual's participation.

Recruitment of the older people will involve a three stage process previously used in care home research^{431,432} that intends to minimise pressure on individuals to take part and provide opportunities for discussion with others:

- *Stage 1* The respective care home managers will give each older person (and/or their consultee) within the sampling frame a letter of invitation to participate in the study and an information booklet.
- *Stage 2* A member of the care home staff (e.g. the care home manager) will introduce a member of the project staff (e.g. the research fellow) to each older person (and/or their consultee) who has indicated they may wish to participate in the study. A time is agreed with each older person (and/or consultee) and when available, an intermediary, to discuss the study.
- *Stage 3* Meeting with an older person, and an intermediary (if available), such as a care worker or family carer, with whom the older person particularly relates to explain the research study and if in agreement, begin initial consenting. The researcher will ensure that the intermediary is present and able to explain and, if necessary to interpret any areas of concern of lack of understanding. The researcher will ensure that the participant is given full opportunity to have the study explained to them in a way that best meets their individual needs.

In situations where an older person has been formally assessed, and it is documented that they do not have the capacity to consent or take part in an interview, we will ask the older person's consultee (e.g. a relative) if, based on their knowledge of the older person, allowing a researcher to review his/her care notes would upset or distress them. The care home manager will be asked to write to the consultee about the study and they will be asked to assent to enrolment of the person with dementia. The researcher will arrange to see the person with dementia and his/her consultee to seek their written support for the older person's participation in the study. In the event that a consultee cannot be identified, then the person with dementia will be excluded from the study.

Amendment – submitted Southampton REC November 2008

The process of engaging consultees in the research study required amendment following a low consultee response rate in the EPOCH-Experiences of Older People in Care Homes research study (PI, Claire Goodman). In the event that a nominated consultee does not respond to a care home manager's letter, additional processes have been put in place to ensure that we have consulted appropriately, comprising:

1. The letter of invitation, sent by the care home manager, requests that the consultee response form is returned (in the SAE) within 2 weeks of receipt.
2. The letter details that if we do not hear from the consultee after 2 weeks we will follow up their response with a telephone call, asking them, if, based on their knowledge of the older person they think they would be interested or not in participating in the study, and allow the researchers to review their medical and nursing notes, and to share anonymous patient data with the EVIDEM Registry. In the event of still not being able to obtain a response from the nominated consultee, we propose to approach the GP, District Nurse or Social Worker, who knows the older person best.
3. If the consultee at any point expresses the opinion that the older person would not wish to take part, that person must be excluded from the study, unless another consultee can be identified.
4. We will then write to consultees who felt the older person would wish to take part, to inform them that the researchers have begun to extract data from the person's medical and nursing notes.

These additional processes are in keeping with the Mental Capacity Act (2005)¹⁷ expectation that 'reasonable steps' have been taken to identify others who could be consulted about what a prospective participant's wishes and feelings about participation in the project would be if they had capacity. These changes reflect the British Psychological Society's recommendations for undertaking research with people who do not have the capacity to consent.⁴³³

The above amendment was approved by the Southampton and South West Hampshire Research Ethics Committee on 6 March 2009, reference no. 08/H0502/74.

Care workers, NHS and social care staff

To address objectives three, four and five (above) we will recruit up to five care home staff from each care home including the care home manager, and up to three NHS professionals (e.g. general practitioner, district nurse and Macmillan nurse) who have ongoing involvement with a care home participating in the study. This will establish how care home, NHS and MHS care staff define end-of-life care for older people with dementia, the assessment and care tools they use, approaches to care, current service provision, access to specialist services and level of training and expertise.

Amendment – submitted Southampton REC July 2009

In addition, early results are indicating that ambulance staff called to the care home will automatically start resuscitation procedures even if a do not resuscitate agreement is in place for the person concerned. We would therefore like to include data from the ambulance service about how they interpret their responsibilities in these situations.

Ethical review and approval for the above amendment has been obtained. The Southampton and South West Hampshire Research Ethics Committee A approved the amendment on 11 August 2009, reference no. 08/H0502/74.

Data collection

In keeping with the study's aim and objectives, data collection focuses on five main areas, summarised as:

- Baseline characteristics of the older people with dementia participating in the study, including: age, gender, ethnicity, funding support, level of cognitive and physical function, medical conditions, function and length of stay in the care home.
- How older people with dementia's health and care needs change over time, the services they receive, and key events in their lives over the 2 years that affect their health and use of services.
- Training and experience of care home and NHS staff to provide care to older people with dementia and understanding of older people's care needs at the end of life.
- Current assessment and management strategies for people with dementia within the care homes (e.g. assessment tools, care protocols and end-of-life care frameworks).
- The physical environment, resources, and current access to health-care services of each participating care home.

Older people with dementia: characteristics and change over time

A pilot of the tool to extract data from residents' care home notes and care plans will be undertaken within two care homes. The development of the tool is informed in particular by previous research projects undertaken in care homes by members of the research team,^{429,430} the broader EVIDEM research programme, and a further study led by Professor Claire Goodman; EPOCH-Experiences of Older People in Care Homes, examining experiences of living and dying in a care home.

To address objectives one, two and five (above) we will record a baseline for all participants, where possible, the following minimum data set of information (extracted from care home notes and care plans):

- (a) Demographic details (name, date of birth, gender, marital status, first language, ethnicity).
- (b) When appropriate: carer information (name, date of birth, gender, address, postcode, relationship to person with dementia).
- (c) GP and practice details (name, address).
- (d) Cognitive status: if available, date of most recent test and score. In instances when unavailable, and an individual is considered by care staff to exhibit symptoms likely indicative of dementia, a validated measure of cognitive function will be undertaken.
- (e) Functional status (date of most recent test and score) and Barthel score in discussion with the older person's key care worker.
- (f) Behavioural/neuropsychiatric status.
- (g) Medication.
- (h) Co-morbidity (e.g. depression, CVD, diabetes).

We will review existing care plans (including details of advanced advance care plans, and other support tools for end-of-life care and current medication, specifically the use of pain relief and sedatives, and (if held in the care home) residents' medical notes. These reviews will be repeated every four months over 2 years. Data extraction will focus particularly upon those areas of care that are most significant for end-of-life care. These will include, for example, episodes of ill health, physical care needs, cognition, discussion of advanced care plans, access and use of primary care and specialist services, out of hours services, and bereavement/deaths in each care home. Particular attention will be given to those care needs of older people with dementia that are modifiable and likely to respond to palliative care interventions (e.g. evidence of experiencing pain, agitation, constipation, low mood, confusion, loss of appetite, fatigue).

Where possible, to complement the notes review, brief unstructured interviews are planned with a small purposively selected sample of the older people participating in the study to explore their health, and experiences of living in a care home. Events, reported by care staff, or documented in the notes, that occur during the 4-monthly data collection intervals will inform the purposive selection. Events are those likely indicative of a change in health status and care needs, for example, episodes of ill health, advance care planning. We will also seek interviews in instances of incomplete documentation or an older person's expression of interest in the study. The interviews with the older participants will help to validate the note review process and identify any changes over time in the older person's function and cognition that may not have been documented. This will also ensure that as far as is possible the person with dementia's experience of living and dying in a care home is acknowledged and documented. To facilitate older people's participation in an interview, we will draw upon different media, for example, 'talking mats' used in previous research involving older people with dementia.⁴³⁴ The media used will inform how interviews are recorded, for example, notes, audio tape.

For those older people who die during the study, care home and GP notes will be retrospectively reviewed, with permission from the respective GP, to establish what services the older person received prior to death, place of death and the care provided. A case study analysis of this group will combine the different data sources for each person (interviews with older people and staff, case notes, field notes, services received) collected over time and allow thematic and outcomes related analysis of the care these older people received.

Amendment – submitted Southampton REC November 2008

Anonymous data from the reviews of residents' care home notes and care plans (part of the study's dataset) will be shared with the EVIDEM Registry research study, entitled; 'A registry of people with dementia using services in the North Thames Dementia and Neurodegenerative Research Network

(North Thames DeNDRoN) Region'. The EVIDEM Registry study intends to develop a unique and comprehensive minimum dataset (MDS) of individuals with dementia (or symptoms likely indicative of dementia) at differing stages in the disease trajectory (from diagnosis to nearing the end of life). Recruitment to the Registry is intended through inclusion of anonymous patient data from the four EVIDEM research studies and direct recruitment to the registry (e.g. via general practices).

Ethical review and approval for the EVIDEM Registry has been obtained. The Southampton and South West Hampshire Research Ethics Committee A approved the EVIDEM Registry research study on 30 June 2008, reference no. 08/H0502/34. Ethical approval has also been given for the EVIDEM research study 'Promoting Continence and Managing Incontinence at Home' that includes sharing of anonymous patient data with the EVIDEM Registry study. Ethical approval was obtained from Camden and Islington Community Local Ethics Committee on 29 September 2008.

The above amendment was approved by the Southampton and South West Hampshire Research Ethics Committee on 6 March 2009, reference no. 08/H0502/74.

Care home and NHS staff training and experience

To address objectives three, four and five (above), and understand how care home and NHS primary care staff conceptualise, recognise and provide end-of-life care for older people with dementia, we will undertake audio recordings of semi-structured interviews with the care home managers from the participating care homes, and up to five care workers (sampled to reflect the range of experiences and seniority within a care home), up to three NHS staff (i.e. GP, district nurse and palliative care specialist). Semi-structured interviews will cover participants' length of employment, training, knowledge on end-of-life care and use of relevant tools for the assessment and care of people with dementia, experience and attitudes towards providing end-of-life care for people with dementia, and working with generalist and specialist palliative care services.

Practitioners will be asked to provide up to three examples of where they have provided end-of-life care to an older person with dementia in the study care homes. These examples will help to illustrate what supports and inhibits good end-of-life care for people with dementia.

Emergency care staff

The focus of the interviews was the impact dementia had on the treatment, and care that was provided and the decision-making processes, as well as the policies and protocols used at the end of life. Particular attention was given to the use of Do Not Resuscitate orders and the challenges of adhering to patient wishes, and other challenges that may arise when treating someone who is at the end of life. Finally, two scenarios were described and participants were asked how they would respond to these fictional scenarios and why, if they received the call out. This helped the researchers understand the circumstances and decision-making process when placed in difficult situations.

The care home environment

To inform objectives three and four, in each of the participating care homes we will review care home documentation and policies for evidence of end-of-life care training, use of frameworks and support tools, and guidance on end-of-life care and evidence of the involvement of older people and relatives in end-of-life decision-making.⁴³⁵ This will include the review of support materials used for training programmes on working with people with dementia and end-of-life care implementing the Mental Capacity Act 2005.

We will also review shared documentation, such as, integrated care pathways, e.g. continence management, and notes that show evidence of older people with dementia's use of related services, for example, specialist palliative care, hospice support and out of hours services, as well as documenting informal support available to the home (e.g. volunteers, older people advocates and faith organisations).

Analysis of data

Quantitative data

This is a prospective study that aims to describe the symptoms, health needs, care received and experiences of older people with dementia resident in a care home, and their pathway to death. Analysis will focus on physical and mental care needs, social relationships, care interventions, access to support, documented hopes and expectations about death, and access and use of primary care, specialist palliative and psychogeriatric services. Quantitative analysis will include descriptive statistics to summarise the attributes and key events in the lives of the older people over time. This data will provide information about the frequency and pattern of death in the care homes, services that were available to the older people, and the place of death. To ensure the volume of data is managed appropriately, the data will be specifically analysed to consider what it reveals about living in a care home with a diagnosis of dementia and the pathway to death, including:

- mapping key events
- episodes of ill health and related prescribing
- care provision within the care home
- access to generalist and specialist NHS services
- place of death, evidence of use and implementation of advance care planning, and care home staff's expectation (or not) of death and impact on the care provided.

Where older people have received palliative care, analysis will draw on Corner *et al.*'s⁴³⁶ matrix of evidence for making judgements about the type of palliative care interventions received.

Qualitative data

Summaries of documentary reviews and interview transcripts will be thematically analysed using computer software for qualitative analysis (N7) to facilitate storage, retrieval, and analysis of the data. Data analysis will follow a process of data reduction and data complication to identify prominent themes and their interrelationships.⁴³⁷ The analysis will involve three stages:

1. a process of familiarisation and categorisation by reviewing and segmenting data into separate and defined categories that are close to the participants' and documents' own categories
2. categorical and thematic comparisons within and between groups (e.g. care staff, NHS staff, older people) and the identification of preoccupations, differences and themes
3. data interpretation and recontextualisation to identify thematic relationships and working hypotheses on, for example, pathways to death for people with dementia in care homes.

Credibility of analysis will be achieved through comprehensive data analysis, such as, searching for rival explanations for emergent themes, and peer debriefing with the research team and the steering group.

Economic analysis

The resource implications of providing end-of-life care for people with dementia resident in a care home will be documented and cost calculated. This will include the health and social care services provided by care home staff, and NHS generalist and specialist practitioners. The skill mix and relative contribution of different services will be compared across the different care homes in a cost–consequence framework.⁴³⁸ This will incorporate the perspectives of health and social care services, older people with dementia, care home staff and other practitioners providing services to the care home.

Ethical issues arising from the study

There are ethical issues about researching sensitive issues and ensuring voluntary and informed consent in a closed community such as a care home. We propose a framework for participatory and inclusionary consent compatible with the Mental Capacity Act 2005. Consent will be seen as an ongoing and context specific process. We will aim whenever possible to include people with dementia or confusion in every stage of the study. It will be stressed throughout the negotiation for access, and within the consent process, that this study is about living in a care home and approaching the end of life. We will also ensure that in each care home processes are in place that support the older person and can address any issues that may arise from participation.

The researchers are very experienced with professional, personal and research experience of working with older people that are vulnerable. Dr Evans as the research fellow is an experienced academic and primary care nurse, who has specialised in the area of gerontology completing a doctoral study that involved working closely with care home staff and interviewing older people in care homes. The researchers will work closely with the senior members of the research team to provide continual supervision, support and guidance. Specific ethical issues arising from this study are:

- *Anonymity and confidentiality* All participants will have a unique identification code. No names, or identifying details, will appear on any data collection forms, analysis or draft and final reports. During data collection, access to the names and contact details of participants will be restricted and these will be kept in a password protected computer at the University of Hertfordshire. Those with access will be the research fellow, and members of the research team. All participants will be guaranteed anonymity in written reports, summaries of data analysis and a summary of the findings will be sent out to participants for their comments prior to publication and dissemination. The care homes will not be identifiable and if necessary distinguishing details that are not central to the study will be changed to ensure they are not recognised
- *Consent* Care home staff, NHS staff and the older people, may feel they are obliged to take part in the study because either their manager or care worker has identified them as possible participants. They may feel that refusal to participate could adversely affect either their relationships with their employer, or their care worker. In introducing the study to the managers and care home staff, care will be taken to ensure no one feels coerced or obliged to take part. The information sheets stress that participation (or not) in the study will not affect the care they receive or their relations with other people in the care home or primary care services. At each stage of the recruitment process, the researchers will re-iterate that participation is voluntary.
- *People with cognitive impairment/limited understanding* The research team in this study have over 10 years experience of working with people who find consent and participation in research difficult, arising from problems of dementia, confusion or illness and fatigue. For people with cognitive impairment, the approach will be informed by the principles of the Mental Capacity Act 2005 that assumes that all adults are capable of giving or refusing consent unless proven otherwise, and that the best interests of the person who lacks capacity are paramount. It is therefore an assumption of the study that older people who may experience short term memory and cognition problems can nevertheless consent in the moment, and that it is the responsibility of the researcher on each occasion to review the study aims, confirm with the participant that they are willing to participate in the study and ensure that they are not alarmed or distressed by the experience.^{439,440} At the stage of initial consenting, the researcher will ensure that the participant is given full opportunity to have the study explained to them in a way that best meets their individual needs. If there is an intermediary, such as a care worker or family carer, with whom the older person particularly relates, the researcher will ensure that this intermediary is present and able to explain and, if necessary to interpret any areas of concern of lack of understanding.

In situations where an older person has been formally assessed, and it is documented that they do not have the capacity to consent or take part in an interview, we will ask the older person's consultee (e.g. a relative) if, based on their knowledge of the older person allowing a researcher to review his/her care notes would upset or distress them (see below).

- *People judged by the practitioner/professional who works most closely with them as lacking capacity to give (informed) consent* For those judged by the care worker/care home manager who works most closely with them as lacking the capacity to give consent, or when an older person during the course of the study loses the capacity to consent, a consultee (as outlined in the Mental Capacity Act 2005) will be consulted about the older person's care notes being reviewed for the purpose of the study. The care home manager will be asked to write to the consultee about the study and they will be asked to assent to enrolment of the person with dementia. The researcher will arrange to see the person with dementia and his/her consultee to seek their written support for the older person's participation in the study. In the event that a consultee cannot be identified, then the person with dementia will be excluded from the study.
- *Risk* There is some risk that involvement in this study may affect an older person's care by an individual providing or expressing information of which care home and NHS staff were unaware, or through the disclosure of risk. At all stages the researcher will make clear that they cannot be involved in an older person's care in any way. However, failure to disclose information about observed or reported poor practice may harm an individual particularly if a researcher chooses not to intervene in a potentially damaging situation.⁴⁴¹ If any risk (e.g. evidence of elder abuse, inadequate care, an acute health need) is disclosed or observed, procedures are in place to address this as part of the study protocol and reflect CSCI, PCT and university guidance and procedures. This will be discussed with the care home staff and NHS staff prior to the commencement of data collection.
- *A vulnerable group* This research will be conducted with a group of people who are ill, easily tired and who may be vulnerable for a number of reasons. The older people will be treated with dignity and respect at all times, and the researchers who will have contact with the participants are experienced in working with people of very advanced age. Data collection procedures, and participants' responses, will be carefully monitored and reviewed by the research team throughout the study. The wellbeing and support of the participants in the study are study priorities.
- *Emotional support and supervision for researchers and members of the Public Involvement Group* This kind of research is challenging. The contact with the older people and their care workers over time means that the researchers will know some of the older people in the study quite well and be affected if they should die during the study. The research team will meet weekly to debrief and review issues together and meet with their respective research manager (CG) every 2 weeks to ensure adequate support.

Project management and governance

This research will operate under the Research Governance Framework, and the University of Hertfordshire will be the sponsor. As the study involves older people in care homes, and care home staff, we shall also apply for ethical permissions from the relevant social services' research governance group within the Local Authority departments of social care who work with the participating PCTs.

User and service involvement

An expert advisory panel of representatives from service and the Public Involvement in Research group has been commenting on and influencing the research process throughout, and will continue to do so. There is a heavy reliance on collaboration and co-operation between the research team and service partners.

Dissemination and development of Phase 2

Throughout this study, the identity of all participants and the care homes will be protected and will remain confidential to the study team. All findings will be reported in a way that ensures that no individual, or the study settings, can be identified. A number of dissemination strategies, in partnership with key stakeholders and representative organisations, will be used to ensure the findings inform policy and practice development in end-of-life care for people with dementia. In addition to the traditional methods of dissemination through peer reviewed and professional publication and conference presentations, we propose to disseminate findings through:

- Presentations to staff, residents and their relatives in the participating care homes and key professional service and user representative groups.
- Workshops for community and palliative care nurses providing end-of-life care to people with dementia in care homes.
- Sending a summary report of findings to all participants who wish to receive this.
- Organisations that the research team have strong links with will be included in a planned process of dissemination, including e-alerts, seminars and publications e.g. Royal College of Nursing, Alzheimer's Society, National Care Homes Research and Development Forum, DeNDRoN, Dementia Care, Royal Society of Medicine (geriatrics and specialist gerontology section), Queens Nursing Institute, Better Government for Older People, Social services' research group 'Making Research Count', Help the Aged and Age Concern. The planned process will include, for example:
 - Production of summary findings and briefing papers, in collaboration with 'My Home Life Programme' for dissemination and discussion with their care home partners (English Community Care Association; National Care Association; National Care Forum), and relative and patient representative organisations.
 - Academic and professional conference presentations (including Dementia and Care Home Congress, and Palliative Care Congress).
 - Links with initiatives by the National Palliative Care Council, Marie Curie, and Alzheimer's Society for end-of-life care for people with dementia in care homes.

The findings from Phase 1 will be fed back to the participants for comment and review. Four care homes from Phase 1 will be involved in Phase 2 of the study. These will be homes interested in developing and testing a toolkit for supporting people with dementia at the end of life. Findings from Phase 1 will inform the development of a protocol to develop and test the toolkit. A separate NRES submission will be made for Phase 2.

Appendix 36 Chapter 4: Phase 2 protocol

REC Ref: 10/H0502/55

EVIDEM-End of Life: Changing practice in dementia care in care homes: developing and testing evidence-based interventions at the end of life – Phase 2.

Introduction

Approximately two-thirds of people living in care homes have limited mental capacity¹¹⁹ and it is estimated that 54% of people with dementia are living in care homes.² Research consistently shows that it is very difficult to identify when someone is no longer living with dementia but dying from or with it.⁴⁰⁶ Consequently, decisions about when to withhold treatment and how to provide palliative care are often influenced by the context of care, professional, and family beliefs and values. To date, research on end-of-life care for people with dementia has been dominated by US-based research and on prognosis and studies on decision-making on withdrawal of particular treatments (e.g. use of antibiotics and artificial feeding), and interventions to reduce unplanned hospital admissions.^{241,442} The majority of research has been conducted in nursing homes rather than residential care homes and the research questions reflect the priorities and concerns of health-care professionals and services.

There is minimal evidence of residents, relatives and care home staff being involved in discussing and identifying research priorities for end-of-life care for people with dementia, or models of care that go beyond the individual patient-focused encounter. There is a need to develop and test dementia-specific approaches to providing comfort and avoidance of distress for this vulnerable and often marginalised population that are grounded in the everyday experience of residents and care home life.²¹¹

An emphasis on improving the quality of end-of-life care for older people living in care homes is the focus of the NHS End of Life Care programme for care homes.²⁰⁹ Within this programme there is a commitment to providing patients with more choice in how they are cared for at the end of their life and where they die. It aims to extend the boundaries of palliative care provision to ensure that when residents in care homes are dying they can avoid emergency hospital admissions and be supported by care home and NHS staff skilled in providing end-of-life care.

Care homes at the time of writing were being encouraged, in collaboration with NHS staff, to use palliative care support tools such as the Gold Standards Framework,²¹³ the Preferred Priorities for Care,⁴⁴³ and the Liverpool Care Pathway.²¹⁵ Studies that have evaluated these interventions report an increase in staff confidence and knowledge, a reduction in unplanned hospital admissions, and an increase in people being able to die in their care home as the preferred place of care.^{216,217} However, other commentators and researchers have asked whether equivalent improvements can be achieved with the use of alternative approaches to joint working between health-care and care home staff, and if, with these tools, there is a danger of medicalising the dying process.⁴⁴⁴ Care homes are a sector that are already under-resourced and the assumption that they can accept end-of-life care responsibilities without appropriate support and resources could have unintended consequences for the overall focus and quality of care that care home staff can provide.²⁴⁶

This protocol is informed by the NHS End of Life Care Programme and builds upon longitudinal research on how people with dementia live and die in care homes. It will be informed by a participatory research approach that will support collaboration between researchers, care home staff and NHS staff that visit the care homes.

It aims to develop and refine an intervention that encourages integrated working between primary care health services and care home providers, to provide end-of-life care for older people with dementia and develop a resource that can inform future service development and research for people with dementia living and dying in care homes. It builds on initiatives and practice development work that have focused on improving/changing the organisation and quality of end-of-life care within care home settings (for example Hewison *et al.*²³⁹).

Study aims and objectives:

Aims and objectives:

1. To identify with care home and primary care staff, and relatives, strategies to support integrated working between care home staff and primary health care services for end-of-life care for people with dementia.
2. To test ways that primary health-care services and care home staff can work together to identify resident and organisational aims/outcomes to support end-of-life care that reflect the priorities, experiences and concerns of older people with dementia living in care homes and support required at end of life.
3. To consider how available palliative care support tools and frameworks act as a resource for primary health care services and care home staff, to manage uncertainty at the end of life.
4. To identify facilitators and barriers to collaborative working to support and sustain effective end-of-life care for people with dementia living in care homes.

Background

Phase 1 of EVIDEM-end of life tracked the care received by 133 people with dementia living in six different care homes (residential) during the 18 months of data collection. Twenty-seven (20%) people died. In the event of a person dying, the research team, where possible, conducted post-death analyses, consisting of a final care note review and a brief interview with an appropriate carer or care home manager about the circumstances of the death. Of the 26 post-death analyses complete, 11 (42%) died in hospital. A further six (4.5%) people were lost to follow-up after being transferred to other care homes or nursing homes. How people died was very variable, shaped by which NHS services were involved, and whether it had been formally recognised that they were dying. The most commonly recorded symptoms at the point of death were decreased appetite, increased sleepiness, decreased mobility, and shortness of breath or breathing difficulties. The majority of the people that died saw the GP and/or the district nurse at least once when approaching end of life. Interestingly, 10 of the 27 deaths were recorded as dying out of hours (when out of hours was defined as from 6.30 p.m. to 8.00 a.m. on weekdays and all day at weekends and on bank holidays), and for a further 10, the time of death was unknown. Furthermore, 16 were recorded as being admitted to hospital at least once during the previous year before death, with seven of these returning to the care home, where they later died. It was also found that there were often discrepancies between what was recorded in the care home notes and what the researchers were told at the point of interview, particularly in relation to wishes surrounding preferred place of care.

Interviews with care home staff, district nurses, GPs and paramedics revealed a commitment to providing high quality, end-of-life care that ensured the person with dementia's symptoms were palliated and they were able to die in their place of choice. However, findings also suggest a lack of confidence and knowledge when supporting people with dementia at the end of life. This was in part because of the heterogeneity of the dying experience for people with dementia and the disconnect between the espoused principles of good end-of-life care and staff's ability to apply them to particular events and situations within the care homes.

Tools to support assessment and recognition of the need for palliative care were known and valued (mainly by NHS staff), but participants expressed uncertainty about how to use them to support people with dementia at the end of life. Staff struggled to provide examples of how the tools had supported end-of-life care for a person with dementia except in one instance where a palliative care register was cited as having improved communication between GPs and out of hours services.

Health service staff definitions of when someone was approaching the end of life varied, and did not necessarily reflect how older people and care home staff identified their needs for support and their priorities for end-of-life care. For NHS staff there was a proscribed amount of time when they were likely to become involved in providing end-of-life care. Despite recognising dying could be a prolonged process, and their belief in the importance of building relationships, their involvement invariably was during the last week and days of life. Furthermore, whilst there was recognition from all participants that providing end-of-life care for people with dementia was difficult and required extra training and knowledge, there was no consensus as to who had (or should have) this knowledge, or more importantly, should lead and co-ordinate the care. However, GPs were most frequently the person suggested. For care home staff it could be a difficult transition to move from providing every day care to someone with dementia to providing end-of-life care.

NHS staff were regular visitors to the participating care homes and there were frequently occurring opportunities to meet with care home staff to talk about residents. However, these encounters were largely unstructured and specific to particular residents in the care home. Findings suggested that participants would welcome strategies that helped primary health care services and care home staff develop ways of collaborating that could be mutually supportive, address their uncertainties about how to support people with dementia, promote shared learning and incorporate regular review of the care needs of the residents.

The majority of NHS primary care staff, (in particular the district nurses and GPs but not the paramedics) were familiar with palliative care support tools such as the Gold Standards Framework,²¹³ Preferred Priorities for Care⁴⁴³ and the Liverpool Care Pathway,²¹⁵ but only a minority had used/were using these resources for people with dementia living in care homes. Many were unsure how to take this forward, or if it was their role to do so. An assumption of many of the palliative care tools that care notes can support and guide how practitioners review care together, and document decisions and future plans was not supported by the review of residents' notes. Phase 1 highlighted that care homes would mainly use notes to record care and past events, and not as a tool to plan and review care with the different services and practitioners involved in the individual's end-of-life care.

Interviews with older people with dementia demonstrated that they were able to articulate their opinions, preferences and concerns about living in a care home, and for some, anxieties and unmet spiritual needs about approaching the end of life. What they appeared to value was having the time to reflect and talk with someone about their end of life as one element and expression of having meaningful relationships with staff and family members. This was linked to the need to find meaning and purpose to their life in the care home and some resolution of past losses and events that had led to them being admitted. For many, what happened in the future was not as important as how they felt now about living in the care home, or the events that had led to their admission to a care home. Older people were not sure with whom, in the care home or from the primary health care staff that visited the care home, they would or could talk to about their preferences and priorities for care. Longitudinal data did, however, demonstrate that for the majority of residents, there was enough time (at least a year) to initiate and sustain these conversations and, where appropriate to involve relatives in discussions before a crisis or event occurred.

The findings indicate that there is a need to review and develop existing resources and palliative care support tools in two ways. Firstly, to contextualise any intervention to support end-of-life care for people with dementia, as one aspect of care that assumes older people with dementia have the opportunity to discuss and express what is important to them about living in a care home. Secondly, to develop or modify

interventions and tools that equips NHS and care home staff, residents and their relatives, to live and work with the uncertainties of providing end-of-life care to people with dementia, and that can be incorporated into, or developed from existing patterns of working and collaboration.

Phase 2 aims to begin to address these issues and develop a model of collaborative working for end-of-life care for people with dementia through working in partnership with care home and primary care staff in three care homes.

Method

Research approach

Phase 2 will use a participatory research approach that is informed by the principles of action research. This is an approach that emphasises shared objective setting, review, and development as part of the research process, and refinement of the intervention.⁴⁴⁵ It offers an opportunity to use the findings from Phase 1 to inform problem identification and problem solving, as an activity shared and negotiated between the care home and NHS staff, the research team, and the residents and their families; a process that will aim to develop an intervention that reflects the preoccupations and context of care which is relevant and grounded in everyday practice.

In three care homes that have already participated in Phase 1 of the study we will facilitate regular meetings over 1 year to:

- review and discuss the findings from Phase 1 of the study together, and their implications for the residents with dementia living in the care home
- identify from a suggested list of changes (drawn from the findings of Phase 1) an aspect of end-of-life care they would want to focus on
- agree study objectives and a strategy for change that can be jointly implemented during the data collection period
- implement, review and refine the intervention
- evaluate the change against the objectives and desired outcomes.

In the three participating residential care homes, care home staff (including the manager or deputy manager), and the NHS staff that work most closely with them to provide end-of-life care for people with dementia (GPs and district nurses) will meet with the research team.

In the *first 3 months* of the study, (following ethical and governance approvals and recruitment of residents and staff) at a series of meetings (up to four per care home) facilitated by the researchers, we will discuss the proposed approach, the level of commitment required participants' preferences for structuring shared working and discussions into existing patterns of contact between primary care and care home staff.

Months 3–6 The participants will review with the research team the findings from Phase 1 and discuss what the findings reveal about how care is provided within the care home and in collaboration with NHS services, key assumptions about what end-of-life care involves and what the priorities are for the different participants. The purpose of the discussions will be to discover how care home and NHS staff interpret the findings, discuss priorities and agree together an aspect of working together that can be improved. Based on the findings we anticipate that the areas they could choose to focus on will be on strategies/interventions that:

- enable NHS staff and care home staff to better work to create opportunities over time for discussion with the older person, and where appropriate their family, their priorities for end of life and review together the implications this has for how they work together, what tools they use and how they can maintain communication

- support NHS and care home staff to review and plan together the care of people with dementia who are not well/showing signs of deterioration, but it is unclear if they are dying
- develop shared approaches when key decisions are needed that involve NHS staff for example need for extra care, management of symptoms experienced by people with dementia as they approach the end of life
- develop strategies that enable care home and NHS staff to incorporate end-of-life care into every day practice, and to manage uncertainty.

As part of this process, and facilitated by the research team, participants will work together to discuss and refine research questions/objectives, plan achievable change, and evaluate the outcomes and effectiveness of the intervention(s).

Months 5–10 The participants will develop with the research team (and where appropriate, experts in end-of-life care and care of people with dementia), the chosen area of end-of-life care they want to work on together. It is anticipated this will be an iterative process of discussion and review facilitated by the researchers.

Months 10–12 The participants will review progress against the stated objectives and desired outcomes.

In order to understand the impact of the intervention on resident experience over time, and ensure their experience is central to the study, we will track the care received by residents with dementia from each of the participating care homes. This will involve approximately 75 residents in total. We will document their access to and use of health-care services continuity of care and involvement in decision-making. Where possible and appropriate we will conduct discussions with up to five older people with dementia in each care home for up to two times over the year, and their key care workers (including health-care staff), review their case notes to identify any key events, assessment and support tools used, frequency of contact with health care and service uptake.

This data will be compared with equivalent data collected in Phase 1 and show if integrated working to plan for and support end-of-life care makes a difference to the process of care, residents' health needs, their quality of life, and use of services including unplanned hospital admissions, length of hospital stay and transfers to nursing home care.

We will carefully monitor the resources involved, and estimate the costs of the chosen interventions. We will use interviews, focus groups and documentary review to complement the older person's experience, and obtain a detailed understanding of the context of the care homes and services that work with them. In addition to the development of the interventions and the related documenting of the process, participants' views and contributions at each of the three care homes, we will undertake the following:

- interviews with family carers/relatives ($n = 5-8$)
- documentary review of care home and PCT related documentation (e.g. shared protocols/assessment/care planning, joint funding agreements, integrated pathways and service level agreements)
- interviews with key stakeholders (e.g. PCT manager, palliative care specialist services, paramedic/ambulance services).

Anonymous data from the reviews of residents' care home notes and care plans (part of the study's dataset) will be shared with the EVIDEM Registry research study, entitled 'A registry of people with dementia using services in the North Thames Dementia and Neurodegenerative Research Network (North Thames DeNDRoN) Region'. The EVIDEM Registry study intends to develop a unique and comprehensive minimum dataset (MDS) of individuals with dementia (or symptoms likely indicative of dementia) at differing stages in the disease trajectory (from diagnosis to nearing the end of life). Recruitment to the Registry is intended through inclusion of anonymous patient data from the four EVIDEM research studies and direct recruitment to the registry (e.g. via general practices).

Ethical review and approval for the EVIDEM Registry has been obtained. The Southampton and South West Hampshire Research Ethics Committee A approved the EVIDEM Registry research study on 30 June 2008, reference no. 08/H0502/34. Ethical approval has also been given for the EVIDEM research study 'Promoting Continence and Managing Incontinence at Home' that includes sharing of anonymous patient data with the EVIDEM Registry study. Ethical approval was obtained from Camden and Islington Community Local Ethics Committee on 29 September 2008.

Data analysis will establish how the findings from Phase 1 impact on how participants set priorities for end-of-life care and work together and whether the chosen interventions and their implementation influence the process and networks of care available to the older person with dementia.

We anticipate that resident and organisational outcome measures will focus on how older peoples' views, priorities needs and choices are supported through the chosen interventions, their effect on quality of life and wellbeing, continuity of care, staff satisfaction, use of resources, services, and the costs of implementation. The cross case comparison of how the three care homes implement shared working to improve end-of-life care for people with dementia will enable us to establish how priorities and outcomes are defined, key achievements, and distinguish between those processes of negotiation and development that are common to all settings, and those that are context specific. It will also enable a comparison of the costs and effectiveness of different approaches to end-of-life care.

Recruitment

We will recruit three care homes from the six care homes that participated in Phase 1 of the EVIDEM-End of Life study. All six care homes will receive a summary of the findings from Phase 1 and the proposal for Phase 2. Recruitment will be primarily based on interest and willingness of NHS and care home staff to participate in Phase 2 of the study and commit to a further 18 months of data collection.

If more than three care homes and their partner NHS primary care teams express an interest in participating, we will purposively select three care homes that represent diversity of approaches to end-of-life care and expertise in palliative and dementia care.

The findings from Phase 1 highlighted that the majority of care homes could provide some examples of providing end-of-life care at the patient level. However, even at the individual patient level of care there was a wide range of how dying was defined, how decisions were made about keeping the older person in the care home and the actual intensity and involvement of NHS staff. For example, in terms of the level of care home contact with primary care services, use of support tools such as the Liverpool Care Pathway, involvement of relatives in decision-making, etc.

Inclusion criteria would be:

- perceived good working relationship between NHS and care home staff and willingness to commit to work together on EVIDEM-EoL
- ability to commit to a minimum of four face-to-face meetings over the year's data collection
- methods of sharing information and some documentation about patients in particular aspects of care for end-of-life care between the care home and primary care staff (GPs, district nurses, specialist palliative care support) linked to the care home.

Exclusion criteria would be:

- only one of the participant groups (NHS or care home staff) are interested in the study.

Recruitment of health-care professionals

The research team will meet with possible participants, either as a group or as individuals, to discuss the study and answer any questions. The research team will then wait a minimum of a week before seeking practitioners' individual written consent to participate. All health-care professionals will fit the following criteria:

- act as the main contact for the care home they work with (where more than one General Practice and attached community nursing team visits the care home we will recruit the team that has the most frequently occurring contact)
- have been going into the care home in question for at least a year
- be able to commit to a minimum number (i.e. four) of meetings at the study care home.

Recruitment of care homes

Care homes will be recruited on the basis that:

- The care home is for older people offering personal care including specialist support for dementia.
- Can identify NHS primary care staff that they would be able to work with.
- Be able to commit to a minimum number of meetings at the care home and support staff in their participation (e.g. agree to release them from other duties for the period of the intervention).
- Regardless of how they are identified initially, recruitment will follow the same process. After an initial meeting between the care home manager and members of the study team, for interested care homes, separate meetings will be set up with care home staff and residents to outline the study, what it involves, give them information sheets and answer any queries. Following these meetings the care home manager will be asked to confirm whether or not the care home has decided to participate. Permission may also need to be sought from the care home organisation it belongs to.

Recruitment of care home staff

Following the initial meeting to explain the study to the staff as a group, give out information sheets and answer queries, those staff who have expressed an interest will be approached individually so they can be given further information and voice any questions. Those agreeing to participate will be given at least 48 hours to decide whether or not they want to participate. They will be asked to sign a consent form endorsing their agreement to take part. It will be emphasised that participation is purely voluntary and that they can change their mind at any time without giving a reason. Where some members of the group do not agree to the interview being recorded, only notes will be taken. Researchers will reiterate to all staff that their participation is voluntary and that they can leave the study at any time.

Recruitment of older people

The older people who will be recruited will fit the following criteria.

Inclusion criteria

- Resident in care home for a minimum of 4 weeks.
- Have a diagnosis of dementia and/or be perceived by staff as having dementia.
- Have the capacity to understand and consent to participate in the study, or have a nominated consultee who could provide an opinion whether the older person, if they had the capacity, would have wanted to take part in the study.
- Anticipated to be resident in the care home for the coming year.

Exclusion criteria

- Has a mental health problem (not caused by the ageing process).
- Does not have capacity to consent in the moment or an identifiable consultee (see above) who can be approached for their opinion.
- Cannot speak English and an interpreter not available in the participant's language.

Following the initial meeting, the older person will be provided with an information sheet and consent form and given at least 48 hours to consider the information before further contact by the researcher. For those who are agreeable, a meeting will be set up with a member of the study team to explain what involvement in the study means for them, and answer any questions they may have. All residents will be given at least 48 hours to consider their participation before a member of the research team revisits them to answer any further queries and confirm whether or not they would like to take part. It will be made clear from the start that a decision to take part in the study is entirely voluntary and a decision not to take part will not affect their care in any way.

All of the older people in this study have complex needs, and will include people who are in difficult circumstances, who may be vulnerable, have communication or recall difficulties and may tire easily. At every stage verbal consent to continue will be obtained and the opportunity offered to defer or shorten the time of involvement in the study. Those who have special communication needs will be interviewed using communication aids if appropriate.

Recruitment of family/relatives

Family members and relatives of older people will be invited to attend the initial meeting with residents to give them information about the study, and will also be given an information sheet outlining the study.

At the end of the study we will invite by letter family members of residents who have died during the study to ask if they would be willing to take part in an interview to gain insight into their perspective on their thoughts and views about end-of-life care. Those who express an interest will be asked to contact the researchers for further information. A member of the research team will meet with relatives individually to discuss the study and answer any queries. They will be given at least 48 hours to consider whether or not they would like to participate, after which they will be consented individually. However, it will be impressed upon them that taking part is voluntary and that they may withdraw from the study at any time without giving a reason. The interview will be held in a private room within the care home, the participant's home, or the host university, depending on which is more convenient for the participants. It is possible that taking part in an interview could trigger distress. The possibility of this will be discussed with participants prior to the interview and what might help to reduce the impact of talking about a recent bereavement. Participants will be offered the option of writing down their thoughts or being interviewed with a friend or relative present if that is preferable to a one-on-one interview. Contact with relatives will not be made before a minimum of 8 weeks has elapsed since the resident has died.

Amendment submitted NRES Committee South Central – Southampton A (May 2011)

Preliminary findings from Phase 2 have demonstrated how influential the relative can be in decision-making around end-of-life care. Following discussion with the EVIDEM-EoL steering group it was agreed that it was important to include the views of relatives of residents living in the care home.

It is proposed to extend the study to include views of all relatives, and not restrict data collection to capture only the views of relatives who have had a relative die in the care home (as stated in the original proposal). The same protocol as before (consenting, information, etc.) will be followed. We will recruit to up to 15 relatives, who will be approached in the first instance by the care staff to see if they are willing to talk. Some of the relatives will have a family member who is taking part in the study and others may not. They will be given at least 48 hours to consider whether or not they would like to participate, after which they will be consented individually. However, it will be impressed upon them that taking part is voluntary

and that they may withdraw from the study at any time without giving a reason. The interview will be held in a private room within the care home, the participant's home, or the host university, depending on which is more convenient for the participants.

The above amendment was approved by the South Central – Southampton A Committee on 27 May 2011 (REC reference 10/H05002/55 – amendment number 1)

Interviews with stakeholders

Semi-structured interviews with NHS health-care professionals and up to three stake holders (e.g. Care Quality Commission, PCT Commissioners, Directors of Primary Care Services) at the end of the study to establish how they understand end-of-life care is provided, how the older person is identified as needing the service, how the older person's needs are assessed and care is planned, and to what extent the care home staff are involved with this, and the time different team members spend in discussing and planning care/end-of-life intervention, the skills and knowledge needed and range of activities this involves.

Data collection

General

Multiple sources of evidence are needed to provide a full picture of how the different end-of-life care related interventions are implemented and experienced across the three study sites by care home staff, health-care professionals and older people resident in the care homes. By triangulating a range of data sources, it will be possible to demonstrate which characteristics of integrated working are specific to certain circumstances, and which are transferable and can be shown to achieve different types of outcomes for older people. This phase of the study will use mainly qualitative data collection methods including face-to-face interviews; care notes reviews, documentary review and field notes.

Data collection will be undertaken as follows:

- (a) Where feasible discussions with a number of older people with dementia per care home, over the period of 1 year to establish their views and perspectives of living and dying in the care home and if this changes over the period of the study, if appropriate to the chosen intervention.
- (b) Two reviews of each older person's care home case notes including, demographic information, care plans and ongoing updates, at 6-monthly intervals, over the period of 1 year to establish their care, planned and ongoing, health-care services received including any hospitalisations and any changes in their health status and needs.
- (c) Field notes and observation documenting the detail and outcomes of meetings between the care home and NHS staff and the researchers and the implementation process in the care homes of the chosen interventions.
- (d) Review of key documents and tools that are shared by the care home staff and health-care professionals such as care pathways, shared notes and assessment tools, to establish the structural and organisational context of end-of-life care.
- (e) Semi-structured interviews with care home staff at the beginning and end of the study to establish, the support they consider the older person needs when they are dying, how they define end-of-life care, how often they see the health-care professional and where, how the health-care professional and the care home staff work together, and any support and training received from health-care staff, or they would like to receive, and what facilitates and or hinders integrated working with the health-care professional.
- (f) One focus group will be conducted with up to 10 care home staff of differing levels of experience and seniority. This will be facilitated by two members of the research team and will be recorded if the group consents to this unanimously, otherwise only notes will be taken. The interview will be conducted in a private room in the care home at the convenience of the staff, using a semi-structured format that will focus on their experiences of the implementation of the chosen intervention and working with health-care professionals to provide end-of-life care. It will explore the level of contact

- they have, how they communicate and feed back information about the older people receiving care, and perceived facilitators and barriers to integrated working with health-care professionals.
- (g) Semi-structured interviews with NHS health-care professionals and up to three stakeholders (e.g. Care Quality Commission, PCT Commissioners, Directors of Primary Care Services) at the beginning and end of the study to establish how the older person is identified as needing the service, how the older people's needs are assessed and care is planned, and to what extent the care home staff are involved with this, and the time different team members spend in discussing and planning care/end-of-life intervention, the skills and knowledge needed and range of activities this involves.
- (h) Interviews (either face to face, or over the telephone) with relatives of older people who have died will be conducted where the relative is able. Contact will not be made before a minimum of 8 weeks has elapsed since the resident has died. Interviews will last up to 30 minutes, and will explore the relatives' experience of the end-of-life care the older person received, including services and communication with the care home and NHS. Alternatively, the relatives will be given the option to write their thoughts down in the event that they feel an interview may be too distressing.

Data collection: older people

For those older people with dementia, who have the capacity to consent in the moment, they will be interviewed up to two times over the study in a private room within the care home. As the research is being conducted with frail older people who may tire easily, the interviews will last for a maximum of 30 minutes or less if it is apparent that the older person is tiring. These semi-structured interviews will focus on:

- their experience of living in a care home and thoughts about end of life
- the amount of support they need from the care home staff
- the health-care services they have received
- how they define their priorities for end of life
- what indicators/measures they use to assess if care received is effective
- how they think that care home staff and health-care professionals work together.

For those residents who consent, their care home notes will be reviewed twice, over the period of a year, to coincide with their interviews. The following data will be collected:

- demographic information
- health conditions
- medication
- use of equipment
- hospital admissions
- health-care professionals involved in their care, for which condition, frequency of contact, planned care, location of consultation (i.e. care home or hospital outpatients)
- care plans
- any shared assessments/care planning between care home staff and health-care professionals in use
- activities of daily living – level of support residents need with these
- evidence of planning for end-of-life care, records of decisions made and where appropriate after death analysis, consisting of a brief interview with a care worker or the care home manager who was involved in the person's death and a final review of the care plan for that person.

These data will reveal the range and intensity of activities undertaken to support residents' care, and where relevant, how effective the integrated working for end-of-life care is over time, as measured by outcomes and by the older people themselves, the care home staff and health-care professionals (outcomes are likely to include quality of life, continuity of care, access to, and satisfaction with care, involvement in decision-making on treatments, opportunities to discuss their uncertainties, priorities and preferences and place of care). The data will also identify preferred practitioners and key drivers for the different types of chosen interventions.

Data collection: care home staff

Care home staff who participate in the research and the shared discussions with NHS staff will be interviewed at the beginning and end of the study. The aim of these semi-structured interviews is to establish:

- the support they consider the older person needs when they are dying
- how they define end-of-life care
- how often they see the health-care professional concerned and where
- how the health-care professional and the care home staff work together, and any support and training received from health-care staff, or they would like to receive
- what facilitates and or hinders integrated working with the health-care professional.

At the end of the study, one focus group will be conducted with up to 10 care home staff of differing levels of experience and seniority. This will be facilitated by two members of the research team and will be recorded if the group consents to this unanimously otherwise only notes will be taken. The interview will be conducted in a private room in the care home at the convenience of the staff, using a semi-structured format that will focus on their experiences of the implementation of the chosen intervention and working with health-care professionals to provide end-of-life care. It will explore the level of contact that they have, how they communicate and feed back information about the older people receiving care, and perceived facilitators and barriers to integrated working with health-care professionals.

Data collection: health-care professionals and stakeholders

Individual health-care professionals who participate in the group discussions and the development and implementation of the chosen intervention to support end-of-life care will be interviewed at the beginning, and end of the study.

The interview will establish their professional backgrounds, training, workload, funding, and how they work together with the care home. We will investigate their perception of the focus of their activities with the older person and the extent and mechanisms of their integrated working with the care home staff to achieve their care, support or treatment objectives for the older people. In addition we will investigate how they evaluate and reflect on their experience of integrated working to promote end-of-life care for people with dementia through interviews, care plans and notes review, we will aim to establish:

- how the older person is identified as needing the service
- how the older person's needs are assessed and care is planned, and to what extent the care home staff are involved with this
- the time different team members spend in discussing and planning care/end-of-life intervention, the skills and knowledge needed and range of activities this involves.

Data collection: relatives of residents that have died during Phase 2 and family members of residents who are living in the care home

Based on the findings from Phase 1 we anticipate 20% of residents recruited to the study will die over the data collection period. A minimum of 8 weeks after the death of the older person with dementia (and following discussion with the care home manager to ensure that there are no reasons not to contact the relative) we will invite by letter a family member or significant other, to take part in an interview to gain insight into their perspective on their thoughts and views about end-of-life care. Those that indicate they are willing to take part in an interview will be contacted by phone and their possible participation will be discussed further.

The interview will be semi-structured and seek to explore their experience as a relative visiting the care home what they thought was significant about the last months of the person's life. As already noted it is possible that the interview will cause distress because of the memories and feelings talking about the deceased person may generate. Every attempt to ameliorate the impact of the interview will be made and participants will be offered the option of writing down their thoughts or being interviewed with a friend or relative present if that is preferable to a one-on-one interview.

Amendment submitted NRES Committee South Central: Southampton A (May 2011)

Interviews with family members of residents who are living in the care home will be open and discursive and ask about their views about living and dying in a care home. We know from securing consultees' opinions about their relatives' possible participation in the study that some relatives will want to talk about their regret and guilt about placing a relative in a care home. We will be careful to ensure that participation does not create any further distress and will ensure that sufficient time is allowed in the interview for relatives to express their views and feelings about a range of issues. It is likely that past experiences will influence how they think about end-of-life care for people with dementia. Once we have explained the purpose of the study very few prompts will be used to ensure participant priorities and views are shared. If any issues are raised that cannot be addressed or resolved in the interview that relate to the care home or the care of their relative the researcher will ensure an appropriate person is identified for the relative to talk further with (e.g. care home manager, Age UK advocate).

The above amendment was approved by the South Central: Southampton A Committee on 27 May 2011 (REC reference 10/H05002/55 – amendment number 1).

Analytical synthesis

All interviews will be recorded, transcribed and analysed using NVivo™ software. Organisational, operational and quality review documents will be analysed through the same framework and using the same software. Statistical data from validated assessment tools, and information on the older persons' use of services, and the professional diaries on service activities will be entered onto an SPSS™ database. The findings generated from the integrated working in the three study sites will be brought together in two units of analysis:

1. the individual care homes
2. cross-case comparisons looking at how the different contexts and mechanisms affect the outcomes for the older person.

To enable comparison and the development of an explanatory model, analysis will then be undertaken within and across sites. Qualitative data analysis will be undertaken using NVivo™ and thematic content analysis to identify key themes and common experiences and priorities of care. Data from the case studies will be analysed to describe the features and impact of end-of-life care on the outcomes. The analysis of outcomes will be guided by the findings of Phase 1 but is likely to be categorised as outcomes for the older person, the care home staff, and the health-care practitioners' roles, and include the older person's understanding of their care, access to services, clinical outcomes. Outcomes for the health-care system will include: transparency of care, service utilisation, and staff resources used as a result of working together to develop end-of-life care interventions that are dementia specific.

Economic evaluation

The resource implications of different approaches supporting end-of-life care with care homes will be documented and costed, including the resource implications of developing an intervention this way, the health and social care services delivered, hospitalisations. The contribution of care home staff and health-care professionals will be compared across models and sites in a cost consequences framework.⁴³⁸ This will incorporate the perspectives of the health-care services, older people, and care home staff.

Ethical issues

Intrusion

Participatory approaches to research are by definition intrusive. There is a risk that individuals participating in the study may feel that their right to self determination is compromised if during the course of the study they do not want to participate in the planned change agreed by their peers. For the residents too, the impact of the chosen intervention on the care they receive may be intrusive in an environment that is their home. Integral to the research questions asked, the design of the study, the role of the facilitator and the stages of data collection methods is a consciousness of the need to be encouraging reflection at each stage of the study and be responsive to the participants and the context of care. To this end, ongoing opportunities will be created for individuals to reflect on the study and withdraw from participation and/or highlight if participation in the research is disruptive and intrusive for residents, care home staff and primary care staff. It is a potential finding of the study that certain interventions are judged too intrusive on staff time and responsibilities and the everyday life of residents.

Anonymity and confidentiality

All participants and study sites will have a code number and no names or identifying details will appear on any data collection forms, analysis or draft and final reports. During data collection only the research team will have access to the names and contact details of participants and these will be kept in a password protected computer and double locked filing cabinet, to which only the research team will have access to. All participants will be guaranteed anonymity in written reports and summaries of data analysis. A summary of the findings will be sent out to participants for their comments prior to publication and dissemination.

Consent

It is possible that health-care professionals, older people and care home staff may feel obliged to take part. They may feel that refusal to participate may adversely affect their relationships with their employer or the services involved in providing their care. In introducing the study to the possible participants, care will be taken to ensure no one feels coerced or obliged to take part. The information sheets stress that participation (or not) in the study will not affect the care they receive or their relations with other people in their organisations. At each stage of the recruitment process, the researchers will re-iterate that participation is voluntary.

People with cognitive impairment/limited capacity

The research team has extensive experience of working with people who find consent and participation in research difficult, perhaps because of problems of cognition, confusion, illness or fatigue. For people with dementia whose level of cognitive impairment means they will not be able to consent to participation, the approach taken will be informed by the key principles set out in the Mental Capacity Act¹⁷ that assumes that all adults are capable of giving or refusing consent unless proven otherwise, and that the best interests of the person who lacks capacity are paramount. It is, therefore, an assumption of the study that patients who experience short term memory and cognition problems can consent in the moment. It is the responsibility of the researcher on each occasion to review the study aims with the participant, and confirm that they are still willing to participate in the study, ensuring that they are not alarmed or distressed by the experience.^{439,440} The study is informed by the principles of inclusionary research whereby every effort will be made to enable people that wish to, to participate, even if that means alternative methods of communication and data collection need to be found.

At the stage of initial consenting the researcher will ensure that the participant is given full and appropriate opportunity to have the study explained to them in a way that best meets their individual needs. If there is an intermediary, such as a family member or key worker, with whom the older person particularly relates, the researcher will ensure that this intermediary is present and able to explain and, if necessary, to interpret any areas of concern or lack of understanding. Where older people are unable to give written consent because of poor vision or if they are unable to write, verbal consent will be recorded

by the researcher with a care home staff member as a witness. If the older person is unable to consent in the moment, or loses capacity over the period of the data collection, their consultee will be approached for their opinion on whether this study is something that the older person would have participated in or would wish to continue participating in, if they had the capacity.

Risk

The focus of the study is end-of-life care for older people with dementia. Discussing such sensitive issues may cause distress for the people involved. There is a risk that by expressing their needs and experiences some older people may become distressed, confused or concerned. If this should happen any serious issues will be communicated to the professional whom they identify as knowing them best, and being most involved in their care. There is some risk that involvement in this study may affect residents' care and outcomes, by older people providing or expressing information of which care home staff were not previously aware. At all stages, the researcher will make clear that they cannot be involved in providing care in any way. However if any risk (e.g. evidence of elder abuse, inadequate care, acute health need) is disclosed, procedures are in place to address this that reflect the care home, PCT and university guidance and procedures. The study relies on close collaboration with the participating sites. Part of the recruitment process involves how the study will address incidents where the participants may become distressed, or there is evidence of need for support or review from health and social care services. The researchers will have a protocol describing who to consult and how, which they will follow in all such cases (see EVIDEM-EoL Bad Practice Protocol V2 260608.)

All interviews will be structured so that they minimise the distress caused by the discussion of sensitive issues and focus on collecting data which is essential to each participant. However, the main participants are older people with complex health and social care needs, so it is possible that the older people may become upset. The researchers will treat all participants with respect and dignity. Moreover, the research fellows who are responsible for data collection have extensive experience in interviewing vulnerable older people about sensitive topics.

If the participants express any sensitivity, embarrassment or upset at any point during the interview, the researcher will remind them that they are free to stop the interview at any time. In this situation, the researcher will switch off the recorder immediately. The research team work closely with each of the care homes involved and the key workers. If a resident becomes distressed in the course of an interview the researcher will ask their permission to ensure that their key worker and other appropriate staff members are aware of this.

There is a small risk of disclosure in the study, as the core participant group includes older people with complex health and social care needs. At the beginning of each interview participants will be reminded that anything they say is confidential but that it will not be possible to keep information confidential if there is any indication that they or any other participant is at risk, or if their care services are deficient or there is evidence of abuse or an acute health need.

The procedures for situations where there is evidence of abuse, neglect or criminal disclosure are:

- if the person is at immediate risk the care home manager will be contacted
- if there is suspicion of abuse, what the participant reported or was observed will be documented by the researcher, the care home manager or appropriate line manager will be informed and the agreed procedure for reporting suspicion of abuse will be adhered to. The Principal Investigators for the study will also be informed
- if there is evidence of negligence in the provision of care or significant shortcomings in the care provided to the older person, the research fellow will document the concerns/issues and notify the care home manager or other appropriate line manager and the procedures for registering and addressing a complaint about the standard of care will be followed

- if during the data collection it becomes apparent that the participant needs medical attention, the researcher will contact a member of the care home staff urgently.

With regards to the NHS professionals and care staff, there is likely to be an increased workload as part of participating in Phase 2. Researchers will make clear what commitments could be involved when explaining the study to potential participants and throughout the recruitment process. Researchers will reiterate that all participants are free to withdraw from the study at any point, without giving a reason.

In addition, there is a risk that the study may highlight areas of tension and disagreement between care home staff and NHS professionals. The researcher designated as the facilitator for the group discussions and meetings has extensive experience in facilitating and managing focus groups and potentially difficult discussions in a range of settings. A semi-structured prompt guide will also be used in aiding the discussions and ensuring they maintain focus.

Interviewing vulnerable older people may be stressful and emotionally demanding.

All researchers will meet with the Principal Investigators regularly to debrief and identify any issues or needs they have for ongoing support.

Conducting interviews with relatives in their own homes incurs a degree of risk to the researcher conducting the interviews. The research team will adhere to the Centre for Research in Primary and Community Care (CRIPACC) lone worker policy.

Vulnerable patient group

This research will be conducted with a diverse group of people who are ill, easily tired and who may be vulnerable for a number of reasons. All participants will be treated with dignity and respect at all times. The researchers are experienced in working with older people who have problems of this nature. Data collection procedures and participant responses will be monitored carefully and reviewed by the research team throughout the study. The wellbeing and support of participants are study priorities.

The research team

The multidisciplinary research team brings together academics and practitioners from nursing, social work, general practice and health economics. The team has worked on a series of research studies, both together and independently, that focus on older people with complex needs living in care homes and community settings. These have included funded work on inter-professional working in: care homes, activity promotion, team working across health and social care, the use of new technologies, case management and shared assessment processes across health and social care to improve care to older people, multi professional networks for the delivery of care to people with long term and disease specific conditions. The Public Involvement in Research Group (PIR Group) has strong links with the voluntary sector and is working closely with INVOLVE. The PIR Group will be contributors to the research design and execution. Members from this group will be involved in the Steering Group for this project and bring to the proposal experience of having been recipients of health and social care services, working with older people's groups, and involvement in other studies that focused on older people including care homes and project management. The PIR Group comprises users, carers, patients, patient and public involvement links, and representatives from the voluntary sector.

Dissemination

The findings from this study will inform commissioners and providers of services in their decision-making about commissioning and providing end-of-life care services to care homes. It will make explicit the managerial processes and tools that enable better integration of care delivery between health-care professionals and care homes, and demonstrate the ongoing support and training required to achieve meaningful outcomes for the older person and the service.

Dissemination of preliminary findings for consultation and the final report will initially be through the participating study sites, following a report to the NIHR and the organisations of the different practitioners, teams and agencies that are involved in the study. This will be done through workshop events, e-alerts and network meetings.

The research team and Steering Group will disseminate findings nationally through their involvement with bodies such as Age UK, Alzheimer's Society, National Care Home Research and Development Forum, DeNDroN, PCRN, Better Government for Older People and relevant research networks. Findings will be presented in professional and peer reviewed journals and at conference events across the relevant disciplines.

Appendix 37 Chapter 4: Care home manager topic guide

REC REF: 08/H0502/74



Topic guide: CH manager

EVIDEM

Date:

Care home ID:

Participant ID:

Sex <input type="checkbox"/> Male <input type="checkbox"/> Female	Age ___ years F/T P/T	
Qualifications: e.g. NVQ		
Length of time in current care home?	Current home	In total
Total time working in care homes?		
Training: Dementia care End of life care	Details	
Residents: Number of residents when full?		
Number of residents currently?		
Staff : (not including auxillary staff?)	Full Time	Part-Time

Number of Care staff? Total _____		
Day staff		
Night staff		
Senior grades		
Junior grades		
Full-time/Part-Time		
Agency staff		
Other		
Staff training: How many staff hold an NVQ2?	State number:	
Staff turn over: How many new appointments in the last 3 months? 6 months?	3 months	6 months

Organisation of care

- How do you organise the care in your care home?
- Could we sketch a diagram?
 - Teams with a senior care worker
 - Named care workers for the older person
 - Formal handover /report
- Probe:
 - Do you have a key worker system? Y/N
 - How many residents does each key worker have?

- Does that key worker stay with a resident all the time they are in the care home or change over time?

- Do you have volunteers with the care home?
 - What to they do?
 - Details? (hrs a week)

- Do any family members contribute to care?
 - What do they do?
 - Details? (hrs a week)

Other Health Services

Can you tell me about how much contact do you have with health professionals who visit the care home?

- GPs:
 - How many GPs do you work with?
 - Do you pay a GP retainer? **Yes/No**

- District nurses
 - How many district nursing teams visit your care home?
 - Can you tell me about what sort of activities they undertake in the care home?

I would now like to discuss different groups of people who may provide services to older people within your care home. Can you tell me about...(each individual in turn)

	Reason/type of care	On req.	Once a week	Every two weeks	Once a month	Never	In-house trained
GP							
GP: out of hours service							
District Nurse							
Night nurse							
Specialist nurses:							
Community mental health nurses							
Admiral nurse							
Palliative care nurse, (Macmillan, Marie Curie)							
Continence nurse							
Stoma nurse							
Dietician							
Chiropodist							
Hairdresser							
Dentist							

Optician							
Occupational Therapist							
Physiotherapist							
SALT							
Social worker							
Counsellor							
Any others not discussed?							

I would now like to talk a little more about end of life care for people with dementia in your care home

- Can you tell me about when you would consider an older person with dementia was nearing the end of their life?
 - How do you define end of life care?
- Who do you feel is responsible for supporting people with dementia as they near the end of their life?
 - Who decides at what stage an older person with dementia requires end of life care, or palliative care?
 - How are GPs involved?
- What other services are you involved with in connection with end of life care in this care home?
 - Probe:
 - Macmillan
 - Marie Curie

- District Nursing
- Hospice support
- Hospice at Home
- Night sitter service
- Charitable support
- Geriatrician
- Psychogeriatrician
- Equipment loan
- Which services do you find helpful?
- What is it that they do?
- Which services do you find not so helpful?
- Do you have any private services coming in? Yes/No
 - Can you tell me a little more about these

Care home and end of life

- What end of life care planning procedures are in place in your care home?

Probe:

- Advance Care Planning in your home?
- The Gold Standard Framework? **Yes/No**
- The Liverpool Care Pathway? **Yes/No**
- Preferred Place/Priorities of Care (PPC)? **Yes/No**

- How do you feel your care home supports older people with dementia at the end of life?

Probe:

- Are things planned in advance?
 - Are things dealt with as and when they arise?
 - What do you think works well?
 - What things could be improved?
 - Do you have any religious/spiritual services offered here in the home?
-
- How do you know if someone with dementia is dying?

Probe:

- Can you tell me what is a usual pattern, for someone in their last 48 hours of life?
 - What services are usually involved?
 - What constraints the care that you would like to provide?
 - When someone dies what happens?
 - What it is like when someone dies?
 - How do you feel?
 - Tell me about someone who had a good death?
 - Tell me about someone who died here where you felt it could have been better?
 - How many people died in the last 6 months? Last year? Of those, how many had dementia?
-
- What do you think are the most important aspects when someone with dementia is dying in a care home?
-
- Is there anything else you would like to say about caring for someone with dementia towards the end of their life in a care home?

Return Questionnaire	
Any changes since last visit (date)	

Appendix 38 Chapter 4: Care worker topic guide

REC Ref: 08/H0502/74



Topic guide: Care Home Staff

EVIDEM

Date:

Care Home ID

Participant ID

Age	Sex <input type="checkbox"/> Male <input type="checkbox"/> Female
Length of time working in care home ____ months Total time working in care homes? _____	Full time/part-time (hours)
Qualifications (NVQ)	Job Title
Have you had any training in: Dementia care End of Life care	Details:
Other Health Services	

How much contact do you have with outside health professionals?

	Reason/type of care	On req.	Once a week	Every two weeks	Once a month	Never	In-house trained
GP							
GP out of hours service							
District Nurse							
Nurse specialists:							
Mental health:							
CMHN							
Admiral nurse ()							
Palliative care:							
Macmillan							
Hospice							
Marie Curie							
Continence Nurse							
Stoma nurse							
Dietician							
Chiropodist							
Hairdresser							
Dentist							

Optician							
Occupational Therapist							
Physiotherapist							
SALT							
Social worker Care manager							
Counsellor							
Any others not mentioned?							

- How much are they involved in supporting older people with dementia at the end of their life?
- Who do you feel is responsible for providing care to an older person with dementia at the end of life?
 - Who decides when someone is dying
 - What stage does this occur?
 - How are GPs involved?)

Dementia and end of life

- How do you know when someone with dementia is dying?
- Tell me about someone with dementia who had a good death?
- Tell me about someone who died here where you felt it could have been better?
- What is the ideal team structure for caring for someone with dementia at the end of life? (in-house staff and outside agencies)
- What constrains you from providing the care you would like to give?
- How many deaths occurred in the care home in the last 6 months? Last year? Of these

how many did you consider had dementia

End of Life Planning

- Tell me a little more about what you define as end of life care for people with dementia?

Probe:

- Are you aware of any end of life care planning procedures in place in your care home?
- Explore each in turn probing for how used within the care home, for whom and when.
- Advance Care Planning
- The Gold Standard Framework? (the seven Cs)
- The Liverpool Care Pathway?
- Preferred Place/Priorities of Care (PPC)?
- Do you have any religious/spiritual services offered here in the home?

Care Home and End of Life

- How do you feel your care home supports residents with dementia and the care they require at the end of life?

Probe:

- Are things planned in advance?
- Are things dealt with as and when they arise?
- What do you think works well?
- What do you think could be improved?
- What do you find particularly challenging when caring for someone with dementia who is thought to be dying?

What do you think are the most important aspects of care when supporting an older person with dementia who is dying in a care home?

Is there anything else you would like to say about caring for someone with dementia

towards the end of their life?

Appendix 39 Chapter 4: NHS and social services staff topic guide

REC REF: 08/H0502/74

**EVIDEM**

Topic guide: NHS & SS staff

Date**Participant ID****Associated CH ID:**_

Sex <input type="checkbox"/> Male <input type="checkbox"/> Female	Age:
Professional qualifications:	
Length of time present post:	_____ years _____ months
Time since qualified (eg DN/GP/SW)	_____ years _____ months
Specialist training: Dementia care End of Life Care	Details:

How long worked with care home [state name]	_____years _____months
On average how often do you go into the care home?	<input type="checkbox"/> Every day <input type="checkbox"/> Regular arrangement (Ward round) <input type="checkbox"/> More than once a week <input type="checkbox"/> About once a week <input type="checkbox"/> Once a fortnight <input type="checkbox"/> Once a month <input type="checkbox"/> Less than once a month

Recognition and assessment of end of life care for people with dementia

- Can you tell me about when you may consider an older person with dementia as nearing the end of his/her life?
- Who decides at what stage an older person with dementia requires end of life care?
 - What is your involvement in this process
 - How are GPs involved?
 - How are you informed about one of your patients dying?
- How do you define end of life care?
- Tell me about someone who had a good death in this home?
- Tell me about someone who died here where you felt it could have been better?

- In what way do you think older people with dementia nearing the end of their life could be better supported within a care home?

Health service provision

- Who do you feel is responsible for supporting people with dementia as they near the end of their life?
- What other services do you draw upon to support older people's needs with dementia when they are dying?
 - Probe:
 - Macmillan
 - Marie Curie
 - District Nursing
 - Hospice support
 - Hospice at Home
 - Night sitter service
 - Charitable support
 - Geriatrician
 - Psychogeriatrician
 - Equipment loan
 - Which services do you find helpful?
 - What is it that they do?
 - Which services do you find not so helpful?

Specifically care home identified as working closely with

- How would you describe your working relationship with care home [state name]?

Probe:

- How do you initiate contact with the care home?
 - Visit regularly to review residents, wait for them to call and respond to a referral – pro-active or reactive?
- How have you been involved in providing end of life care to older people with dementia in care home [state name]
- How do you work with the care home staff to meet a resident's health needs who has dementia?
- In the past year, how many residents have you provided care to who died in the care home? Of these how many did you consider had dementia?

End of Life Planning

- Are you aware of any end of life care planning procedures in place in the care home?

Probe: Ask re each procedure and explore how used and involvement in use

- Advance Care Planning
- Gold Standard Framework
- Liverpool Care Pathway
- Preferred Place/Priorities of Care (PPC)?
- What do you think are the most important aspects when someone with dementia is dying in a care home?
- Is there anything else you would like to say about caring for someone with dementia towards the end of their life in a care home?

Appendix 40 Chapter 4: Emergency services topic guide

REC REF: 08/H0502/74

**EVIDEM****Topic guide: Paramedic and Ambulance staff****Date****Participant ID****Associated CH ID:**

Sex <input type="checkbox"/> Male <input type="checkbox"/> Female	Age:
Professional qualifications:	
Length of time present post:	_____ years _____ months
Time since qualified	_____ years _____ months
Geographical area covered?	
Specialist training: Dementia Mental Capacity Act (MCA)	Details:
On average how often do you go into a care home?	<input type="checkbox"/> Every day <input type="checkbox"/> Regular arrangement <input type="checkbox"/> More than once a week

	<input type="checkbox"/> About once a week <input type="checkbox"/> Once a fortnight <input type="checkbox"/> Once a month <input type="checkbox"/> Less than once a month
--	---

Emergency treatment for people with dementia

1. In your experience, what are the most common reasons for an emergency ambulance being called to people with dementia in residential care homes?
2. How does somebody having dementia impact on the treatment you give?

Working with residential care homes

- How would you describe your working relationship with residential care homes?
- Do you feel calls to people with dementia in care homes are usually justified?
 - Why/ Why not?
- Who is responsible for contacting you?
- Do you find some residential care homes call for 999 ambulances more than others?
- In the past year, how many times do you think you've been called out to a residential care home?
 - Are you aware you'll be seeing a patient with dementia?
 - At which point are you informed? (i.e at arrival, receipt of the call)
- Can you think of a visit to a residential care home where you felt that things could have gone better?

End of life planning and protocols

- Are there any protocols in your ambulance trust regarding older people and resuscitation?

- If somebody has written instructions about DNR, are you obliged to follow these?
 - How often do these need to be updated?
- If there are verbal or informal written instructions how far are you able to follow these?
 - What is your legal position?
- Is it a difficult decision not to transport to hospital?
 - Are you under any pressure to convey to hospital, or not to convey?
- Does a resident having dementia, or not, have an influence on commencing or withdrawing CPR?
- What do you think are the most important aspects when you are called out to someone with dementia that is very poorly or dying in a residential care home?
- Are there any changes you would like to see with regard to emergency ambulance calls to care homes for people with dementia towards end of life?
- Is there anything else you would like to say about being called out to someone with dementia towards the end of their life in a residential care home?

Finally, we would like to give you two scenarios to consider?

1. *Ben*, 81 years old. Admitted to a residential care home approximately 2 years ago. Pre-existing conditions include a diagnosis of dementia (type unspecified) and heart failure (CCF).

The care staff feel he has been deteriorating over the last 3 weeks, and saw his GP 2 days ago with a chest infection, for which Ben was prescribed a course of antibiotics. The care home staff report, as directed by the GP, Ben is now receiving tlc.

At around 9pm a care worker dialled 999 for an ambulance because Ben was becoming more and more breathless and was 'struggling'.

In the care notes, there is a DNAR order and a wish to die in the care home informally recorded, dated 2 years ago.

How would you respond and why?

2. *Doris*, 93 years old. Admitted to a residential care home approximately 6 months ago.

Has memory problems, particularly with short term memory and gets confused, but does not have a formal diagnosis of dementia. She has osteoarthritis and is generally very frail and most of time she is cared for in bed.

At around 4.30pm, *Doris* suffered a brief loss of consciousness and was then very sleepy, so the care staff dialled 999 for an ambulance.

Doris has stated she would like to die in the care home, and this was recorded in her care notes at point of admission. There is nothing recorded about resuscitation.

How would you respond and why?

Appendix 41 Chapter 4: Care notes data extraction form

REC REF: 08/H0502/74

EVIDEM EoL Resident's Data Extraction Form-

1. Please give the resident ID number

2. Please give the Care Home ID number

A. TIMEPOINT (There will be a different form for each extraction point)

3. **Baseline Data**

dd mm yy yy

3. **Data Extraction 1**

dd mm yy yy

3. **Data Extraction 2**

dd mm yy yy

B. HEALTH STATUS

13. Long Term Conditions (*Please circle all that are documented*)

1 Diabetes

- 2 COPD
- 3 High blood pressure
- 4 Stroke
- 5 Heart disease
- 6 Dementia
- 7 Parkinson's disease
- 8 Cancer
- 9 Arthritis
- 10 Epilepsy
- 11 Other (Please specify) _____

C. ADMISSION INFORMATION

10 a. Is there a documented diagnosis of dementia? Yes/No

If yes, please give details:

b. Type _____

c. Source of diagnosis _____

d. Date of diagnosis _____

D. Current Health Problems

14. Acute Conditions in last 2 weeks (*Please circle all that are documented*)

1. Upper respiratory tract infection
2. Chest infection
3. Flu-like illness
4. Urinary tract infection
5. Gastro-enteritis
6. Other (Please specify) _____

15a. Any Falls in the last 2 weeks? Yes/No

If yes:

b. Number of falls _____

E. ASSESSMENTS

16. Please give details of recorded assessments

Type of Assessment	Scales or Measures Used	Date Conducted	Score/Other Details
i. Pain Assessment Y/N	(Free text: To code when entered into SPSS)		Score _____ Not Assessed <input type="checkbox"/>
ii. Cognitive assessment	(Free text: To code when entered into SPSS) Eg MMSE		Score _____ Not Assessed <input type="checkbox"/>
iii. Depression	(Free text: To code when entered into SPSS) Eg GDS		Score _____ Not Assessed <input type="checkbox"/>
iv. Dependency	(Free text: To code when entered into SPSS) Eg Barthel		Score _____ Not Assessed <input type="checkbox"/>
v. Activities of Daily Living (ADL)	Breathing		1 No problems 2 Some problems 3 Immobile due to breathing problems 4 Needs Oxygen 5 Not recorded

Maintaining a safe environment		<p>1 No problems</p> <p>2 Walks with aid</p> <p>3 Needs supervision to mobilise</p> <p>4 Safety rail in use</p> <p>5 History of falls</p> <p>6 Other _____</p> <p>7 Not recorded</p>
Expressing Sexuality		<p>1 No problems</p> <p>2 Needs assistance with privacy and dignity</p> <p>3 Other _____</p> <p>4 Not recorded</p>
Eating and Drinking		<p>1 Self caring</p> <p>2 Needs assistance of one person</p> <p>3 Needs assistance of two people</p> <p>4 Other _____</p> <p>5 Not recorded</p>
Elimination		<p>1 Self caring</p> <p>2 Needs regular reminding</p> <p>3 Needs assistance of one person</p> <p>4 Needs assistance of two people</p> <p>5 Incontinent</p> <p>6 Not recorded</p>
Personal Care		<p>1 Self caring</p> <p>2 Needs assistance of one person</p> <p>3 Needs assistance of two people</p> <p>4 Variable assistance</p> <p>5 Not recorded</p>
Sleeping		<p>1 No problems</p>

			<p>2 Takes night sedation</p> <p>3 Has disturbed sleep</p> <p>4 Sleeps during day</p> <p>5 Walks in their sleep</p> <p>6 Not recorded</p>
	<p>Death and dying (wishes, hopes, fears)</p>		<p>1 Has been discussed with person</p> <p>2. Not discussed</p> <p>3. Not resorded</p> <p>Consultee involvement? Y/N</p>
vi. Pressure ulcer assessment	<p>(Free text: To code when entered into SPSS)</p> <p>Eg Waterlow</p>		
vii. Falls Risk Assessment	<p>(Free text: To code when entered into SPSS)</p> <p>Eg Fall Risk and Fracture Assessment Tool</p>		
viii. Manual Handling Risk Score	<p>(Free text: To code when entered into SPSS)</p>		
ix. Nutrition Assessment	<p>Weight__ (Kg)</p> <p>Date _____</p>		<p>Not assessed <input type="checkbox"/></p>
x. Other			

Assessments			
xi. Other Assessments			
xii. Other Assessments			
xiii. Other Assessments			

F. Preparation for End-of-Life-Care

15. Evidence of Physical Decline towards the End-of-Life

(Please tick one box) Yes No

If Yes please circle all codes that apply:

- 1 Falling
- 2 Infections
 - a chest infection/pneumonia
 - b urinary tract infection
 - c septicaemia
 - d skin infections
 - e other please state _____
- 3 Chair bound
- 4 Bed bound
- 5 Incontinence: a urine; b faeces
- 6 Diarrhoea
- 7 Vomiting
- 8 Pressure areas: skin breakdown
- 9 Increased confusion
- 10 Eating and Drinking
 - a loss of appetite
 - b weight loss
 - c difficulty in swallowing
 - d supplementary feeds
 - e unable to eat
 - f unable to drink
- 11 Contractures
- 12 Other (please specify) _____
- 13 Not recorded

16. Is there evidence of the resident being actively involved in advanced planning or in the assessment, care planning and evaluation process for end-of-life care?

(Please tick all that apply)

Resident Yes No

Consultee involvement? Yes No

Family involvement Yes No

Please give details _____

17. Preferred place for end-of-life care

(Please circle code that applies)

- 1 Care home
- 2 Hospice
- 3 Hospital
- 4 Other (please specify) _____
- 5 Not recorded

18. Use of Protocols for End-of-Life Care

(Please circle codes that apply)

1. Care home specific
2. Organisation specific (please specify) _____

National Palliative Care Guidelines

3. Gold Standard Framework (Care Home) GSFCH

4. Liverpool Care Pathway LCP

5. Preferred Place of Care PPC

6. Other (please specify) _____

7. Not documented

G. TOTAL SCORE OF ALL ASSESSMENTS

ASSESSMENT	TOTAL SCORE	DATE and COMMENTS
Disability Assessment for Dementia (DAD)		
Cornell Scale for Depression in Dementia (CSDD)		
Cohen-Mansfield Agitation Inventory (CMAI)		

CLIENT SERVICE RECEIPT INVENTORY

A

1. Please state the name of the organisation that manages the facility and *tick* whether

this is local authority social services, an NHS organisation, private (for-profit)

organisation, voluntary (non-profit) organisation or other.

(social services)

(NHS)

(private)

(voluntary)

(other)

2. What is the **total** weekly charge per week for the resident?

£

3. Who contributes towards the cost of this placement? (*Circle all codes that apply*)

1 DSS

5 Resident

2 National health service

6 Resident's family

3 Local authority

7 Insurance policy

4 Voluntary organisation

8 Other (*please specify*) _____

**If no, go
to
question 6**

4. Has the service user lived anywhere else during the last three months?

Yes No

(excluding hospital stays)

→

5. If yes to Question 4, what type of accommodation was this?

Accommodation type	Approximate number of nights spent in this accommodation in last 3 months
Nursing home	
Other <i>(please specify)</i> _____	

B. SERVICE RECEIPT

6. Please list any use of the following **hospital services** over the last 3 months

Service	Name of ward, clinic, hospital, centre	Reason for using service	Number of contacts
Accident & Emergency			_____ visits
Hospital inpatient ward in an acute hospital			_____ inpatient days
Community Hospital ward			_____ inpatient days
Day hospital			_____ attendances
Outpatient services (list all)			_____ appointments
			_____ appointments

			_____ appointments
			_____ appointments
Other (Please specify):			

7. Please list any use the service user has made of **community-based services** over the last 3 months. *Code outpatient services at Q8 above

Primary Care, Community Health and Emergency Services*	Tick if yes	Total number of contacts	Typical duration of contact (mins)
Paramedic (ambulance service)			
Community Matron			
Community/District Nurse			
Practice Nurse			
Night Nurse			
Specialist nurse <i>e.g. palliative care, continence, diabetes</i>		_____ home _____ office	_____ home _____ office
Occupational Therapist			
Speech and language therapist		_____ home	_____ home

		_____ office	_____ office
Physiotherapist		_____ home _____ office	_____ home _____ office
General practitioner		_____ home _____ office _____ phone	_____ home _____ office _____ phone
Other community doctor, <i>describe:</i>		_____ home _____ office _____ phone	_____ home _____ office _____ phone
Palliative care services e.g. Marie Curie nurse, hospice outreach			

Social Care	Tick if yes	Total number of contacts	Typical duration of contact (mins)
Social worker or Care manager		_____ home _____ office _____ phone	_____ home _____ office _____ phone
Sitting scheme (e.g. Crossroads, Marie Curie)			
Voluntary sector e.g. Age Concern befriending service, 'pet a dog'			

Community Mental Health Services	Tick if yes	Total number of contacts	Typical duration of contact (mins)
Psychiatrist		_____ home	_____ home
		_____ office	_____ office
Psychogeriatrician		_____ home	_____ home
		_____ office	_____ office
Psychologist		_____ home	_____ home
		_____ office	_____ office
Counsellor		_____ home	_____ home
		_____ office	_____ office
Community psychiatric nurse/ Community mental health nurse		_____ home	_____ home
		_____ office	_____ office
Other mental health professional, describe:		_____ home	_____ home
		_____ office	_____ office
Other mental health professional, describe:		_____ home	_____ home
		_____ office	_____ office

Adaptations, Equipment and products	Tick if yes	Type of adaptation or equipment (<i>list all</i>)	Who supplied this?	Who/what organisation paid for this?
Special equipment (<i>e.g. for mobility, pressure area care, safe moving and handling, pain management (syringe driver).</i>)			<i>Equipment provided by NHS and those by CH included in fees?</i>	
Continence products (<i>e.g., pads, pull up pants</i>)			Supplied NHS or in CH fees?	
Aids to getting to and using the toilet or protecting bedding/furniture (<i>e.g. raised toilet, urinal bottles</i>)				

Other services: e.g. dentist, optician, chiropodist, other social care	Tick if yes	Total number of contacts	Typical duration of contact (mins)	Who/what organisation paid for this? (eg NHS, purchased by individual, included in CH fees)
1.				
2.				
3.				

8. Please list any use of the following **day services** over the last 3 months

Day Services	Tick if yes	Name of centre/ service	Number of contacts per week	Total number of contacts over last 3 months
Day care – local authority social services department			_____ Days	
Day care – voluntary organisation			_____ Days	
Day care – NHS (community-based)			_____ DaYs	
Social activities (<i>Include activities inside care home, or external activities</i>)			_____ Visits	
Patient education/Expert Patient group - Please describe:			_____ Visits	
Exercise class (<i>Include activities inside care home, or external activities</i>)			_____ Sessions	
Other				

9. Please list below use of any medications taken over the last 3 months (write additional on separate sheet)

Name of medication	Dosage (if known) (mg)	Dose frequency (e.g. daily)	For how long has service user taken this drug?
1.			
2.			

3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			

C. BENEFITS *(Difficult to obtain from residents in CHs, only likely receive state pension and, for the minority, a private pension. Not entitled other payments if LA funding CH placement)*

11. Over the past 3 months have you received any of the following payments? (include payments made jointly to others in household)

	Service user (tick as many as apply)	Other member of household (describe which)	How long has service user received this benefit (in weeks, over the last 3 months)
State Retirement (old age) Pension			
A Widow's or War Widow's Pension			
Pension Credit			
War disablement Pension			
Any other state benefit not listed (please state)			

Any other state benefit not listed (please state)			
Any other state benefit not listed (please state)			

Appendix 42 Chapter 4: Care home manager/ senior carer topic guide

REC REF: 10/H0502/5

**EVIDEM**

Topic guide: Care home manager/Senior carer

Date**Participant****Associated CH**

Sex <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	
Professional qualifications:	
Length of time present post:	_____ years _____ months
Time since qualified (eg DN/GP/SW)	_____ years _____ months
Specialist training: Dementia care End of Life Care	
How long worked with care home [state name]	___ years Total <input type="checkbox"/> Every day

--	--

Recognition and assessment of end of life care for people with dementia

- Can you tell me about when you may consider an older person with dementia as nearing the end of his/her life? Assessment, generalise about?

AI intervention

- Since we had the Appreciative Enquiry meetings with Caroline, do you think that care for pwd at EoL in the care home has changed at all?
 - If yes - In what way?
 - If no – why not do you think?
- What are your thoughts about the AI as a process to improve client care?
 - What worked well?
 - What were the challenges?
- Have your views about EoL care changed at all as a result of the AI meetings?
- How would you judge good EoL care now?
- Who decides at what stage an older person with dementia requires end of life care?

- Has this changed with AI?
 - What is your involvement in this process
 - How are GPs involved? (any different because of meeting)
 - How are DNs involved?
 -

- Has the AI process influenced you as a CH manager at all?

- Overall, what sort of impact would you say AI has had on the CH, if any?

- If there has been an impact/change in practice, do you think this will be sustained?
Why/ why not?

- Is there anything else you would like to say about AI?

Appendix 43 Chapter 4: Care home staff topic guide

REC REF: 10/H0502/5

**EVIDEM**

Topic guide: Care staff

Date**Participant****Associated CH**

Sex [] Male [x] Female	
Professional qualifications:	
Length of time present post:	_____ years _____ months
Time since qualified (eg DN/GP/SW)	_____ years _____ months
Specialist training:	
Dementia care	
End of Life Care	

How long worked with care home [state name]	___years Total <input type="checkbox"/> Every day
---	--

Recognition and assessment of end of life care for people with dementia

- Can you tell me about when you may consider an older person with dementia as nearing the end of his/her life? Assessment, generalise about?
- How are you informed that someone with dementia is nearing EoL?

DNACPR

- Do any of the residents have DNACPR forms? How recent? Where stored? Etc.
- Will ambulance staff be satisfied to see a copy of the original form?

Do any residents have DNACPR forms? How recent? Where stored etc?

Will ambulance staff be satisfied to see a copy of the original form?

AI intervention

- Have you been made aware of the intervention that has been introduced by the care home through taking part in the research?

Appendix 44 Chapter 4: NHS staff topic guide

REC REF: 10/H0502/5



EVIDEM

Topic guide: NHS staff

Date

Participant

Associated CH

Sex [] Male [x] Female	
Professional qualifications:	
Length of time present post:	_____ years _____ months
Time since qualified (eg DN/GP/SW)	_____ years _____ months
Specialist training:	
Dementia care	

End of Life Care	
How long worked with care home [state name]	___years Total [] Every day

Recognition and assessment of end of life care for people with dementia

- Can you tell me about when you may consider an older person with dementia as nearing the end of his/her life? Assessment, generalise about?

AI intervention

- Since we had the Appreciative Enquiry meetings with Caroline, do you think that care for pwd at EoL with the care home has changed at all?
 - If yes - In what way?
 - If no – why not do you think?
- What are your thoughts about the AI as a process to improve client care?
 - What worked well?
 - What were the challenges?
- Have your views about EoL care changed at all as a result of the AI meetings?

- How would you judge good EoL care now?

- This care home; who decides at what stage an older person with dementia requires end of life care? Do care staff ring you or do you regularly review patients?

- Anyone on the palliative care register?

- Has this changed with AI?
 - What is your involvement in this process
 - How are you involved? (any different because of meeting)
 - How are DNs involved?

- Has the AI process influenced you as a GP at all?

- Overall, what sort of impact would you say AI has had on the CH, if any?

Do you see any changes with the OOHs checklist? Has it been used?

When they ring have you noticed any differences?

Less inappropriate calls?

- If there has been an impact/change in practice, do you think this will be sustained?
Why/ why not?
- DN working together with care staff

- Is there anything else you would like to say about AI?

Appendix 45 Chapter 4: Relatives prompt guide

REC REF: 10/H0502/5



Relatives Prompt Guide

Date of Interview	
Participant ID	
Associated PWD ID	
Associated Care Home ID	

Thank you for being willing to talk to us about your relative.

1. Looking back over the time leading up to when your relative died, is there anything that you particularly remember?

2. How effectively do you feel the NHS staff and the care home worked together to provide good end of life care?

3. How well do you feel decisions about your relative's care were communicated with you?

4. When your relative died did it come as surprise?

Probe:

- i. If no what prepared you for the death?

OR

- ii. If yes, can you explain why?
-
- 5. Can you remember who was involved when your relative died e.g. GP, district nurse, hospital staff
-
- 6. What did you find helpful?
 - a. For your relative
 - b. For you
-
- 7. Was there anything you think could have been done differently?

Appendix 46 Chapter 4: Emergency services prompt guide

REC REF: 10/H0502/5



EVIDEM

Topic guide: Paramedic and Ambulance staff

Date

Participant ID

Associated CH ID: _

Sex <input type="checkbox"/> Male <input type="checkbox"/> Female	Age:
Professional qualifications:	
Length of time present post:	_____ years _____ months
Time since qualified	_____ years _____ months
Geographical area covered?	
Specialist training:	Details:
Dementia	
Mental Capacity Act (MCA)	
On average how often do you go into a care home?	<input type="checkbox"/> Every day <input type="checkbox"/> Regular arrangement <input type="checkbox"/> More than once a week

	<input type="checkbox"/> About once a week <input type="checkbox"/> Once a fortnight <input type="checkbox"/> Once a month <input type="checkbox"/> Less than once a month
--	---

Emergency treatment for people with dementia

1. In your experience, what are the most common reasons for an emergency ambulance being called to people with dementia in residential care homes?
2. How does somebody having dementia impact on the treatment you give?

Working with residential care homes

- How would you describe your working relationship with residential care homes?
- Do you feel calls to people with dementia in care homes are usually justified?
 - Why/ Why not?
- Who is responsible for contacting you?
- Do you find some residential care homes call for 999 ambulances more than others?
- In the past year, how many times do you think you've been called out to a residential care home?
 - Are you aware you'll be seeing a patient with dementia?
 - At which point are you informed? (i.e at arrival, receipt of the call)
- Can you think of a visit to a residential care home where you felt that things could have gone better?

End of life planning and protocols

- Are there any protocols in your ambulance trust regarding older people and resuscitation?
- If somebody has written instructions about DNR, are you obliged to follow these?
 - How often do these need to be updated?
- If there are verbal or informal written instructions how far are you able to follow these?
 - What is your legal position?
- Is it a difficult decision not to transport to hospital?
 - Are you under any pressure to convey to hospital, or not to convey?
- Does a resident having dementia, or not, have an influence on commencing or withdrawing CPR?
- What do you think are the most important aspects when you are called out to someone with dementia that is very poorly or dying in a residential care home?
- Are there any changes you would like to see with regard to emergency ambulance calls to care homes for people with dementia towards end of life?
- Is there anything else you would like to say about being called out to someone with dementia towards the end of their life in a residential care home?

Appendix 47 Chapter 4: Intervention design, Phase 2

Appreciative Inquiry

Devised in the USA as a complement to conventional forms of action research, AI is a research approach, method and philosophy for promoting positive personal or organisational change and development. AI seeks to discover those things that 'give life' to people, organisations and human systems when they are most effective and healthy. It is founded on the assumption that inquiry into, and conversation about, strengths, successes, values and hopes triggers change. It assumes that in every situation or organisation something works well and change can be leveraged through discovering, sustaining and spreading these moments of excellence within the wider system. Widely used in public and corporate institutions to develop organisations, the central tenet within AI is that in order to understand a person or situation (necessary for change and development) one needs to appreciate and openly inquire. Thus at the centre of AI participatory research is a subtle but fundamental shift from 'diagnosis' (determining why something is like it is) to 'inquiry' (questioning to understand another person's view and thus seeing new perspectives and possibilities within a situation). AI argues that the way people talk about an organisation or situation is important and affects the way people view their work and their role. Furthermore, AI assumes that an organisation is dynamic – with a past, present and future. People within an organisation will have more confidence to move towards the future (the unknown) if they carry forward within their working practices the best parts of their past (the known). The exploration and enhancement of what is going well in a system is often framed as a four-dimensional (4-D) cycle (*Figure 31*).

Modified Appreciative Inquiry for care homes

Appreciative Inquiry Light

Typically, AI interventions work intensely over a period of 2–5 days and assume a stable unitary organisation. In the EVIDEM-EoL study, care home and health-care staff were spread over different locations and with limited time resources. The AI method was modified (*Figure 32*). Hour-long sessions, were held three times over a period of 6 months in the three care homes. There was a focus on creating a 'team in the moment', whose members carried ideas generated back into their own professional place of work.

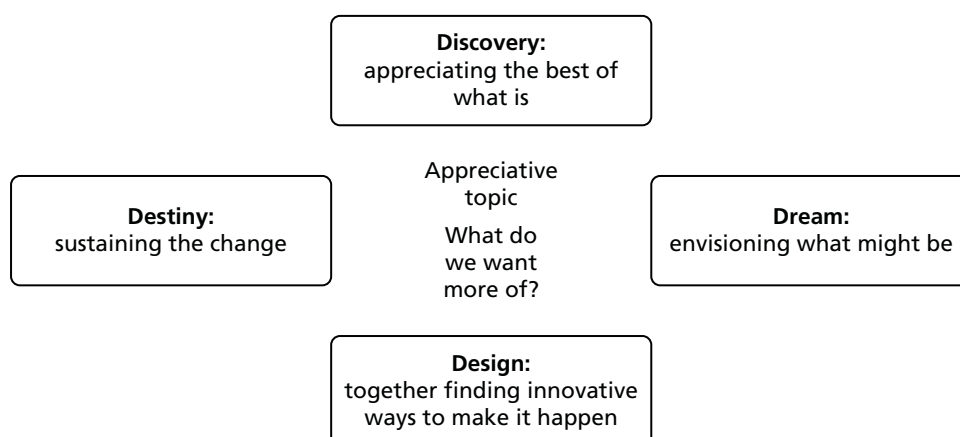


FIGURE 31 The AI 4-D model of positive change.

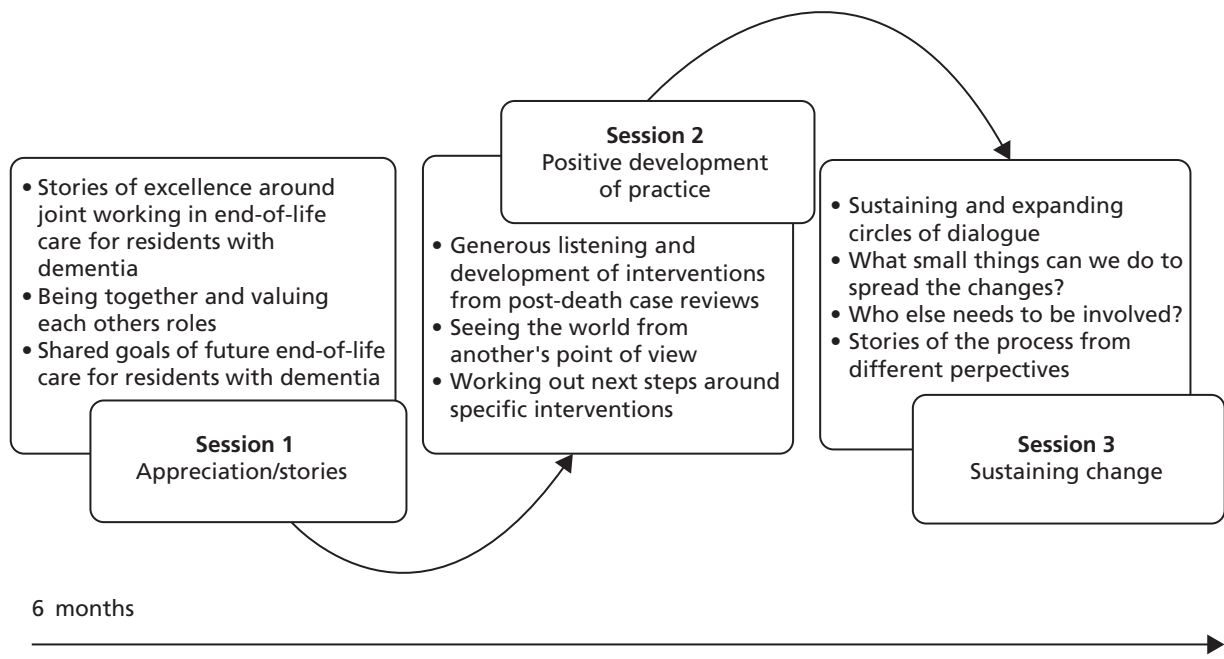


FIGURE 32 Modified AI for care homes.

Appreciative Inquiry sessions

All sessions were facilitated by a nurse researcher ('facilitator') and attended by at least two other researchers ('researchers') from the EVIDEM-EoL team. Sessions brought together care home staff and visiting health-care practitioners with the expressed intent of discussing end-of-life practice. There was considerable preparation before the sessions and follow-up by the research team in between the meetings. The researchers' role was to ground sessions in actual practice by providing participants with evidence of end-of-life care gathered in Phase 1, as well as evidence from Phase 2, as it became available. Researchers gave absent stakeholders (i.e. residents and relatives, emergency services) a voice over the course of the sessions using interview data collected over the course of the study. Researchers also summarised key themes and points for participants in between sessions, and provided updates in newsletters. Initiatives arising from the intervention were linked to practice development within the wider system by providing care homes with current and up-to-date resources in end-of-life care (Dying Matters leaflets, East of England DNACPR forms) and links to the care homes' local support networks (local hospices, end-of-life facilitators, Hertfordshire Partnerships).

Session one: appreciation/stories

Prior to session one, participants were sent a letter introducing AI and encouraging reflection and sharing of stories of good practice (see intervention information). This introduction to 'good gossip' enabled some familiarity with AI and the emphasis on positive experiences before the structured sessions. Session one used the principles of the Discovery and Destiny phases of AI to reveal current excellent practice, value the shared capacity among participants and together create a shared intent about the future of end of life within that care home. Following a brief introduction participants were paired and invited to tell each other a story of 'a positive memorable moment of working with others to provide end-of-life care for a resident dying with dementia'. Each pair recounted and listened to experiences of working well and then spent time comparing their stories for > 15 minutes. Each pair reported back to the wider group, and participants were invited to respond to what they had heard. This enabled participants to notice and value the role of each group member. Participants were encouraged to comment on any similarities they had noticed in the stories and together the group constructed a number of key attributes, values, skills and abilities they identified around shared working which were written down, for example 'families are really

important and we value keeping them involved'. The whole group were then asked to imagine the care home 5 years on, and together to think about their best ideal for end-of-life care for people with dementia. Several questions were used to help direct this thinking: i.e. What is different? What is going on in the home? Who is here? How have residents benefited? These future-directed statements were recorded, and the session ended by each participant reflecting on their own practice and shared working.

Session two: positive development of practice

The second round of AI session across care homes built on session one and used the principles of the AI design phase to focus on prioritising and choosing a particular innovation for participants to co-design together. Session two used reflections on real-life practice and end-of-life care within the care home to reflect on collaborative working and tease out the specifics of each innovation.

The meeting began with a check in about session one and anything participants wanted to share. An after death analysis of a care home resident was presented to the group (see *Appendix 51*) by the research team, using data from care notes, interview with key staff members and the time line of death. The emphasis on using these after-death analyses was on the process of care giving, and the alignment of strengths and adjustment of practice, where necessary, to move towards the future-directed statements. This emphasis on moving care forward to the intended ideal allowed for the telling of real-life/nuanced stories within a framework of generous listening, in which problem talk is framed in appreciation and possibilities, and forward thinking reflection. The tension between reflection on, and judging, specific practices was held by asking each participant to see the case from a variety of different perspectives. Thus, the discussions of the end-of-life pathway within the cases were looked at first from the point of the primary care doctor/district nurse, second from the care home staff perspective and then from the resident and family viewpoint. This proved a powerful tool in keeping participants open to the point of view of others and valuing difference, but with enough detail to enable realistic plans to develop the future-directed statements about the organisation and quality of end of life within the care home. For example, one GP was able to imagine himself as a member of care staff confronted with a collapsed resident, calling OOH for urgent medical advice. He acknowledged the inevitability of calling paramedics when the OOH response was slow, which often ends with a resident being transferred to hospital and possibly dying there. The remainder of session two was given over to the participants prioritising an innovation, and working within the groups to allocate responsibilities as to what needed to happen next, with whom and how to work with wider systems, for example OOH doctors.

Session three: sustaining change

The final session built on the previous two phases and the AI Destiny phase to concentrate on sustainability and embedding the practice innovation into the wider care home system. Although the emphasis throughout the Phase 2 study has been on a specific innovation in each care home, participants has taken the principles of AI into wider everyday practices. Thus, although session three reflected on the particular innovation of each care home and spreading, there was also an emphasis on reflecting on collaborative working and end-of-life care and how this can continue to be developed within each case study site. Also throughout the 6 months the participants had become a stronger group and more self-directing and in this last session the facilitator's role was more supporter than coach.

Thus the facilitator asked questions of the group to enhance their own learning and capacity to sustain and spread the processes, for example 'Where are we now compared with where we hoped we would be?' 'What more needs to happen?'. Essentially, this allowed each group to negotiate with each other about what realistic sustainability might look like rather than taking on imposed targets from outside. Using this context-based approach, three different structures emerged based on the strengths and interests of participants. One care home is using an existing GP visit as a strategic overview meeting to attend to the development of end-of-life care in the home. Another is creating structures to involve the other GP practice and spread their learning. The third is using AI principles to collaborate more with the district nurses who were unable to continue to attend the facilitated meetings. Participants reflected on the positives but also the challenges of the AI intervention, and set their own plans for furthering the work.

Appendix 48 Chapter 4: Intervention information – general

Appreciative conversations

Part of the EVIDEM project is about acknowledging and sharing what experiences and skills we already have in caring for people with dementia dying in care homes. We know from research that people work best when they work from a place of strength acknowledging what they do well and having conversations with others. These conversations create a shared understanding of what is good practice and what needs to be in place so it can happen more of the time. Usually we ask about things that are broken – the problems – so that we can fix them. In this case, we are trying to look at things at their best – the successes – so that we can find out what works and do more of it.

In January we will be doing this through ‘appreciative conversations’, asking you to tell your stories to other care home staff and the primary care team staff about times when you saw things working at their *best* in relation to people dying of dementia in your care home.

So, in preparation for this, we would like you to think about a situation where you felt you or the team you were working with, delivered care that allowed a resident to die well?

This may be in relation to *symptom control*, how you worked with *the NHS professionals*, or perhaps were able to carry out the *wishes of the resident or their family*.

Think about

What made the situation really special?

What was your contribution?

How did it feel?

Has it changed you in any way, if so how?

How did the care home or primary care team help you in this?

What were other people doing that helped?

What do you think was really making it work?

Talk about

Find a colleague and talk about it together – are your experiences similar?

We call this Good Gossip and can happen over a *tea break*, coming *on and off a shift*, as well as *structured meeting times* in the course of work.

Appendix 49 Chapter 4: Intervention information – care home staff

Information for care home staff

We are really pleased that you are joining with us in Phase 2 of the EVIDEM project and excited about working with yourselves and the Primary Health Care Team.

What we want to do in January

Our aim is to help you use your experiences and knowledge of what works well to create shared interventions to support and enhance practice. We all want the care of people dying with dementia to be as good as it can possibly be.

What we have asked you to do

We have asked you to tell stories of times when you felt you and the team have delivered care that allowed a resident with dementia to die really well. Although you may have remembered a difficult experience was there a moment when you remembered something good that came out of it? Perhaps you felt proud about how you or your care home handled the difficulty? We are not denying that there are lots of challenges in your work but we are interested in your capacity with your colleagues to overcome these.

The idea of talking about the good things with other colleagues we call Good Gossip because:

- Good Gossip not only makes you feel better, but also your listener and the organisation in which you are working.
- You can only gossip by talking to others, no one gossips on their own.
- Good Gossip is ongoing conversation when you talk and listen to colleagues in your organisation, about what you are proud of, what you do well, what you have seen others do that makes you feel good.

What we want you to do now . . .

Experience and Practice Good Gossip . . . For many of us we need others to help us practice and talk about what we do well. Here are some ways to do that:

1. Think about your wishes for your care home and residents dying of dementia, what you would love to see happening or in place . . .
2. Go tell someone else and ask them to tell you their wishes. If that feels hard then what would things look like if it were a little better in your care home?
3. What would be the smallest thing you could do to bring your wishes into being . . . it may start with saying good morning to someone or learning someone's name.

Appendix 50 Chapter 4: Intervention information – district nurses/general practitioners

Information for district nurses and general practitioners

The EVIDEM-EoL Phase 1 tracked over 1 year the care received by people with dementia in six care homes. The findings suggested that fundamental to good care is the way of working together of NHS care home staff, family members and, where possible, people with dementia.

Phase 2 is an intervention-based study with three care homes, underpinned by collaborative working. Care home and primary care staff identify an area for improvement around the care of a person dying with dementia, and develop strategies to implement this. To facilitate this we are using an AI approach. The originator David Cooperrider first worked with physicians in USA and noted that when he asked doctors about success rather than failure their energy, enthusiasm and motivation shifted.

Appreciative Intervention is both a philosophy and process that has been widely applied to change in health care. Fundamentally, it is the search for the best in people and their organisations and the assumption that within a system there is always something that is working. This strength-based change uses enquiry, positive questions, and good experiences to explore, discover and open up new possibilities with others who are important in the system.

In January we will begin this through ‘appreciative conversations’, asking you when you saw things working at their *best* in relation to people dying of dementia in care homes. So in preparation we would like you to think about a situation where you felt you or the team you were working with, delivered care that allowed a resident to die well. This may be in relation to symptom control, how you worked with the care home or were able to carry out the wishes of the resident or their family.

Think about

What made the situation really special?

What was your contribution?

How did it feel?

Has it changed you in any way, if so how?

How did the care home or other primary care team members help you in this?

What do you think was really making it work?

Talk about

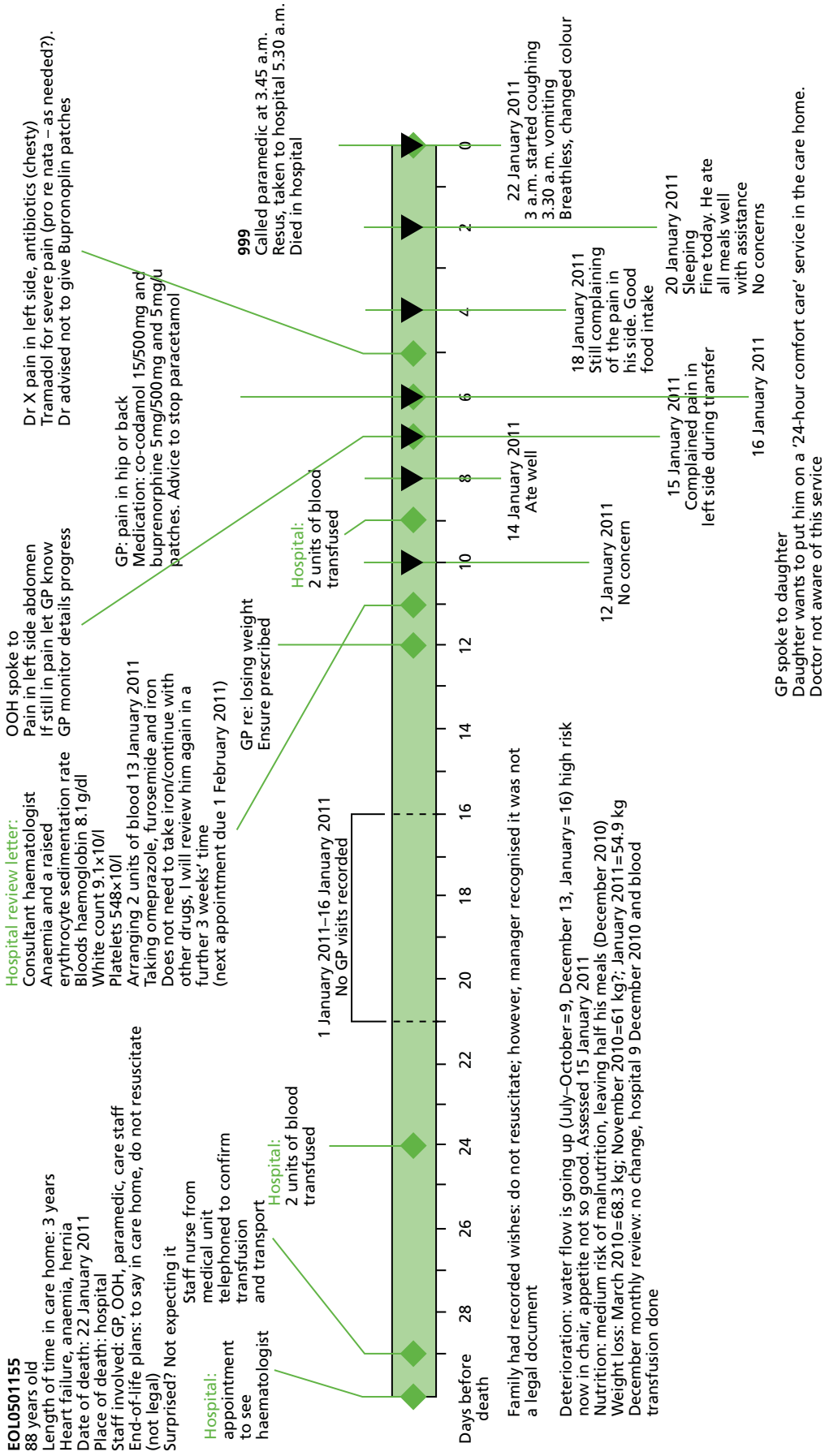
Find a colleague and talk about it together, are your experiences similar? We call this Good Gossip and can happen over a break, as well as structured meeting times in the course of work.

Cooperrider D. Appreciative Inquiry: towards a methodology for understanding and enhancing organizational innovation. Doctoral Dissertation. Cleveland, OH: Western Reserve University; 1986.

Reed J. Older people maintaining wellbeing: implications for future developments. *Int J Older People Nurs* 2008;**3**:76–8.

Alfred R, Shohet R. 'What's the best day you've ever had at work?' Appreciative Inquiry at the Manchester Heart Centre. In Edmonstone J, editor. *Building on the Best: An Introduction to Appreciative Inquiry in Health Care*. Chichester: Kingsham Press; 2006.

Appendix 51 Chapter 4: Intervention material – post-death analysis



Key:
 Below the line = care notes from staff
 Above the line = contact with primary care staff and hospital

Appendix 52 Chapter 4: Participant developed tools – prompt sheet

Starting to have conversations about dying with residents and relatives

There is something about looking for clues from residents or relatives as to when they might be ready to talk about their wishes and being able to respond outside of a need to fill in a form, for example:

- when they have received news of a death, may be a friend, family, pet . . .
- when someone else in the home has died . . .
- when they have just been through a time of change or something out of the ordinary routine, e.g. a hospital admission/not feeling so well/family member has visited . . .

Sometimes an open question, e.g. 'How are you today?' can open up a lot and often it is allowing yourself to not close this down. In one care home, passing by a resident, I said 'How are you?' and she said 'I'm past my sell by date just waiting now to go . . .' It could be a start of a conversation. My neighbour said to me yesterday, 'I shouldn't be here any longer.' These are openings for us to listen.

Some ways of asking

- I wondered if you minded thinking about the care you want for the future, for instance when you become unwell or your health starts to deteriorate.
- I am not bringing this up because you/your relative is ill at the moment but just so that we can plan for the future and provide the best care for you/your relative in the coming months.
- Some people have very definite views about how they want to be cared for at end of life and others do not want to think about it. We understand everyone is an individual.
- It has been shown that it is sometimes easier to think about these things while you/residents are well, rather than have to make decisions at short notice.
- You might not want to talk about this with me at the moment, or ever and that is absolutely fine. We just wanted to ask and hope you don't mind. Or I can give you a form to take away and we can talk again. You might want to talk to other relatives, chat together or talk to your GP. There are some leaflets.

You (the resident or relative) are welcome to discuss the issues at any time they feel prompted to do so and for whatever reason.

- We sometimes ask our residents if they have any anxieties about dying when the time comes. Is this something you would like to talk about?'
- None of us know what the future holds but sometimes it helps to talk about our hopes and fears. Is there anything you would like to talk about with me or your relative, a GP a spiritual or religious person? Please let me know and we will make some time for a conversation.

From research findings

Residents/relatives may talk informally with carers about their wishes (or what they don't want, or what happened to a close relative that was good or bad), ask them if this can be recorded in the care notes. Follow up those conversations. It is not just the manager who has the conversations – in one care home the woman who worked in the laundry had the most open discussions with residents and relatives.

Possible times to talk with resident/relative – after a hospital admission, after a death of a fellow resident, when a resident's health declines.

Advice from another care home manager: start the subject at the initial assessment (6 weeks), give them the form to take away and then review in another few months' time. Keep offering the opportunity to follow up, especially as health deteriorates. It is easier to have the difficult conversations, if you have already had some earlier.

Some specific questions

Any wishes for your last days?

Where would you like to be cared for in the future? (care home or hospital?) 'Care home as long as possible?'

Would you want any more hospital admissions? Resuscitation? Transfer to a nursing home?

Examples from other documents/care homes

A Preferred Priorities of Care (final wishes) document can help you/us prepare for the future. It gives you an opportunity to think about, talk about and write down your preferences and priorities for care at the end of life. You do not need to do this unless you want to . . .

- Remember your views may change over time and you can change what you have written whenever you wish to.
- What are your preferences and priorities for your future care?
- Where would you like to be cared for in the future?

A final wishes plan is designed to inform people around me of my 'wishes' regarding the atmosphere and environment I would like to be in as my life draws to a close – and any specific requests I have. Please note this is for guidance and not legally binding.

- Resident Have you spoken to anyone about your wishes? Would you like help to do so?
- Relative Has your relative ever spoken to you about what they might like?
- When you (or your relative) comes towards the end of your/their life, what would you/they like around you/them?
 - favourite flowers, music, pictures, favourite perfume, prayers, physical contact, massage, personal care
 - relatives/someone with you
 - any spiritual/religious needs
 - if the condition is prolonged I would/would not like to venture out of my room.
- Subjects you might need to talk about:
 - the type of care someone would like towards the end of their life
 - where they'd like to die
 - whether they have any particular worries they'd like to discuss about being ill and dying
 - how long you would like doctors to keep treating you
 - resuscitation.

Some questions about funeral arrangements

(Not the key for advanced planning but sometimes a way to start a conversation; some people may feel more comfortable talking about funeral plans.)

- I would like my death and funeral to be announced in the following ways
- My preferred funeral director is
- The person I would like to deal with my funeral arrangements is
- The type of funeral I would like is (traditional, less traditional, hymns, music, readings, poems)
- Buried or cremated
- Flowers and or donations at the funeral
- I would like to take with me (leave from); to wear (clothes, jewellery) to take with me (photo, book)

Appendix 53 Chapter 4: Participant developed tools – out-of-hours information sheet

Information out-of-hours services need to know about a resident

Prompt guide for care staff – out-of-hours services information sheet

These are questions for care home staff to think about before ringing OOH services. Please try and have answers ready for as many of these questions as you can.

_____Date

Resident's name	Answers
Medical history/background	
Symptoms (what is wrong?)	
How long has this been going on?	
Is this:	
<ul style="list-style-type: none"> an expected palliative situation (i.e. when someone is approaching end of life or not for further active treatment is being considered by their usual doctor) 	
or	
<ul style="list-style-type: none"> person getting acutely unwell all of a sudden? 	
What were they like before this problem arose?	
What are they usually like?	
What is normal for them/what has changed?	
How has the problem altered/what are they normally like?	
Wishes of the residents	
Wishes of the family/relative	
Preferred place of care?	
(anything else known – resus.?)	
Any more hospital admissions?	
Would resident want to go to hospital?	
What do you want OOH to do?	
Why is OOH being called?	
Are they acutely unwell now?	
Do they need an ambulance (999)? Is it an emergency situation?	
Can their symptoms be managed?	
Further treatment for infection?	
Other	

Appendix 54 Chapter 4: EVIDEM-EoL advisory group members

Marion Cowe	Member of the Public Involvement Group for CRIPACC (University of Hertfordshire). Lay perspective, former carer of brother with dementia
Jaleh von Wagner	Lay perspective. United Carers for Dementia. Carer for 8 years (24/7) of mother, who died from vascular dementia/Alzheimer's disease then cared for elderly, disabled blind father for further 2.5 years (24/7); with both at the death
Rachel Dutton	Member of Housing 21 Association. Specialist area is social care provision for people with dementia towards end of life
Catherine Evans	Former EVIDEM-EoL lead researcher; research specialises in older people; background in nursing
Hillary Speller (attended one meeting)	Lay perspective. Father died with dementia in distressing circumstances
Jane Wilcock	Senior Research Fellow, University College London and EVIDEM Programme Manager
Allan Kellehear	Professor of Sociology, University of Bath. Specialist areas include dying, public health and end of life
Derek Baker	Lay perspective, wife has dementia and is living in a care home. Chairman of the Mid Essex Branch Committee, Alzheimer's Society
Nicole Jackman	Senior doctor at St Francis Hospice – specialist interest in palliative care for the elderly
Louise Robinson	GP academic, University of Newcastle. Specialist areas include dementia (diagnosis, quality of life, end of life), promoting older people's health
Sheila Peace	Professor of Gerontology, The Open University. Specialises in sociology, care homes, end of life and older people
Clive Evers	Director of Education and Information, Alzheimer's Society
Ram Awatar	Director of Clinical Services, Nightingale House. Specialist areas include care homes, dementia and older people
Karen Harrison Denning	Specialises in research for OPWD and is a consultant Admiral Nurse
Priya Jain	Assistant Research Manager, EVIDEM Early Diagnosis
Kalpa Kharicha	Senior Research Fellow and EVIDEM Programme Manager (covering Jane Wilcock's maternity leave)
Jan Dewing	Professor at University of Kent at Canterbury and Visiting Professor at the University of Wollongong, Australia. Holds extensive national and international experience, particularly in the field of dementia and care for the elderly, and has made a great contribution to consenting with people who lack capacity
Heather Maggs	Member of the Public Involvement Group for CRIPACC (University of Hertfordshire). Lay perspective. Father had dementia. Member of Alzheimer's Society Quality Research in Dementia

Appendix 55 Chapter 4: Care home characteristics

TABLE 106 Organisation of care, dementia training, palliative care training^a

Care home	Organisation of care	Dementia training	Palliative training or other
CH1	Dedicated Dementia Unit; staff allocation by duty manager night before shift on basis of experience – less experienced placed with more experienced; high level of continuity; key worker	Need to have completed basic dementia training to work on Dementia Unit. Can do further training BTEC diploma over 2.5 days or 1-year course – Champion in Dementia. Yearly update given to staff regarding use of antipsychotics	Informal in-house training provided by district nurses dependent on needs (e.g. stoma care, catheter care). Informal in-house training on mouth care, pressure area care, basics of pain relief and constipation management
CH2	Team of workers; key worker system; key worker for two to three residents, may change if poor rapport with resident. At beginning of shift, three staff members decide how to allocate work. Duty manager gives handover to all staff for morning shift and again for afternoon shift, which starts at 3.30 pm	On dementia unit all staff will have undertaken basic dementia training	District nurses advise CH staff on mouth care, request turning charts, fluid/food intake charts, monitoring passing of urine
CH3	Three staff per shift on dementia unit; allocated on daily basis at beginning of shift by senior staff. Communication – verbal and written, notes in diary, district nurse book and GP book	On dementia unit all staff will have undertaken basic dementia training	
CH4	Dedicated dementia unit; 6- and 12-hour shifts; separate night staff (12-hour shifts). Verbal handover through notes. Verbal to senior who transfers information to team	Training compulsory for all care staff run by organisation – 3 days over 3 weeks, including some homework	
CH5	Key worker system; hierarchical system; not clear how work organised; night staff entirely separate – not same support system available to them, fewer staff, no senior, theoretically home manager contactable	Training (information on office wall) but not clear what is involved	Informal in-house training provided by district nurses (nursing sisters) in the past, e.g. diabetic training
CH6	Senior carer on each unit, on each shift. Seniors handover to everybody but anything more specific to do with staff it would be senior to senior	Unclear	

BTEC, Business and Technology Education Council; CH, care home.
 a Source: care home manager and district nurse interviews.

TABLE 107 End-of-life care framework utilisation^a

Care home	CH1	CH2	CH3	CH4	CH5	CH6
Use end-of-life care framework	District nurses use LCP	None	LCP used once in conjunction with district nurses	Made enquiries about GSF	Services Director looking at GSF; looked at LCP but not progressed	Looked at LCP but not progressed
Other end-of-life arrangements	Organisation-specific end-of-life care plan, staff do not attempt resuscitation (although trained, they wait for paramedics)	Organisation-specific end-of-life care plan	Organisation-specific end-of-life care plan; staff do not resuscitate (although trained, wait for paramedics)	Resuscitation unless chosen otherwise, asked as soon as possible after admission	Organisation-specific end-of-life care; everyone for resuscitation unless otherwise stated	Organisation-specific end-of-life care; everyone for resuscitation unless otherwise stated

^a Source: care home manager interviews.

Appendix 56 Chapter 4: Care home resident needs and deaths in year prior to study

TABLE 108 Care home residents' significant areas of need^a

Areas of need	CH1 (N = 44): n (%)	CH2 (N = 58): n (%)	CH3 (N = 57): n (%)	CH4 (N = 62): n (%)	CH5 (N = 66): n (%)	CH6 (N = 54): n (%)
Bedfast	0	0	3 (5.3)	0	0	0
Help with dressing/undressing	41 (93.2)	46 (79.3)	50 (87.7)	42 (67.7)	52 (78.8)	38 (70.4)
Help with washing/bathing	44 (100.0)	56 (96.6)	57 (100.0)	59 (95.2)	63 (95.5)	51 (94.4)
Help going to the toilet	33 (75.0)	32 (55.2)	42 (73.7)	32 (51.6)	30 (45.5)	21 (38.9)
Singly incontinent	34 (77.3)	15 (25.9)	7 (12.3)	39 (62.9)	16 (24.2)	13 (24.1)
Doubly incontinent	18 (40.9)	22 (37.9)	18 (31.6)	9 (14.5)	21 (31.8)	3 (5.6)
Dementia	31 (70.5)	34 (58.6)	29 (50.9)	30 (48.4)	55 (83.3)	23 (42.6)
Other mental health needs	1 (2.3)	6 (10.3)	1 (1.8)	0	4 (6.1)	0
Learning disabilities	1 (2.3)	1 (1.7)	2 (3.5)	0	0	0
Physical disabilities	19 (43.2)	17 (29.3)	0	0	0	1 (1.9)
Two or more staff to help with their care	14 (31.8)	11 (19.0)	8 (14.0)	14 (22.6)	13 (19.7)	4 (7.4)
Help/supervision/prompts to eat meals	23 (52.3)	17 (29.3)	11 (19.3)	23 (37.1)	29 (43.9)	4 (7.4)
Impaired vision	24 (54.5)	13 (22.4)	25 (43.9)	37 (59.7)	42 (63.6)	2 (3.7)
Impaired hearing	2 (4.5)	8 (13.8)	16 (28.1)	20 (32.3)	19 (28.8)	2 (3.7)
English not first language	1 (2.3)	2 (3.4)	0	0	0	0
Specialist communication needs	4 (9.1)	0	0	0	3 (4.5)	0
Alcohol dependence	0	1 (1.7)	0	0	0	1 (1.9)
Drug dependence	0	0	0	0	0	0

^a Source: AQAA data.

Appendix 57 *Chapter 4: Care homes' access to primary and specialist services*

TABLE 109 Access to primary and specialist care services^{a,b}

Care service	CH1	CH2	CH3	CH4	CH5	CH6
GP (no. of associated practices; visitation rate)	Two practices; once a week and on request	Two practices; once a week and on request	Four practices; once a week and on request	Four practices; once a week and on request	Three practices (new residents registered with only one); once a month and on request	Two practices; on request and annual medication review
GP (no. of visiting GPs)	One regular from each practice but up to two or three GPs from each practice	One regular from each practice but one or more from each practice	One regular from each practice but up to two GPs from each practice	No designated GP. Up to 6 different GPs	One regular from one practice, but up to eight different GPs	Full contact with each practice; eight GPs in one practice; unclear how many GPs in other
GP OOH	On request	Every 2 weeks on average	On request	On request	Once a week on average and on request	On request
District nurse	On request	Every day (insulin dependent diabetic) and on request	Twice a day (insulin dependent diabetic) and on request	On request	On request	Twice a day (insulin dependent diabetic) and on request
Night nurse	On request	Never	On request	Never	Never	Never
Community Mental Health Nurse/MHT	Once a week	Once a month (patient review)	On request	Every few months and on request	Once a month	Never, MHT occasionally
Admiral Nurse	No	Never	Never	Never	Never	Never
Counsellor	On request (GP referral)	In-house trained	Never	On request	Never	Never
Palliative care nurse (e.g. Macmillan, Marie Curie)	On request (only for people with cancer)	Never	Never	Once a month	Never	Occasionally (Macmillan by referral from GP)
Other	Psychogeriatrician (on request, 3-month wait, GP referral); hospice support – on request (only for people with cancer); night sitter service – on request (only for people with cancer from hospice)	Psychogeriatrician has been involved	None mentioned	Parkinson's Nurse – once a month and on request; psychiatrist – from time to time; psychogeriatrician – infrequent support	Chaplain – twice a week/once a month (different churches)	None mentioned

MHT, Mental Health Team.

a Source: care home manager interviews.

b Source: AQAA report.

Appendix 58 Chapter 4: Resident baseline characteristics

TABLE 110 Phase 1: recruitment and retention rates

Care home	Recruitment (n)	Recruitment rate (%)	Retention (n)	Retention (%) at end of Phase 1
CH1	20	71.4	15	75.0
CH2	25	62.5	19	76.0
CH3	16	50.0	12	75.0
CH4	23	76.7	19	82.6
CH5	34	54.0	25	73.5
CH6	15	71.4	10	66.7
Total	133	62.2	100	75.2

TABLE 111 Resident age, length of stay^a

Care home	CH1	CH2	CH3	CH4	CH5	CH6
Median age at admission, years (mean, SD)	84.4 (84.4, 6.15)	87.3 (86.3, 8.55)	87.5 (86.0, 4.63)	86.5 (83.7, 5.61)	82.7 (82.0, 6.56)	83.7 (82.8, 7.06)
Median age at baseline, years (mean, SD)	88.7 (87.4, 6.16)	90.4 (89.51, 8.33)	89.7 (88.7, 5.77)	88.1 (85.7, 5.85)	84.9 (83.5, 6.22)	84.3 (83.7, 7.41)
Median length of residency, years (mean, SD)	2.5 (3.0, 2.16)	3.4 (3.2, 1.84)	2.0 (2.8, 2.13)	1.6 (2.0, 1.77)	1.3 (1.5, 1.00)	0.2 (1.0, 2.20)

a Source: care notes.

TABLE 112 Admission route^a

Place of previous residence (N = 120)	n	%
Own home	52	43.3
Relative's home	7	5.8
Hospital	35	29.2
Care home	13	10.8
Sheltered housing – warden controlled	13	10.8
Total	120	100.0
Reason for admission (N = 91)		
Following death of spouse	3	3.30
Resident isolated	5	5.50
Concerns about safety	8	8.80
Deterioration of health	16	17.60

continued

TABLE 112 Admission route^a (continued)

Reason for admission (N = 91)		
Resident unable to cope living independently	31	34.10
Carers no longer able to cope	11	12.10
Short-term stay into long-term placement	7	7.70
Needs unmet in previous accommodation	4	4.40
Other	6	6.60
Total	91	100.0

a Source: care notes.

TABLE 113 Dementia diagnosis^a

Recorded diagnosis of dementia (N = 98)		
Type	<i>n</i>	%
Alzheimer's disease	38	38.80
Vascular dementia	16	16.30
Mixed	5	5.10
Lewy body	2	2.00
Korsakoff syndrome	1	1.00
Other	1	1.00
Not recorded	35	35.70
No recorded diagnosis	35	26.30

Source		
Neurologist	1	1.00
Social worker	2	2.00
Consultant psychiatrist	12	12.30
Assessment	4	4.10
Brain scan	1	1.00
SMHT	7	7.20
CPN report	1	1.00
Memory clinic	2	2.00
Not recorded	68	69.40
No recorded diagnosis	35	26.30

CPN, community psychiatric nurse; SMHT, Specialist Mental Health Team.
a Source: care notes.

TABLE 114 Activities of daily living record in care notes

ADL	Recorded (N, %)	No record (N, %)	Total (N, %)
(In)continence	131 (100)	0 (0.0)	131 (100)
Personal care	131 (99.2)	1 (0.8)	132 (100)
Maintaining a safe environment	128 (97.7)	3 (2.3)	131 (100)
Eating and drinking	128 (97.0)	4 (3.0)	132 (100)
Toilet use	92 (70.2)	39 (29.8)	131 (100)
Sleeping	61 (47.7)	67 (52.3)	128 (100)
Expressing sexuality	19 (14.5)	112 (85.5)	131 (100)
Breathing	13 (9.8)	119 (90.2)	132 (100)

TABLE 115 Function within care homes (ADL; N = 133)

Function	CH1	CH2	CH3	CH4	CH5	CH6	Total
ADL^a							
<i>(In)continence, n (%)</i>							
Incontinent	13 (68.4)	5 (20.8)	7 (43.8)	11 (47.8)	13 (38.2)	4 (26.7)	53 (40.5)
Occasional accident	0 (0)	2 (8.3)	1 (6.3)	0 (0)	2 (5.9)	1 (6.7)	6 (4.6)
Continent	6 (31.6)	17 (70.8)	8 (50.0)	12 (52.2)	19 (55.9)	10 (66.7)	72 (55.0)
<i>Personal care, n (%)</i>							
Needs assistance of up to two people	4 (21.1)	8 (33.3)	7 (43.8)	18 (78.3)	7 (20.6)	6 (40)	50 (38.2)
Needs assistance of one person	15 (78.9)	16 (66.7)	7 (43.8)	4 (17.4)	26 (76.5)	5 (33.3)	73 (55.7)
Independent	0 (0)	0 (0)	2 (12.5)	1 (4.3)	1 (2.9)	4 (26.7)	8 (6.1)
<i>Maintaining a safe environment, n (%)</i>							
Immobile	3 (15.8)	2 (8.7)	1 (6.7)	2 (8.7)	3 (9.1)	0 (0.0)	11 (8.6)
Needs supervision	5 (26.3)	7 (30.4)	4 (26.7)	2 (8.7)	11 (33.3)	5 (33.3)	34 (26.6)
Independent (with or without mobility aid)	11 (57.9)	14 (60.9)	10 (66.7)	19 (82.6)	19 (57.6)	10 (66.7)	83 (64.8)
<i>Eating and drinking, n (%)</i>							
Full assistance	7 (35)	6 (28.6)	4 (25)	4 (17.4)	8 (24.2)	2 (13.3)	31 (24.2)
Minimal assistance	3 (15)	2 (9.5)	1 (6.3)	2 (8.7)	3 (9.1)	1 (6.7)	12 (9.4)
Independent	10 (50)	13 (61.9)	11 (68.8)	17 (73.9)	22 (66.7)	12 (80)	85 (66.4)
<i>Toilet use, n (%)</i>							
Needs assistance of up to two people	2 (15.4)	3 (15)	3 (25)	0 (0)	4 (21.1)	2 (15.4)	14 (15.2)
Needs assistance of one person	7 (53.8)	7 (35)	2 (16.7)	2 (13.3)	2 (10.5)	3 (23.1)	23 (25)
Independent	4 (30.8)	10 (50)	7 (58.3)	13 (86.7)	13 (68.4)	8 (61.5)	55 (59.8)
a Source: care notes.							

TABLE 116 Event categories

Event category	Detail as recorded in care notes
Infection	Upper respiratory tract, chest, urinary tract, eye, thrush, catheter-induced penile tear, discharge (anal, penile), raised temperature
Gastrointestinal	Vomiting, diarrhoea, constipation
Pain	Increased pain, headache
Stroke/transient ischaemic attack	Suspected stroke or transient ischaemic attack
Carcinoma	Suspected or spreading carcinoma
Leg/ankle swelling	Leg and/or ankle swelling
Tissue viability	Pressure ulcer, blister, tear, soreness
Confusion	Increased confusion, absence
General deterioration	General ill health, general deterioration, generally unwell, increased frailty, increased weakness
Falls ^a	Falls
Eating and drinking	Loss of appetite, difficulty swallowing, supplementary feeds, unable to eat, unable to drink, weight loss
Sleepiness	Increased sleepiness
Withdrawal	Increasingly withdrawn, no longer enjoys activities as s/he used to
Skin colour	Pale, skin colour change
Decreased mobility	Reduced mobility, increased stiffness
Incontinence	Urine, faeces
Refusing personal care	Repeatedly refusing personal care
Breathing	Laboured breathing, breathlessness
Agitation	Increased agitation, aggressive behaviour towards other residents
Distress	Low mood, tearfulness, 'wants to die'
Other	Muscle spasms, 'floppiness', not his or herself, lethargy, altered level of consciousness, increased difficulty in communicating, disturbed sleep, dehydration, mouth sores, seizure, unsteadiness, nausea, drowsiness, weight gain, shaking, rectal prolapse, renal and heart failure, dizziness, fainting, bleeding (penile, vaginal, nose, blood in stools), lip swelling, face swelling, unresponsive

^a Falls as recorded in care notes up to 3 months preceding baseline extraction or up to the previous date of extraction at time point 2 and time point 3.

TABLE 117 Events at baseline, time point 2, and time point 3^a

Type of event ^b	Baseline (N = 133)		Time point 2 (N = 127)		Time point 3 (N = 112)	
	n	%	n	%	n	%
Infection	31	23.30	20	15.70	29	25.90
Gastrointestinal	9	6.80	16	12.60	27	24.10
Pain	3	2.30	5	3.90	3	2.70
Stroke/transient ischaemic attack	2	1.50	2	1.60	2	1.80
Carcinoma	1	0.80	2	1.60	4	3.60
Leg/ankle swelling	4	3.00	3	2.40	4	3.60
Tissue viability	10	7.50	15	11.80	11	9.80
Confusion	11	8.30	13	10.20	15	13.40
General deterioration	1	0.80	8	6.30	4	3.60
Falls ^c	29	21.80	39	30.70	33	29.50
Eating and drinking	36	27.10	45	35.40	37	33.00
Sleepiness	11	8.30	22	17.30	36	32.10
Withdrawal	0	0.00	4	3.10	8	7.10
Skin colour	0	0.00	2	1.60	2	1.80
Decreased mobility	0	0.00	2	1.60	4	3.60
Incontinence	15	11.30	36	28.30	38	33.60
Refusing personal care	0	0.00	1	0.80	3	2.70
Other	8	6.00	10	7.90	19	17.00
Breathing	1	0.80	1	0.80	3	2.70
Agitation	2	1.50	9	7.10	12	10.70
Distress	0	0.00	2	1.60	5	4.50

a Source: care notes.

b See Table 116 for detail of event categories.

c Falls as recorded in care notes up to 3 months preceding baseline extraction or up to the previous date of extraction.

TABLE 118 Falls at baseline, time point 2 and time point 3

Time period	CH1	CH2	CH3	CH4	CH5	CH6	Total
At least one fall up to 3 months preceding baseline or up to the previous date of extraction							
Baseline (N = 133), n (%)	5 (25.0)	6 (24.0)	2 (12.5)	4 (17.4)	9 (26.5)	3 (20.0)	29 (21.8)
Time point 2 (N = 127), n (%)	8 (40.0)	9 (37.5)	4 (26.7)	5 (22.7)	10 (32.3)	3 (20.0)	39 (30.7)
Time point 3 (N = 112), n (%)	9 (47.4)	2 (10.0)	2 (14.3)	9 (42.9)	6 (23.1)	5 (41.7)	33 (29.5)

TABLE 119 Level of involvement in end-of-life discussions (n, %)

Resident, consultee and family	8 (6.0)
Resident and consultee	3 (2.3)
Resident and family	7 (5.3)
Consultee and family	10 (7.5)
Family	18 (13.5)
Consultee	14 (10.5)
Resident	10 (7.5)
No evidence of discussions on end-of-life wishes	53 (39.8)
Unclear	10 (7.5)

TABLE 120 Phase 1 attrition

Attrition	CH1	CH2	CH3	CH4	CH5	CH6	Total
Baseline							
Deceased: care home		<i>EoL0201064</i>	<i>EoL0301074</i>				2
Deceased: hospital					<i>EoL0501171</i>		1
Transferred					<i>EoL0501165</i>		1
Time point 2							
Deceased: care home	<i>EoL0101015</i>			<i>EoL0401148^a</i>			2
Deceased: hospital					<i>EoL0501154</i>		4
					<i>EoL0501156</i>	<i>EoL0601223</i>	
					<i>EoL0501209</i>		
Transferred			<i>EoL0301083</i>		<i>EoL0501181</i>	<i>EoL0601215</i>	3
Time point 3							
Deceased: care home	<i>EoL0101013</i>		<i>EoL0301090</i>	<i>EoL0401127</i>		<i>EoL0601217</i>	6
	<i>EoL0101021</i>			<i>EoL0401133^a</i>			
Deceased: hospital	<i>EoL0101023</i>	<i>EoL0201044^a</i>			<i>EoL0501192</i>	<i>EoL0601233</i>	7
		<i>EoL0201062^a</i>			<i>EoL0501206</i>		
		<i>EoL0201067^a</i>					
Transferred					<i>EoL0501199^a</i>	<i>EoL0601221</i>	2
End of Phase 1							
Deceased: care home	<i>EoL0101022</i>	<i>EoL0201056</i>	<i>EoL0301091</i>	<i>EoL0401130</i>			5
		<i>EoL0201068</i>					
Total deaths (%)	5	6	3	4	6	3	27 (20.3)
Total transfers (%)	0	0	1	0	3	2	6 (4.5)
Total (%)	5 (25)	6 (24)	4 (25)	4 (17.4)	9 (26.5)	5 (33.3)	33 (24.8)

^a Care notes unavailable for review at time point (post-death analysis interview only, where appropriate). Italicised resident identifiers denote inclusion in survival analysis.

Appendix 59 Chapter 4: Service utilisation and associated costs

TABLE 121 Distribution of service use (per month): median (IQR^a)

Type of visit	Overall (n = 122)	Alive (n = 105)	Dead (n = 17)	Wilcoxon test p-value
Primary care	0.9 (0.5–1.3)	0.8 (0.5–1.2)	2.0 (1.0–3.0)	0.0006
Hospital	0.3 (0–0.8)	0.2 (0–0.7)	0.8 (0.4–13.8)	0.002
Community health	0.4 (0.2–1.1)	0.4 (0.2–0.7)	1.1 (0.6–1.6)	0.008

IQR, interquartile range.
a IQR, i.e. 25th percentile to 75th percentile.

TABLE 122 Phase 1: distribution of costs (£ per month): median (IQR)

Costs	Overall (n = 133)	Alive (n = 116)	Dead (n = 17)	Wilcoxon test p-value
Primary care	76 (45–123)	67 (39–107)	127 (106–279)	0.0003
Hospital	39 (0–199)	34 (0–111)	273 (96–6984)	0.0018
Community health care	45 (21–92)	44 (20–83)	89 (29–167)	0.0401
Accommodation	2243 (0–2473)	2243 (0–2447)	2243 (1754–2473)	0.4958
Total care and accommodation	2488 (413–2890)	2438 (194–2834)	2917 (2226–9867)	0.0152
Medication	57 (31–92)	57 (30–95)	43 (38–66)	0.4015
Total (including accommodation and medication)	2549 (463–2974)	2490 (251–2927)	2964 (2253–9925)	0.0168

Appendix 60 Chapter 4: Sample information – interviews

TABLE 123 Care home managerial staff interviews

Staff	CH1	CH2	CH3	CH4	CH5	CH6
Care home manager	X	X	X	X	X	
Care home deputy manager	X		X	X		X

TABLE 124 Care home staff focus groups (female): sample information

Participant information	CH1 (N = 5)	CH2 (N = 5)	CH3 (N = 3)	CH4 (N = 3)	CH5 (N = 4)	CH6 (N = 4)
Age, years: age range, median (n)	41–56, 48.7 (3)	27–58, 41.0 (4)	46–68, 57.0 (2)	20–47, 30.0 (3)	31–46, 40.25 (4)	18–39, 27.0 (4)
FT spread; PT (n)	1 FT; 4 PT (5)	3 FT; 2 PT (5)	1 FT; 2 PT (3)	3 FT; 0 PT (3)	3 FT; 0 PT (3)	2 FT; 1 PT (3)
Length of time working in care home, months: range (n)	1–240 (4)	11–36 (3)	50–178 (2)	30–36 (3)	24–48 (4)	3–27 (3)
Qualifications: received detail (n)	4 NVQ2 (4) 2 BTEC (4)	2 NVQ2 (4)	1 NVQ2 (2)	3 NVQ2 (3)	2 NVQ2 (3)	2 NVQ3 (3)
Dementia training: received (n)	5 in-house (5)	5 (5)	3 (3)	3 (3)	4 in-house (4)	3 (4)
End-of-life training: received (n)	2 (5)	5 (5) included in general training	2 (3)	0 (3)	0 (4)	1 (4)

BTEC, Business and Technology Education Council; CH, care home; FT, full time; PT, part time.

TABLE 125 NHS staff: sample information

Staff	GPs (n = 5)	District nurses (n = 5)	Emergency services (n = 3)
Length of time in post: range, years	7–18	0.5–7	6–7
Length of time working with care home: range, years	4–11	0.5–7	N/A
Dementia training	2/5	2/5	No (MCA only)
End-of-life training	No	4/5	No

N/A, not applicable.

Appendix 61 Chapter 4: Phase 2 – documentation changes

TABLE 126 Evidence of end-of-life discussions and involvement ($N = 74$)

Time point	Baseline ($n = 74$)	Time point 2 ($n = 73$)
Evidence of end-of-life discussions: n (%)	54 (73)	58 (79.5)
<i>Involvement in end-of-life discussions: n (%)</i>		
Resident involvement	7 (13.0)	7 (12.1)
Family involvement	34 (63.0)	44 (75.9)
POA	4 (7.4)	6 (10.3)
Care home staff involvement	9 (16.7)	19 (32.8)
GP involvement	4 (7.4)	10 (17.2)
Other (i.e. witness to living will, minister)	4 (7.4)	4 (6.9)
District nurse involvement	–	2 (3.4)
Hospital Medical Assessment Unit	–	2 (3.4)
a Source: care notes.		

Appendix 62 Chapter 5: EVIDEM-MCA protocol

Introduction

EVIDEM-MCA is a part of the NIHR-funded EVIDEM programme of research (Principal Investigator Professor Steve Iliffe) and has the ultimate goal of developing an evidence-based resource to enhance practitioners' awareness of the MCA to the benefit of people with dementia and to develop new knowledge about the interaction between the MCA and adult safeguarding systems and practice. This study will evaluate the impact of the Mental Capacity Act (MCA) 2005 over time, how it affects people with dementia and carers, and develop educational outputs in support of the Act. Based on an investigation into the implementation of the Act at practice level, the study will produce practice guidance on the use of the MCA, with a special focus on its use in adult safeguarding work. The study will take place in the North West London area as part of the EVIDEM programme and will connect to other parts of the programme. Specifically the study will evaluate the impact of the MCA on people with dementia, carers, professionals and the culture of the health and social care organisations. It will produce case series to inform adult protection approaches in the context of the MCA at Trust, local authority and national level.

Background

The Mental Capacity Act 2005 (MCA) in England and Wales, implemented 2007, enshrines much of the practice established under case law to safeguard people who lack ability to make specific decisions, to enhance personal autonomy and to enable people to make advance decisions to refuse treatment. It introduced new proxy decision-making roles to address health, welfare and financial matters and specialist advocacy for people who do not have family or friends where major health and welfare decisions are to be made. The implications of the MCA for health and social care practitioners around the areas of planning and working with others in new roles remain unclear.^{250,251}

It has been estimated that over two million people in England and Wales may be personally affected by the provisions of the Act.²⁵² These include many people with dementia and those who are carers, their representatives or service provider.²⁵³ The MCA provides a statutory framework to empower and protect people, notably those who fear cognitive impairment or those who have received a diagnosis of a dementia, or those who have early and advancing symptoms who may not be able to make specific decisions at specific times (www.dca.gov.uk) currently or in the future.²⁵⁴ It clarifies who can make decisions, in which situations, and the steps that should be taken. It also enables people to plan ahead in the event of loss of capacity to make particular decisions.²⁵⁶

The procedures and the ability to make choices about future care and treatment decisions mean that the MCA has potential to enhance practice and user empowerment, and thus contribute to better outcomes for service users and carers.²⁵⁷ People with dementia may require specialist advice sensitive to their particular values and networks to make valid and applicable advance decisions to refuse treatment and to formulate and communicate their wishes and preferences about care and treatment. However, there are likely to be key transitions or times when this type of advice and assistance may be most pertinent. These include encounters, such as the communication of a diagnosis of dementia, transitional periods when planning and setting up care packages or facing end of life. Professionals may need to devote time to assist people with dementia and their carers to benefit from the Act, and to make sure that they are ready to explain and debate its implications within teams and across agencies.²⁵⁹ Whilst savings of professional time may emerge if people with dementia and carers are better informed and more confident, practitioners may feel compromised by work pressures and unable to provide the necessary support. Furthermore, proactive promotion of the Act on the part of managers and professionals in a range of local settings may be required if people with dementia are to maximise their opportunities for planning their

care and making their wishes known. In these respects, the Act offers people with dementia a crucial opportunity to influence professional-decision-making so that capacity is presumed unless proven otherwise, that best interests should be the basis for decisions if a person is not able to make a specific decision, and provides people with a dementia with greater confidence that they are able to shape their future social care and treatment.²⁰⁹ Lastly, the new criminal offences of ill-treatment and wilful neglect under the Act offer new means of adult protection that may be of benefit to people with dementia. The full implementation of this Act in late 2007 has provided a unique opportunity to explore the early operation of the Act and its incorporation into practice and service cultures.

Rationale for the study

Implemented in 2007, the Mental Capacity Act (2005) has a number of implications for the practice and governance of research, most of which reflect existing good research practice. The specific implications for the responsibilities of local authority social care research governance procedures are given here. More general issues for research involving people who lack capacity are given in the Mental Capacity Act Code of Practice.⁴⁴⁶

Section 1 of the MCA establishes some basic principles: that a person must be assumed to have capacity unless it is established that he lacks capacity; that a person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success; that a person is not to be treated as unable to make a decision merely because he makes an unwise decision; that an act done, or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his best interests; that before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action.²⁴⁹ (Please note that 'he' also refers to 'she'.)

Someone is thought to lack capacity because of 'impairment or particular problems with the functioning of the mind or brain' (Section 2 Sub section 1). A person is thought to be unable to make specific decisions if he or she is unable:

- to understand the information relevant to the decision
- to retain that information
- to use or weigh that information as part of the process of making the decision, or
- to communicate his decision (whether by talking, using sign language or any other means) (Section 3 sub section 1).

However, if a person can understand information with appropriate explanations they are seen as capable of making that decision. Further, a person's inability to recall information for long periods does not make them incapable under the MCA.

The MCA requires that decisions taken on behalf of people who are deemed to lack capacity are taken explicitly in their best interests. Such decisions should be made after considering all relevant features and not simply on the person's age, appearance, condition(s) or known behaviour patterns. In particular, those making such decisions should take into account views expressed when the person did have capacity and the possibility he or she might regain capacity in the future.

A person judged to be unable to make decisions or consent under the MCA should be involved as much as possible in making choices and their known or suspected feelings and beliefs need to be taken into account in making any decisions on their behalf. Those acting for someone deemed not to be capable under the MCA should also consult any individual named by the person to consult on such matters and the person's carers (unpaid or paid). Such individuals include someone granted lasting powers of attorney by the person or a deputy appointed by the Court of Protection to manage his or her affairs (i.e. welfare).

In addition to these requirements, the individual making the decision must reasonably believe the course of action is in the best interests of the incapable person.

Study aim and research approach

This study aims to:

- identify the implementation issues arising from the introduction of the MCA in the services and practices of staff working with people with dementia and their carers over a 5-year period
- explore and make recommendations about continued professional development programmes around the MCA for staff and their links to adult safeguarding training and practice.

There are five main research questions:

1. In 2007 what challenges face staff when they come across issues of mental capacity in their practice with people with dementia?
2. What are the expectations of professionals working with people with dementia about the MCA?
3. What are the expectations of older people and carers about the MCA?
4. What is revealed by a study of professional records about practitioners' work in passing information about the MCA to people with dementia and their carers and how does this change over the period of 5 years?
5. What links between the MCA and adult protection arise in practice and is the MCA assisting the safeguarding of people with dementia?

This study has two main phases. Phase 1 involves an audit of staff perceptions of issues arising in decision-making and assessment of capacity among people with dementia, collection of data about training received on the MCA and information provided. Phase 2 will build on this audit to continue to engage with staff about their work in assessing capacity and implementing the provisions of the MCA, will undertake a review of case records, and will seek information from staff and people with dementia and carers about their contact with professionals over issues of mental capacity and decisions about care and treatment.

The results from Phase 1 will thus be used to develop tools for data collection about advice and recommendations (Phase 2). Details of Phase 2 will be submitted for peer and ethical review.

The development of this protocol has been informed by the main EVIDEM advisory group and the EVIDEM-MCA study advisory group, which involve people with experience of using services, carers, practitioners, advocates and managers. The latter has commented in particular on the draft interview schedule and the proposed list of participants.

Phase 1

Methodology

Qualitative research methodology, using individual in-depth interviews will be used over time to obtain a range of perspectives from practitioners working with people with dementia and carers. Interviews will be conducted at baseline and follow-up will be conducted 12–18 months after baseline interviews.

Practitioner sample and recruitment

Participants will be recruited through contact with employers. Interviews will be semi-structured and will start through an audit of training and experiences in the management of issues surrounding decision-making and mental capacity. Those interviewed will also be asked about adult protection

connections with the MCA. Interviews with the new IMCA will explore the nature of these roles in the Trust area and their expectations about the size and type of work with people with dementia as the service becomes established.

These first interviews will provide a baseline for the main interviews in 2009, 2010 and 2011 as participants will be asked if we can return to them in future years as part of the study. The interviews will be semi-structured.

The interviews will target specific individuals in specific settings in North London as being likely to have particularly pivotal experiences:

- community-based mental health nurses whose practice involves the day to day support of carers of people with dementia (Admiral Nurses, $n = 15$)
- adult protection staff ($n = 10$)
- medical staff with experience of clinical work with people with dementia at times of transition ($n = 6$)
- carers, former and current, of people with dementia who have volunteered to assist dementia related studies through the voluntary sector ($n = 15$)
- senior social workers/approved social workers/care managers working with people with dementia at times of transition or change in care packages ($n = 20$)
- voluntary sector staff supporting people with dementia and carers ($n = 30$) (Age Concern, Alzheimer Society and Carers Groups)
- independent mental capacity advocates (IMCAs) ($n = 5$)
- care home staff, ranging from managers and deputies ($n = 10$) to care assistants ($n = 15$)
- home care staff ($n = 15$)
- older people attending a science interest group; a multicultural social group and an advocacy group (a set of groups chosen for their diversity of memberships) ($n = 30$).

Staff from a range of agencies will be invited to participate as well as a small number of carers and older people (Phase 2 will be the opportunity to focus on the research questions with people using services for support with dementia or caregiving). Key agencies will include the local authorities, independent sector providers of health and social care services, and support groups for older people and people with dementia and their carers. The community and voluntary sector have been interested in this area for a long time⁴⁴⁷ and Phase 1 will include interviews with groups that advise older people as well as older people.

Data collection and analysis

Data will be gathered through individual interviews (face to face or by telephone) using a semi-structured interview schedule to ensure key themes are explored. Interviews will focus on the training practitioners had, their experience of the Act and their expectations of it as it was implemented. An attempt to obtain case examples will be made. Interviews will be taped, with permission, transcribed and the tapes deleted and telephone interviews will be recorded in note form. Each transcription will only be known by an identifying number not the person's name and all items that might identify the informant, such as names or care homes, will be made anonymous. Data will be coded using the Framework qualitative method of data analysis^{261,262} to draw out issues, concepts and themes. Data analysis will be an iterative process of identifying, organising, refining and re-organising the data into themes and sub-themes to describe the key elements of practice, including describing similarities and differences in training, knowledge and confidence. Background literature will be used to establish consistencies and inconsistencies between the reports of knowledge and practice and to identify the general issues and research questions raised by the data.

Ethical considerations

People will be approached following contact with their employer. This person would explain about the research and pass on an information leaflet which has been adapted to provide key points in straight forward language. After consent to approach the person has been gained the researcher will repeat the explanations and check consent at that point in time. A consent form for signing will be offered, although if the informant is unwilling to sign this will not be pursued and verbal consent will be noted. The researcher will thank the person for their time and involvement and offer to send them a summary of the study's findings and to leave a short leaflet of information sources about the MCA.

All participants will be assured of anonymity and confidentiality in the transcription, analysis and reporting of their interview. Any direct quotations used in the report will be non-attributable.

Approximate timescale

Development of topic guide – Winter 2007

Phase 1 baseline interviews – Spring to Winter 2008

Analysis and writing up of baseline interviews – Spring 2009

Concurrent Phase 1 follow-up interviews – Spring to Winter 2009

Analysis and writing up of Phase 1 follow-up interviews – Spring 2010 and ongoing

Feedback to participants – ongoing according to their convenience

Reports and dissemination

The findings will be written up as a brief report for circulation to participants. A full report will be used as the basis for papers and articles to be submitted to professional journals and local and national voluntary organisations' newsletters. An abstract will be submitted for presentation at a service users' and professional conference, such as the Dementia Congress.

Phase 2

Methodology

This study adopts a longitudinal qualitative, exploratory approach and people with dementia and carers will be interviewed at three or four time points over the course of 2 years. Issues explored will include day-to-day decision-making issues, whether plans and decisions have changed, whether certain individuals or groups have been particularly helpful and to identify whether the MCA 2005 has been helpful or useful in the formalising of these plans and decisions. We are aware that individuals and their carers may choose not to continue for the full duration of the study, and there may be people who die through the course of the study. However, following people with dementia and their carers prospectively will give a more accurate picture of their experiences, as well as facilitate identification of when assistance might have been most beneficial.

Sample and recruitment of people with dementia and carers

This study mainly includes interviews with people with dementia and their family carers. In a small number of cases, professionals involved in care will be approached with permission of the person with dementia and carer. The research team is working closely with local specialist agencies, such as the Alzheimer's Society and other carers groups in order to recruit people with dementia and carers who will be willing to speak to us. The moderator or the organiser at each of these groups will approach suitable participants and inform them of the research study. Only after both the person with dementia and the carer consent to

being approached by the research team will contact details be passed to the research team. A researcher will arrange to meet both of them at a mutually convenient time and location.

In accordance with the principles of the MCA, people with dementia will not be thought to lack capacity and everyone referred for the study will be approached to participate. The procedure for establishing a person's ability to decide whether or not they want to participate will proceed in accordance with the guidance for the Mental Capacity Act 2005; this will include the following four steps:

1. The Information Sheet will be explained to the person with dementia by the researcher, with any necessary assistance from the carer.
2. The ability to retain the information will be determined by asking the person with dementia to repeat to the researcher the salient points of the Information Sheet, namely what participation will involve, that it is entirely voluntary and that follow-up interviews may be conducted.
3. The researcher will ask the person with dementia whether they are happy with taking part, followed by querying the reason for this; this will again determine that they recognise that participation is voluntary.
4. Finally, all participants will be asked to sign the Consent Form as the means to communicate their decision. If they are unable to sign the form due to any other physical or cognitive problems, their relative or carer will be approached to sign for them, after obtaining verbal assent from the person with dementia. Any sign (verbally or in body language) that the individual is not happy about taking part or continuing to take part in the research will be interpreted as withholding consent, or a desire to withdraw. The researcher will end the conversation, thanking the person for their time and involvement. The researcher will check throughout the discussion that the participant is willing to continue and cease if the person indicates they wish the discussion to end.

Carers will also be asked to participate in the interview. They will be provided with an Information Sheet and the study explained to them by the researcher. Carers willing to participate will be interviewed either before or after the interview with their relative with dementia, depending on their preference. Consent will be obtained from carers prior to interviews and the same procedure for obtaining consent will be followed. However, we are not expecting carers to lack capacity. In total, we are hoping to interview 10 people with dementia and 10 carers and we estimate that moderators of groups that are involved in working with this client group may need to approach around 15 to 20 people for this.

We will also ask people with dementia and carers if it possible for us to speak to their wider social and professional network, such as friends, lawyers, bank managers, in order to obtain a more holistic picture of the role of external sources of support in the making of plans and decisions by people with dementia and carers. If both parties are willing for this contact to be initiated, we will ask for relevant contact details and they will be approached and invited to take part in the study. An Invitation Letter, an Information Sheet and a Consent Form will be sent to all such parties. Similar procedures for obtaining consent will be followed. Interview with this group will be conducted depending on the professional or social role they have played in the life of the person with dementia and carer, based on the anecdotal information supplied by them.

At each subsequent contact, consent to participate will be again obtained, following the same procedure. At subsequent contacts over the 2 years, the person with dementia may have lost the capacity to make a decision to consent i.e. understand information about the decision to be made, retain that information in their mind, use or weigh that information as part of the decision-making process, or communicate their decision (by talking, using sign language or any other means). In these instances, these will be excluded from the study and the researcher will conduct the interview with carer. Consent will be obtained from them prior to conducting the interview. Once again, we are not expecting carers to lack capacity.

Data collection

Making plans and decisions for the future is a sensitive, personal topic for people with dementia as well as carers and supporters. All interviews will be conducted by empathic researchers aware of the potential problematic nature of the issues being discussed and with experience of working with both groups of participants. Interviewers will use language understandable and acceptable to the interviewee. Should an individual become distressed during the interview, the interviewer will pause, offer sympathy and check whether the person wishes to discontinue the interview. All interviewers carry relevant contact information on key support agencies to leave with participants. All participants will be reassured of confidentiality and anonymity in the transcription, analysis and reporting of interviews. Any direct quotations used in the report will be non-attributable.

Participants will be made aware that if any information is shared that suggests that a vulnerable older adult is suffering neglect or abuse then the researcher has a responsibility to share that information with the service manager (in case of abuse or neglect from a service provider) or in the case of individuals, gain their consent to share that information with the named Local Authority Officer for safeguarding adults. In extreme cases, where a crime appears to be suspected, then the researcher will discuss with the Principal Investigator or call the police.

Data analysis

Data will be coded using the Framework Analysis method (Pope *et al.*, 2000;²⁶² Ritchie and Spencer, 1993²⁶¹) to draw out issues, concepts and themes. Data analysis will be an iterative process of identifying, organising, refining and re-organising the data into themes and sub-themes to describe the key elements of practice, including day to day support, decision-making and formal and informal sources of support and information with formalising plans. We will use NVivo™, a qualitative data analysis software package that can manage pooled data. The trustworthiness of the data and analysis will be framed in terms of its credibility to others with experience of the topic, transferability to other settings, dependability (depth of description of methods, peer analysis of data, third party evaluation of data gathering) and if possible, confirmability (by independent review of the data). The advisory group (consisting of professionals, carers and people with dementia) will also be consulted during this process in order to refine developing codes. Data will be anonymised before presenting or discussing with any member outside the research team.

Approximate timescale

This project is contracted to end in September 2012. The following are the timescales that have been generated for this phase (Phase 2) of the study:

Development of Phase 2 topic guide – Spring 2010.

Phase 2 baseline interviews – Spring to Winter 2010.

Concurrent Phase 2 follow-up interviews – Winter 2010 to Summer 2011.

Analysis and writing up of Phase 2 interviews – Winter 2011 and ongoing.

Feedback to participants – from Winter 2011 onwards.

Report writing – Spring 2012.

Completion of project: September 2012.

Reports and dissemination

The study will be disseminated in five main ways:

1. A brief report presenting the salient findings in an easy-to-read style will be generated and circulated to participants.
2. A full report to the study funders.
3. This report will serve as the basis for papers and articles which will be submitted to professional journals and local and national voluntary organisations' newsletters.
4. Abstracts will be regularly submitted for presentation at service users' and professionals conferences, such as the Dementia Congress, British Society of Gerontology Conference and Alzheimer's Disease International Conference.
5. The groups and moderators who have helped us with recruitment will be offered presentation days when the researcher will go down and present the study findings either to volunteers and staff who work there or to clients at these centres.

Appendix 63 Chapter 5: Details of the four phases of study design

Phase 1 This phase explored the needs, wishes, experiences and challenges facing ‘well’ older people’ (with no reported suspicions of declining mental capacity or dementia) many of whom have little or no contact with health or social care services. The MCA potentially affects this group, as it does us all, by enabling a person to set out their choices, and for these to be respected even if decision-making capacity eventually deteriorates. By setting up a LPA, for example, people may nominate trusted family member(s) (or others) to make decisions on their behalf should they lose the capacity to do so themselves. Our research questions were:

1. RQ1: How do ‘well’ older people conceptualise and consider future care needs? How do they plan for their future within the remit of the MCA?
2. RQ2: What are the knowledge, views, experiences and expectations of the MCA among staff working with ‘well’ older people living in the community who may be interested in making plans for their futures?

We conducted semi-structured qualitative interviews with a diverse population of ‘well’ older people and with information and advice staff working in local Age Concern (now Age UK) offices to answer these research questions.

Phase 2 This phase investigated the needs and experiences of people who had recently been diagnosed with dementia (and their carers) in order to explore their views of short- and longer-term planning. Although decision-making capacity is likely to not be severely impaired in this group, the MCA offers options for planning in such circumstances that may seem more personally relevant. We also wanted to explore the experiences and attitudes of people newly diagnosed with dementia and the practitioners who support them about decision-making. We sought to understand the possible impact of the MCA on everyday decision-making for people living in the community (an under-researched area compared with decision-making at end of life or when major medical options are under consideration). Research questions for Phase 2 were:

1. RQ3: What are the knowledge, views, experiences and expectations of the MCA among staff supporting people in the early stages of dementia? Has this changed over time and how?
2. RQ4: What advice, information and support are available about decision-making after receiving a diagnosis?
3. RQ5: What framework, if any, does the MCA provide people with dementia and carers living in their own homes who make decisions on an everyday basis?

We conducted semi-structured qualitative interviews with four groups: (1) people with dementia and carers; (2) staff at Alzheimer’s Society branches; (3) staff at Carers’ Centres; and (4) SACs, often at the forefront of implementing the MCA.

Phase 3 This phase investigated the needs and experiences of those whose capacity may be impaired, and who as a result of this, need help with decision-making and possibly safeguarding against abuse. As the MCA incorporates provisions for this group, we wanted to explore the training, experiences, attitudes and expectations of practitioners who work with people with dementia and their carers. Research questions for Phase 3 were:

1. RQ6: What are the knowledge, views, experiences and expectations of the MCA among staff supporting people in the later stages of dementia, when capacity may be impaired? Has this changed over time and how?

2. RQ7: What advice, information and support are available to those who are caring for relatives with dementia whose capacity is impaired?
3. RQ8: What arrangements can be put in place so that people with dementia with and without capacity are safeguarded against abuse? Does the MCA help?

Semi-structured qualitative interviews were carried out with four groups: (1) social workers, (2) Admiral Nurses (specialist dementia nurses), (3) people with dementia and carers living in the community, and (4) SACs. An online survey of Alzheimer's Society staff was also conducted through the Society.

We further undertook specific consultations about an issue that emerged across many of the interviews from this and earlier phases; practitioners' knowledge of and practice experience with the two new offences of wilful neglect and ill-treatment created by the MCA. Our first consultation event included practitioners from NHS, social care and criminal justice backgrounds on 10 March 2011. Our second sought the views of older people about what type of information they would find helpful, without being alarmist. We met with this group on 15 November 2011 and recorded this discussion. Following these consultations and analysis of the interview data we produced a preliminary paper for the *Journal of Dementia Care* (Manthorpe and Samsi, 2012)⁴⁴⁸ and will be writing another paper for an academic journal. We will also be liaising with the SCIE to encourage them to host a version of these on their website.

Phase 4 This final phase of the research study explored the potential relevance of the MCA for people with severe dementia who may be at the end of life. Capacity at this stage is likely to be consistently impaired, proxy decision-making is likely to be needed on a regular basis, and advance care plans may be in place. We sought to elicit the attitudes of staff working in care homes about the practice of decision-making on behalf of or by their residents, and the possible impacts of the MCA on their work more generally. The research questions for this phase were:

1. RQ9: What are the knowledge, views, experiences and expectations of the MCA among staff who work with people with dementia at the end of their lives and their carers regarding advance care plans or other similar plans?
2. RQ10: How does MCA proxy decision-making work in practice?

Semi-structured confidential interviews were conducted with staff in a variety of care homes (small single owner to part of a large chain of care homes) at two time points to ascertain their training, experiences and attitudes towards the MCA.

Nested within Phase 4 was a substudy of an NHS acute hospital trust where several untoward incidents involving patients lacking capacity had indicated that use and knowledge of the MCA were partial among the hospital staff. This substudy engaged with the author of an audit commissioned by the hospital trust to produce a report with lessons for the wider NHS and health-care providers that was made available to the wider public.²⁷⁴

Appendix 64 Chapter 5: Semi-structured interview schedules

1. Interviews for Practitioners' Audit Time 1.
2. Interviews for Practitioners' Audit Time 2.
3. Interviews with 'well' older people.
4. Interviews with people with dementia.
5. Interviews with carers.

EVIDEM – Mental Capacity Act 2005

Interviews for Practitioners' Audit Time 1

Revised according to practitioner group being interviewed

Introductions

- Explain purpose of this audit, no right or wrong answers but interest in hearing about practitioners' experiences. Explain part of EVIDEM (info provided).
- Assurances of confidentiality (draw attention to Consent Form).
- Seek permission to tape.

Brief details of interviewee

- Job title.
- Role (key activities).
- Qualifications (including registrations/NVQ).
- Number of years since qualified.
- Place of work (employer/department/team).
- Time in present post.

Section 1: training

1. Have you heard of the MCA 2005?
2. If yes, please tell me what you have heard/if you have been involved in implementation.
3. Have you had any training on the Act? If yes, please outline when, where and who supplied it, content.
4. Was this helpful in terms of information? If yes, what in particular? – If no, why not?
5. Has the training proved useful in practice? If yes, please give some examples of how, if no, why do you think this is? e.g. prompts, not my line of work, no one has heard of it . . .
6. Have you explained the MCA to anyone (colleagues or patients/carers)? If yes please outline, with some examples.
7. Have you delivered training yourself? If yes please outline when, where, to whom, how did you do this?
8. Specifically, how confident are you in your own knowledge of the Act, say, if 0 is not at all confident and 5 is very confident, where would you place yourself?
9. And where do you think you should be (0–5)?

Section 2: roles and activity

10. Is the MCA affecting your work? Please outline if yes, and explain which areas or no and why?
11. Where would you seek advice from about mental capacity/making decisions matters if you had any problems?
12. Is there any new paperwork/guidance in place? If yes, where and are you using it?
13. In your opinion, do you think that people with suspected or early dementia will use the MCA to make plans for their future?
14. Is discussion about this something that you might get involved in, in your work?
 - i. If yes, please outline the possible areas of MCA that are raised in your work e.g. advance decisions about treatment, lasting powers of attorney, assessment of capacity.
 - ii. If no, where do you advise people with early/suspected dementia and their families to go if they have queries or want advice? Would this be within your team/organisation/or elsewhere?
15. What do you think might be the advantages of the MCA? (prompt to whom, people with dementia, carers, professionals)
16. And what about any disadvantages (and to whom, why)?

Section 3: looking ahead

17. Have you any predictions about the MCA? (e.g. lots of interest, no real help)
18. Do you think it will be useful in adult protection/safeguarding people with dementia? If yes, please explain. If no, why not?
19. Just briefly, and this is not an exam, but we are trying to find out how familiar these new terms are – have you heard of the following:
 - i. Independent Mental Capacity Advocates (IMCAs) – if yes, what do they do?
 - ii. Lasting Powers of Attorney – if yes, what can the LPAs do?
 - iii. Deprivation of Liberty or Bournewood safeguards?
 - iv. The new offences of mistreatment and wilful neglect under the MCA?
 - v. And how would you define 'capacity'?

Section 4: personal perspectives

20. Would you say you have had experiences of looking after someone with dementia in your own family or network, e.g. partner/friend? Could you briefly outline if you think this has affected any of the matters we have been talking about?
21. Finally, have you been thinking of making any plans yourself or for a person you know (e.g. discussion with parents or partner) about this area? If yes, please outline.

End of interview

Demographic details

- Male/female
- Age
- Are you a carer? Or recent experience?

- Ethnicity (Census categories):
Ethnic group
Choose *ONE* from A to E, then indicate cultural background.
 - A. *White* Options of British; Irish or any other White background (*please describe*).
 - B. *Mixed* Options of White and Black Caribbean; White and Black African; White and Asian or any other Mixed background (*please describe*).
 - C. *Asian or Asian British* Options of Indian; Pakistani; Bangladeshi; any other Asian background (*please describe*).
 - D. *Black or Black British* Options of Caribbean; African; any other Black background (*please describe*).
 - E. *Chinese or other ethnic group* Options of Chinese; any other (*please describe*).

Conclusion

Thanks and assurances of anonymity

Ask permission to get back in touch over the course of the project to ask for updates/Best method of making contact again? [phone number]

Offer to leave information sheet about MCA training materials and contacts

Interviews for Practitioners' Audit Time 2

Revised according to practitioner group being interviewed

Thank participant for allowing us to talk to them last year about the MCA. We interviewed over a hundred practitioners and have found it really useful to learn what their initial experiences and expectations were. We'd like to ask you a few (five) follow-up questions – is that convenient?

1. When we talked last time, you said that X was happening – is this still the case? (e.g. revised policy/procedures)
2. What are your main experiences of the MCA – now it's bedded in?
3. Last time you had experience of/did not have experience of . . .
 - i. Has anything changed? If yes, what?
4. Last time you predicted . . .
 - i. Were you right?
 - ii. What's happened since?
5. In what ways has the Act changed your practice or that of staff team colleagues – if at all? Is there anything you would like to add?
6. Any developments/experiences around the new offences under the Act – wilful neglect or ill-treatment?
7. Any other observations around the links between adult safeguarding and the MCA?
8. Have you made any plans yourself or for your family?

Many thanks for your help – we would be happy to send you a copy of our findings. Would you like this?

Interviews with 'well' older people

1. Please can you tell me if you have made any plans for managing your money and so on for now and in the future and what these are?
 - i. What about a will/any advanced decisions, a LPA.
 - ii. Have you told people any wishes you might have?
 - iii. Why is it that you have this (all aspects) (Why not?)

2. What about any plans for your future care if you needed to be looked after?
 - i. What about where you want to live?
 - ii. Why is it that you have this (all aspects) (Why not?)

3. What about any medical plans or decisions?
4. Do you think you might think about making plans in the future (what circumstances/events?)
For example:
 - i. if you got a diagnosis of something serious
 - ii. if you felt you were having memory problems
 - iii. if your family/friends change/move
 - iv. if suggested by family and friends and so on
 - v. (Why/why not?)

5. Have any professionals talked to you about making plans? Explore if HSC or if lawyer/accountant, etc.
6. We would just like to ask if you have heard of any of the following and what they mean to you:
 - i. The Mental Capacity Act?
 - ii. LPA or Enduring Power of Attorney (EPOA)?
 - iii. Advance decisions? (sometimes termed Living Wills)

7. If you have made/will make any plans, do you think that professionals (e.g. doctors, nurses, social workers, care workers) will take any notice of them?
 - i. Why do you think this? – Do you have any experiences?

8. Have you made any decisions on behalf of other people (adults), like relatives when they are poorly, confused?
 - i. What happened here?
 - ii. Who encouraged you?
 - iii. (Why/why not?)
 - iv. How has this affected how you feel about making plans for your own future?

9. Have you ever discussed any of these issues with your friends/family?
10. If you decided to make plans or had a friend who wanted to make plans, whom do you think you would you seek advice from?
11. Is there anything we have not covered that you would like to add?

Demographic details

- Male/female
- Age
- Are you a carer? Or recent experience?
- Ethnicity (Census categories):
Ethnic group
Choose ONE from A to E, then indicate cultural background.
 - A. White Options of British; Irish or any other White background (please describe).
 - B. Mixed Options of White and Black Caribbean; White and Black African; White and Asian or any other Mixed background (please describe).
 - C. Asian or Asian British Options of Indian; Pakistani; Bangladeshi; any other Asian background (please describe).
 - D. Black or Black British Options of Caribbean; African; any other Black background (please describe).
 - E. Chinese or other ethnic group Options of Chinese; any other (please describe).

End of interview

- Permission to get back in touch over the course of the project to ask for updates.
- Best method of making contact again? [phone number]

Interviews with people with dementia

Introduction and assurance of confidentiality: explain pilot process, informed consent, seek permission to record.

1. Could you tell me what an ordinary day for you is like?

- Does anyone support or help you in any way? (Who is the main person?)
 - Establish relationship, co-residency, frequency of contact.
- What, if anything, does X (main person) help you with?
- On an average day, do you have to make a lot of decisions?
 - Explore what these are.
 - Prompts:
 - what time to get up
 - what to wear
 - paying bills
 - going shopping
 - cleaning the house.

2. Do you make all of your own decisions?

- Does anyone help you with some of them?
 - For example, banking, bills.
 - Has this always been the case?

- Do you choose who makes decisions for you?
 - Are you happy with decisions you have made recently?
 - Can you tell me about any decisions that you have been happy with?
 - Have you give away responsibility to someone else to make a decision for you that you were unhappy with?
 - Can you tell me any specific instances when you might need the help of someone to make a decision for or with you?
 - What about things like managing finances?
 - Paying bills, investments, savings.
 - What about things like your health, such as taking medicines, going to the doctor, etc.?
 - Having dental treatment, getting new glasses, hearing aids, etc.
 - What about just everyday decisions, like shopping for clothes or deciding what groceries to buy?
 - Lifestyle issues:
 - Driving and car-related items, such as car repairs.
 - Repairs and major household items/decorating.
 - Valued activities and hobbies.
 - Looking after yourself (dressing, hairdressing, toileting, washing and so on)
 - Choice about type of care.
 - What about having paid people to help around the house or to help with other things?
3. Did you have any plans about what to do in retirement?
- Did you have any wishes for retired life?
 - Like staying in this house/flat.
 - What were these?
 - Did you talk to anyone about this?
 - Have you had to change any plans recently?
4. Did you have any formal or written plans for this time or period of your life?
- Such as a will.
 - Joint bank accounts/utilities.
 - Insurance policies.
 - An enduring power of attorney or LPA.
 - Statements of wishes.
 - Advance decisions about care and treatment (sometimes called Living Wills).
 - Any other written wishes or plans?
 - When did you set these out and why?

5. Has anyone been involved in helping you make any decisions or plans?

- Family/relatives?
- Professionals?
 - Medics/nurses/etc.
 - Bank managers/solicitors/accountants/etc.
 - Alzheimer's Society/Age Concern (now Age UK)/Carers' centres, etc.
- Friends?
- How did you feel about this?
- Do you wish they had?

6. We would like to learn more about how people make everyday decisions. How do you think we might be able to do this best?

- Prompts:
 - Could you see yourself writing a diary?
 - Telephone calls at regular intervals?
 - Visiting for a talk?
 - Other?
 - How often could we contact you?
 - How can we find the times when people are 'wondering what to do', 'thinking', 'pondering'?
 - Using vignettes (think aloud around imaginary case studies).

7. Do you think there is anything we have not covered?

8. Would it be possible for us to speak to the main people involved in helping you? Such as your GP/social services person/Community Psychiatric Nurse (CPN)/Alzheimer's Society? Is there anyone you would particularly recommend?

Thank you for your time today. Offer reassurances of confidentiality and anonymity.

Interviews with carers

Introduction and assurance of confidentiality: explain pilot process, informed consent, seek permission to record.

1. Could you tell me about your role as a person supporting/looking after x.

- How did it begin?
- How long have you been involved in caregiving?
- What do you do for X?
 - Has it changed from when you first started helping him/her?
- (Flesh out relationships and carer role/responsibility).

2. Could you tell me about any decisions you make or think about together with or on behalf of X?

- Could you tell me who was involved, why they were involved, in what capacity they were involved and how they contributed.
- Expand around finance (managing money, accounts, bills, etc.).
- Law.
- Health (medical, physical, medication, dentist and so on).
- Consumer decisions, like shopping and deciding what groceries to buy.
- What about issues of everyday life, such as driving.
- What about decisions to do with care, such as toileting, washing and so on.
 - What about whether or not they need help?
- Family contact and relationships with others (family, services, etc.)
 - What works well and not so well?
 - What is comfortable for you?
 - What is troubling or tricky?
- Do you tend to give X a chance to make the decision first, even if it's not something you agree on?
 - Why/why not?

3. Could you describe a 'tricky' day or 'tricky event'?

- How do you deal with making decisions for X?

4. What guides how you make decisions for X?

- Previous discussions?
 - Can you tell me about the kinds of discussions you have.
 - Context and content of discussions.

5. Does what you do come from any plans made by X?

- Enduring power of attorney.
- LPA.
- Statements of wishes.
- Advance decisions about care and treatment (sometimes called Living Will).
- Your knowledge of X as a person.

6. Is anyone else involved (professionals, relatives, etc) in helping you making such decisions?

- Family/relatives?
- Professionals?
- Friends?

7. We would like to learn more about how people make decisions and are thinking about decisions on an every day basis, as well as major ones, over a period of time. How do you think we might be able to do this best?

- Prompts:
 - Diary format?
 - Telephone calls at regular intervals?
 - Visiting for a talk or interview?
 - Other?
 - What intervals would be best to balance the detail of everyday life and yet not being a bother?
 - How can we capture times when people are 'wondering what to do', 'thinking', 'pondering'?
 - Using vignettes (think aloud around imaginary case studies).

8. Do you think there is anything we have not covered?

Thank you for your time today. Offer reassurances of confidentiality and anonymity.

Appendix 65 Chapter 5: Five main stages in framework analysis

Familiarisation

This early stage is for the researchers to get familiarised with the data and sensitised to early themes. It encourages the research to see the individual differences inherent in transcripts that can sometimes get lost when coding begins. The process of sensitisation to these individual differences also enables the researcher to better identify within- and between-participant differences. In a few cases, the researcher felt the need to revert to the original recorded interview to get a better feel for the data. Any emergent early impressions were noted, relating to reactions to transcript/participant, how they felt as they listened to the participant, and any specifics that they wanted to remember for later. These were jotted on one side of the paper transcript.

Identifying a thematic framework

This stage of framework analysis is commonly referred to as 'coding' in other qualitative methodologies. This principally involves identifying key themes, issues or discussion points embedded in the transcript. These are delineated and assigned a 'code' or a name that best captures the essence of the theme or issue identified. In framework analysis, 'a priori issues' questions can form the basis of the themes – we therefore used the interview topic guide as a starting point for creating overarching categories and any emergent themes from transcripts were coded as responses to each question. As Pope and colleagues describe,²⁶² the outcome of this stage is a 'detailed index' of the data into 'manageable chunks for subsequent retrieval and exploration', which is what we achieved.

Example

- We were keen to ascertain the training on the MCA practitioners had been offered. We therefore labelled 'Training' as one of our a priori categories and coded (1) 'no training', (2) '1-day training course', (3) '1+ day training programme', and (4) 'MCA training as part of other activities'. We were able to identify and make inferences regarding the amount of training one participant group had had compared with another.

Indexing

Indexing refers to the process of numerically annotating transcripts in order to identify consistencies, which then go on to develop the coding framework. However, we followed this process slightly differently. All of the word codes (as opposed to numerical) that had been generated during stage 2 were listed on a separate sheet of paper. We then grouped together all codes that shared commonalities or consistencies. These clusters were given an appropriate name.

Example

- One of our interview questions referred to 'Practice experiences' – we named this as an overarching category, incorporating (1) 'intrinsic impact', (2) 'community role of X', (3) 'role of safeguarding', and (4) 'change and extension to job role' as separate codes under it.²⁶⁹

- This also helped us to identify and be mindful of individual participant differences. For example, while community nurses saw safeguarding as less of a priority in their jobs during time 1 interviews²⁵⁸ SACs talked about the significant impact of the MCA on their practice experiences.²⁶⁴

Charting

Framework analysis describes this stage as a process of rearranging the data and thematic framework to create order, not dissimilar to the iterative principle of grounded theory.⁴⁴⁹ We applied this stage as a principle for synthesising and developing our final coding framework through a process of abstraction, in order to derive all the detail from the data and ensure that we were coding elements that may have been missed with simply an a priori approach.

Example

- The question asking all participants about their personal experiences of caregiving (family caring) was asked as a final question to round off the interview. Family caring experiences were commonly reported and participants offered examples of how these had contributed to their professional understanding of dementia and caring. In relation to this, five main codes were developed: (1) 'informing the professional role', (2) 'insight into services', (3) 'professional influences on caring', (4) 'planning', and (5) 'no apparent effect of MCA'.

Mapping and interpretation

Mapping and interpreting essentially are ways of representing pictorially or graphically all of the themes and investigating how each of the themes relates to each other. This detailed exploration of the iteratively developed and revised thematic framework enabled us to gain a clearer understanding and explanation of the 'bigger picture'. For instance, we examined the association between three categories: (1) 'training', (2) '(self-reported) knowledge of the MCA', and (3) 'self-reported confidence'; and we were able to identify and offer explanations for individual discrepancies between these three categories.

Example

- In Manthorpe *et al.*²⁶⁸ we describe how some participants, with no training and limited self-reported knowledge, reported high levels of confidence in abiding by the Act. We questioned the reliability of some self-reported knowledge about the MCA, and have considered the adequacy of training now the Act is no longer 'new' and the potential for mandatory training for all staff.

Appendix 66 Chapter 5: Narrative account of findings

Universal appeal of the Mental Capacity Act

3.2.1.1. Beneficial	Practitioners across the range of professional groups felt that the MCA was beneficial as it clarified and consolidated a previously confusing legal system that had baffled older people, and sometimes practitioners. Most thought it enhanced the autonomy of people with impaired cognition, by assuming that people are able to make decisions unless proved otherwise; encouraging professionals to better consider ability to make decisions, and 'giving a voice to older people at risk' (Manager 02)
3.2.1.2. Dignity and rights protected	While recognising that individual decision-making was supported (even unwise or 'eccentric' decisions), many participants believed that the Act provided better safeguards for people who might be particularly vulnerable to neglect and abuse. Overall, the Act was seen as supporting the rights and dignity and decisions of people with dementia
3.2.1.3. Details not widespread but growing	Alongside the universal appeal of the MCA, however, it was evident that awareness of details and experience of using the Act were still not widespread, but these were steadily growing. ²⁹⁴ Those who had direct contact with people with dementia and carers said that the Act made them more aware of questions related to capacity, and one intrinsic impact was the more common practice of now routinely questioning whether a capacity assessment had been done. Understanding of the MCA was seen as increasing overall, and there appeared to be steady advances of understanding, confidence and experience when time 1 and time 2 interviews were compared

Training

3.2.2.1. Frequency and format of training offered	Training appeared to have been available to nearly all practitioners who participated in our study. However, not all had undertaken it for various reasons. There was also variability in the level and type of training each participant had received. Although some participants had undertaken in-house training, others had attended more detailed training provided by external consultants, geared towards professional HSC workers. Some training had lasted for less than an hour, or half a day, whereas others attended day-long sessions. Formats varied too, ranging from conferences, 'awareness-raising' sessions, specific to the MCA (e.g. through an employer) or as general updating (part of Continuing Professional Development)
	Most who had received training deemed it useful, providing a good overview, being informative and helpful in outlining a job-defined formalised code of working and 'crystallising what [I] do' (AN13). However, in terms of day-to-day work, some perceived minimal change and reported little benefit from training. Other accounts varied according to participants' experiences. Although some felt that senior staff were responsible for cascading the information to more junior levels, this did not seem to happen systematically, but occurred instead during staff meetings or by putting items on a notice board to convey the 'basics'. A number of junior care home workers tended to rely on paperwork and care plans to come from 'head office' and demonstrated little knowledge of the MCA. Few professionals had received training that incorporated safeguarding practice and the MCA

3.2.2.2. Challenge of translating training into practice

Training sometimes appeared to be over-didactic, with limited use of case studies and examples. High-level information was imparted at these events, which often resulted in most participants knowing about the general principles of the MCA but not its specifics. Many appeared to use guesswork when asked about specific points, suggesting that they had gleaned overviews of the MCA rather than acquired detailed understanding

Ongoing training was considered important, as these provided opportunities to share emerging challenges. A minority of practitioners across all professional groups said they had missed the training offered or had not been able to attend owing to work commitments. Two participants talked of having recently started at a particular organisation and, therefore, had missed training at their old place of work as well as at their new one

Given the high turnover of staff and frequent changes to staff and organisational structures, the need for training to be a continuous process was identified. Renewing and refreshing training at local levels could also incorporate new information and developments. Following the Act's initial implementation, there have been many changes to procedures and structures, as well as results of early evaluations and research findings, all of which could be incorporated into regular training. Use of the Mental Health Foundation's Assessment of Mental Capacity Audit Tool (AMCAT) (easily accessible and free: URL: www.amcat.org.uk/audit_your_assessment/) material could be enhanced (Mental Health Foundation 2010)⁴⁵⁰

Implementation

3.2.3.1. Quick and easy incorporation into safeguarding practices and procedures

Practitioners working in adult safeguarding were especially positive about the Act and considered that it had enhanced their everyday practice. They felt that much of their work was already guided by the principles of the MCA, but considered that the MCA had reinforced these principles. Many of these participants particularly appreciated that the MCA provided a framework for mental capacity assessments. They welcomed the focus on specific rather than global capacity (is the person able to make a specific decision and does it need to be made now?) and the provisions for planning, either by appointment of a LPA or by greater encouragement for people to make their wishes known about future care and treatment.⁴⁵¹ Over the different time points, these participants were enthusiastic in extolling the Act's potential to support defensible decision-making for professionals and carers, protecting people's rights from abuse, and achieving good outcomes for those who lacked capacity

However, all practitioners considered that it would be some time before the MCA was completely embedded in practice. Given that HSC policy and commissioning are increasingly driven by the policy of personalisation, greater clarity will be needed around challenges arising from concerns about safeguarding risks (e.g. of exploitation, abuse and neglect). We were able to witness this major change to adult social care services in the course of the study and have produced some of the first findings about the MCA and its link to personalisation and safeguarding²⁶⁷

3.2.3.2. Confidence and expertise

We explored practitioners' level of professional confidence in implementing the MCA. In order to encourage discussion and to avoid the uncertainties of language (e.g. differences between 'much', 'a little', 'somewhat'), we used a five-point scale as a means to get practitioners to state how confident they felt, where '1' was 'not confident' and '5' was 'very confident'

We noted some lack of association between confidence and knowledge. Participants who said they were very knowledgeable about the MCA did not always feel confident about implementing it. Perhaps more worryingly, those who indicated that they did not feel knowledgeable about the MCA sometimes indicated higher than expected levels of confidence. A majority of participants, however, talked of feeling confident about other sources if they needed more information

Confidence seems likely to accumulate with familiarity and experience in using the Act. Confidence was also related to whether practitioners felt able to access advice and expertise locally

There was limited confidence about conducting assessments of capacity, with some practitioners stating their belief that only medical professionals were able to 'verify' whether or not a client with dementia had capacity. Although most practitioners were aware in principle that capacity had to be understood and assessed by the person closest to the specific decision, many suggested that, for a formal report of capacity, a medical practitioner was needed. Others held the erroneous view that next-of-kin status granted family members the rights to make decisions for their relatives

3.2.3.3. Risk of information 'merry-go-round'

An information 'merry-go-round' was evident, by which practitioners appeared to be signposting queries on to other practitioners or agencies who then passed these queries back to them in a potential loop of confusion. There was not always a central point of expertise locally that could deal with queries, signpost appropriately and answer questions that practitioners encountered. Where this was available, it was highly valued

An additional challenge was a lack of clarity about the specific content of information and advice and consequently the roles of advice and information agencies. This also led in part to the information 'merry go-round' when staff in agencies that provided information were approached for advice that they did not feel equipped to supply. For example, making a LPA involves completing a lengthy form with which some professionals said they did not feel able to assist²⁶⁹

Although some third-sector groups were keen to describe themselves as safeguarding agents and champions of older people, they often perceived their roles as gatekeepers to more detailed sources of information and routes to intervention, rather than providing these themselves. For instance, groups that traditionally provided information and advice, such as Age Concern (now Age UK), felt rightly not able to respond to specialist legal queries falling outside their competence²⁵⁸

Signposting to other services was becoming an expanding task. Although many information-providing agencies were responding to basic enquiries from older people, as well as those closely involved with decision-making, and encouraging drawing up of LPAs, they also suggested other sources of help. When responding to enquiries related to a dementia, many of those providing basic information and advice turned to health practitioners or solicitors as specialists, sometimes to supplement their own in-house national resources, such as telephone helplines. This suggests that sources of information and advice were not clearly mapped at local levels. There is the potential for people to be passed on from agency to agency. Commissioners may wish to satisfy themselves that the local map of information and advice has linear pathways and is not circular

3.2.3.4. MCA expertise at all levels unlikely, but central expertise required

A striking conclusion from interviews held with staff at all levels in care homes was the need for a single authoritative lead on the MCA. Most junior care workers (generally termed 'care assistants') and some senior care workers had rudimentary, if any, understanding of the Act and indicated that they would rely on care home managers or senior staff to identify or answer any complex questions.²⁶⁸ Although some care home managers were well informed, others indicated that they too had fairly rudimentary understanding of the Act themselves and would turn to other specialist sources if the need arose. However, there was little consistency in nominations made. They included the home's regional manager or other headquarter's staff (in homes that were part of large chains), local social workers, community mental health nurses, the local mental health team, an IMCA helpline, Age Concern (now Age UK) (local voluntary sector) advocates, a GP and solicitors. Each manager's choices were different and a minority were uncertain of any source of authority, advice or expertise. For example, some managers emphasised the role of the family in making decisions, whereas others emphasised the role of social workers or mental health professionals

There appears to be scope for the principles of the Act to be more explicit in everyday practice and record keeping in care homes. Although in most homes participating in this study, there was anecdotal evidence of this (i.e. making best-interests decisions based on a resident's past preferences), there was little formal record of these procedures which could stand up to legal challenge or regulatory scrutiny. Moreover, some care home staff themselves confessed to a lack of confidence in dealing with more complex cases when quick decisions may need to be made, e.g. about whether a resident lacking capacity could lawfully be moved from a care home to another setting for treatment or assessment or who could consent to treatment. By time 2 some homes had clarified these matters, often through the making of advance care plans or similar decisions being recorded on a person's move to the care home. Nonetheless, at time 2 there were still care home staff who were unfamiliar with the MCA, largely because they were new in post and new to the work. Some were not familiar with English law and their level of English was basic

Everyday decision-making

3.2.4.1. Everyday negotiation

Analysis revealed a significant theme around the number of everyday decisions people with dementia and carers who lived together made jointly, including what to do, what to wear, what to eat and what holidays to plan. Both people with dementia and carers talked of the potential of making decisions as important to individual autonomy. Most, however, acknowledged that, since the diagnosis of dementia, things had changed and almost half the participants with dementia said they now found it difficult to make decisions

Many carers reported trying to actively involve their relative with dementia in decision-making; some provided them with cues or reduced possible stress, for example, by offering fewer options. Some carers revealed that, over time, shared decision-making had given way to them making decisions unilaterally. While some tried to involve their relative with dementia in general or domestic decisions, four carers described deliberately not doing so in order to protect or 'save' them from the stress of minor decision-making, in order to better participate in more important decisions. Spousal carers were more likely to make joint decisions through the interchange of everyday conversation

	<p>Such changes can be seen as part of a life course of changes to family decision-making and so need to be contextualised within biographies and gendered relationships. For example, retirement appeared to have been the point at which many participants' lifestyles and routines had changed and when joint domestic decision-making often seemed to have started. One man with dementia talked of how, when he was working, he left decision-making about meals to his wife, but since retirement, they had made such decisions together. Similarly, deciding how to spend the day was a joint enterprise for some, another change since retirement</p>
<p>3.2.4.2. Past preferences and best-interest decisions key to making proxy decisions</p>	<p>Many carers were making decisions on behalf of their relative with dementia without reference to the MCA but in line with its values of acting in a person's best interests and in the least restrictive way. Although most recognised the reasons for having to make such decisions, there were some expressions of frustration when carers felt responsible, strained and confused. Mostly they used their knowledge of their relative's past habits, preferences, likes and dislikes to help them make decisions. In some cases, however, they confessed to resorting to doing what suited them best. For instance, one carer talked of his wife with dementia never liked having sugar in her tea, although lately this had changed. However, when he ran out of sugar, he reasoned that his wife would not mind as it was in keeping with her past preferences</p>
<p>3.2.4.3. Weighing best-interest decisions</p>	<p>The principle of making decisions in the PWD's best interests appeared to underlie many carers' interactions with their relatives with dementia, albeit in different ways. There appeared to be a divide between two groups of carers. One group described their relative's well-being or best interests being at the heart of decisions that they made on their behalf. A second group described making decisions in terms of what might be beneficial to them both. In many cases, this constituted what was least stressful to carers. Carers in this group felt that maintaining their health was important in being able to support their relative with dementia and, therefore, they adopted the most pragmatic solution they judged necessary for the long term</p>
<p>3.2.4.4. Inequalities in access to information</p>	<p>We asked participants whom they had approached, if anyone, for information and advice when facing major or difficult decisions. Their responses indicated that such decisions rarely occurred in isolation. A range of support was accessed, from friends and family to solicitors and members of support groups. Many of the participants had family members upon whom they felt they could rely, relatives who were sufficiently knowledgeable and whom they felt had their best interests at heart. In most cases, this 'family' was adult children; in one case, it was a sister and her family. Adult children were more likely to use the internet and seek other sources of information, and many of our participants felt happy to leave any complex decisions to their children whom they felt were able to access advice and expertise. Although there were no apparent gender differences, adult daughters were more often involved in supporting day-to-day practicalities, whereas adult sons were involved in more long-term care planning. However, from such a small number of participants, it would be premature to make any generalisations. What emerges is a lack of evidence about effective support for older people who have no social support networks that they trust or who are not able to access local support services. This is an area in which research may have much to offer practitioners about how to meet specific needs and how to sustain resourcefulness</p>

Long-term planning

3.2.5.1. Planning influenced by personal factors

A significant theme that emerged was that participants had individual and personal approaches to planning.²⁷² A range of predisposing factors was identified, including disposition, belief systems and spirituality, participants' living situations, the current (2010–11) uncertain state of the economy, and their confidence and trust in medical practitioners. Some participants declared their personal tendencies and preferences were to avoid planning for the future. They described beliefs such as 'living for today', enjoy life to the maximum, not thinking much about the future, and not letting worries and problems affect their life. Making detailed plans for the future had, therefore, not featured in their lives prior to dementia or old age

Some participants discussed this disinclination in the context of spiritual beliefs. Illustrating this, apart from funeral arrangements and despite being concerned about finances, one older person had not drawn up a will nor any made health or social care plans. She did not feel that it was appropriate for her to interfere in 'God's work'

A significant subtheme was identified from discussions with people living alone and with no relatives. This group spoke about being unable to appoint anyone to hold a LPA or to ensure their wishes and preferences were carried out because they had no direct or even distant next of kin. They highlighted that their friends, being elderly themselves, were compromised in their ability to act as effective attorneys. This particular group indicated the strongest intentions to plan but it was difficult for some to find members of their social networks who could take on the responsibility

A small group of participants said that they did not have any finances or valuable personal effects to leave their children and hence viewed planning as irrelevant to their situation. They conceptualised plans in terms of financial transactions or for functions of inheritance and appeared to find it difficult to think about planning for health and personal welfare decisions as matters that might affect them

3.2.5.2. Financial and funeral plans commons, less so HSC plans

Of the arrangements that had been made, the most common were financial. Making a will was frequently mentioned, followed by granting EPOA (the earlier Power that applied to financial decisions alone and not health and welfare decisions), setting up joint bank accounts, taking out health insurance, and consolidating investments and bank accounts. A tendency to plan for financial security did not necessarily mean that individuals also planned for other aspects of their future. For example, one participant talked of her household insurance, health insurance, income protection plans and financial arrangements. Despite having made difficult decisions for her late mother through final stages of cancer, this participant had not considered making plans of this nature for herself although she expressed interest in these when the subject was raised during the interview

Funeral arrangements were also discussed, ranging from having a separate bank account for funeral costs, to more elaborately planned procedures, including hymns participants would like to have sung at the ceremony

Housing and residential care appeared to be significant discussion points (rather than explicit planning measures) for participants. Most had spoken to partners, family members and close friends about these subjects. Some described how much their home meant to them emotionally and that they hoped to stay in it until the end; others spoke of their willingness to move into residential care in order to relieve their children of caring responsibilities. It appeared, however, that few were aware of the complexities of the social care system in England and did not understand how they could state their preferences or how the MCA could support these

There was an absence of HSC plans in the formats permitted under the MCA (Advance Decisions and LPAs) and most participants admitted not having thought about these. They seemed interested in the provisions of the MCA when they were introduced during the interviews and asked for information afterwards. This was in contrast with the many financial arrangements that they had already put in place around joint accounts, direct debit for bills, Powers of Attorney, and wills

3.2.5.3. Limited support with knowing where to turn

Most participants did not know where to turn if they were interested in taking forward plans for the future. The interviews conceptualised possible serious debilitating conditions as a way to start these exploratory discussions about planning. Participants were asked about their familiarity with and understanding of key terms and phrases, such as the MCA, LPAs and Living Wills (the legal term being Advance Decisions but this term was not widely understood). None of the participants had heard of the MCA specifically, despite some understanding that principles of the Act were respected in health and care settings. Some appeared to have an understanding of LPAs, knowing that this involved appointment of a trusted person to manage one's affairs when one is unable to do so. However, few appeared aware of the change in terms since the introduction of the Act and assumed that the EPOA meant the same as the LPA. Living Wills/Advance Decisions were rarely understood, and, in some cases, associated with what participants called 'clinics in Switzerland' and euthanasia. Many participants assumed that Living Wills could not be honoured by medical professionals because assisted suicide is illegal in the UK

Participants on the whole appeared unsure where to turn for support with planning. Financial advice appeared easier to come by and participants knew where this could be accessed. Having reliable financial advisers to give sound advice was described positively and participants appeared reassured by them

The role of the GP appeared to be crucial. Some participants were unsure if they could rely on their GP, reporting not always seeing the same GP and not feeling particularly supported by the primary health-care team. Others felt they could rely on their GP for advice about making plans and that these would be honoured. These were confident in the GP's information and advice regarding Living Wills/Advance Decisions. When asked whether any local information and advice agencies would be helpful, white British participants said that they were likely to visit local branches of Age Concern (now Age UK), whereas black Caribbean participants appeared reluctant to share personal information with these voluntary agencies. The latter group felt that if they wanted to make plans they were more likely to consult family members and friends who would direct them to appropriate agencies and people rather than talking to strangers. These findings are indicative but may suggest that professionals should explore people's confidence in voluntary sector groups as sources of advice when advising people to contact them

One reason for making plans was the onset of a debilitating illness. The current high profile of dementia in the media may explain why this condition was generally known about by almost all participants. Dementia was discussed as one of these conditions, when participants speculated that there might be little chance of recovery and the prospect of losing capacity to make decisions was heightened

Safeguarding

3.2.6.1. Inherent safeguarding value

Most participants, including practitioners and some people with dementia and carers, felt that the principles of the MCA provided safeguards to protect the autonomy and well-being of the person with dementia, through respecting capacity, enabling the setting up of LPAs and best-interests decision-making. Most were optimistic about its use and value, and some highlighted that its greatest benefit was in providing safeguards against false allegations of abuse for practitioners and carers as well.⁴⁵¹ Many practitioners also considered that carers would benefit from knowing details of the Act, as it would provide them with knowledge of when and how they would be able to make decisions for their relatives if the need arose or to act on their behalves

The principles and procedures of the MCA were perceived as placing the individual at the heart of the safeguarding process by those with local responsibilities for adult safeguarding (formerly adult protection, also known as elder abuse) in local authorities (SACs). Rights to draw up a LPA were, in several instances, described as part of 'protection plans' (SAC04) and could be one outcome of a safeguarding investigation (SAC07). Access to the IMCA (paid advocacy) service in cases of suspected abuse was universally valued. The Deprivation of Liberty Safeguards (introduced later than the MCA) were providing another layer of protection. In one example, a person's wish to remain in a care home against family pressure had been supported (SAC05). In another, a case of neglect had emerged (SAC11). (This study did not focus on Deprivation of Liberty Safeguards as there are other major research studies on this subject in progress.) The Act's potential to shift the boundaries of traditional relationships and to empower vulnerable adults was observed, but a new emphasis on its role in reducing victimisation and positive risk-taking also emerged

However, some raised criticisms that there was insufficient publicity about the Act and that written material was not always readily available (most of it is online). One SAC was particularly concerned that there were limited opportunities for people to find out about the Act and considered that at the time of its introduction: 'a bigger national drive would have been better'

3.2.6.2. Financial management and safeguarding

Safeguarding Adult Coordinators felt that the MCA might potentially address one significant area of concern for them – money management and financial abuse. They discussed the safeguarding potential (but limited current use) of the MCA in these areas and the hazards that might be faced by carers and people with dementia who had not yet set out prespecified plans, but when the latter had deteriorating capacity. Most SACs interviewed described this area as a major element of their work

Current data collection systems make it hard to be specific about the prevalence of actual abuse or the even the composition of formal referrals to SACs. One participant noted that although financial abuse featured in about 12% of local investigations, they lacked information about whether alleged victims had dementia or cognitive impairment. Some described situations as common place in which family care was insufficient, yet services were declined because their cost would reduce the family inheritance. Within families, unusual interest in a person's financial affairs could be suspicious, with some relatives described as being financially motivated. One SAC reflected 'having money does not protect you from abuse in old age; it can make you more vulnerable'. Other examples of the abuse of people with dementia encountered following referrals included valuables missing without explanation; undue influence and theft; misuse of direct payments (cash for care); taking the 'free' item under a 'buy one get one free' supermarket offer; or 'borrowing' money from an older vulnerable person

Although having dementia in itself was acknowledged as problematic when raising safeguarding alerts (because people might not realise the risk or danger), most practitioners reported using strategies to engage a person with dementia to find out what was happening or of concern. These included face-to-face interviews, involving advocates, liaison with partner agencies (e.g. the police and the Department of Work and Pensions) and exploring legal options. However, they deemed the highest priority was remaining vigilant about the risks of financial abuse

In a modified form of data triangulation, interviews with SACs were compared with responses from a survey of staff of the Alzheimer's Society to see if they considered that money management was a problem for people with dementia. These staff similarly thought that risks of financial abuse were widespread. The MCA and financial systems were reported to be not always sufficiently sensitive to the needs of people with declining, rather than greatly impaired, capacity to make fine judgements and to take account of their changing circumstances

3.2.6.3. Warning signs of financial abuse should be publicised

Participants from the Alzheimer's Society suggested that there should be greater publicity about the warning signs of financial abuse to raise awareness among practitioners, community support networks such as shops, banks, and post offices, and society in general. In their experience, discussions about managing money were not easy and this suggests that skills may need to be developed in this area of practice. We worked with the Alzheimer's Society to develop a series of evidence-based policy recommendations to promote the safeguarding and rights of people with dementia, pointing to the provisions of the MCA as helpful for some people lacking decision-making capacity and as part of a prevention or protection plan.²⁸⁷ This study attracted substantial media publicity

In addition to individual planning to minimise abuse or to minimise common confusions over money management, SACs referred to other preventative measures including:

- Setting up direct debits to pay bills from a person's bank account
- Restricting access to bank details and Personal-Identification-Number
- Prohibiting junk mail or 'cold calling'
- Reducing unsolicited (scam) telephone calls by barring 'number withheld' calls

The SACs considered that the risks of exploitation of people with dementia are not always identified by NHS professionals. Greater recognition of such risks and preventative measures may be needed among community support teams and memory clinic staff. However, one problem in their experience was that many of those at risk still retain decision-making capacity and are not yet under the protection of an attorney (under the LPA provisions) or other appointments under the Office of the Public Guardian

Almost all SACs highlighted the potential for people with decision-making capacity to draw up a LPA under the MCA. This was widely regarded as the most significant means of prevention of abuse once mental capacity was severely affected. Allied to these positive views of LPAs, and acknowledging that they had to be drawn up while a person was still able to make this decision, SACs generally expressed confidence in the system of deputies appointed for people without LPAs. One also reported that the Office of the Public Guardian was proving extremely helpful in managing an errant attorney in complex and difficult circumstances. There seems greater scope for professionals who inform people with dementia and their carers about the MCA to highlight the Office of the Public Guardian's potential role in prevention of exploitation

For people with minimal income and savings, the Department of Work and Pensions system of appointeeship (appointment of a suitable person to collect pension or benefits on behalf of another person, typically a relative) was viewed positively but not to the same extent. SACs made criticisms of the lack of checking of those who took on the role of an appointee although even drawing up a LPA, where greater checks and monitoring are required, could not ensure protection, as this example indicated

3.2.6.4. Role of banks and community support networks

The procedures and rules of banks reportedly presented significant barriers to safeguarding people with dementia from financial abuse. Most participants raised this problem and alluded to the impersonal nature of high street banks, bank staff's reluctance to question suspicious activity and defensiveness about information sharing, even when MCA arrangements had been made. Memory clinic staff and others may wish to suggest that people with a new diagnosis should consider current and future financial arrangements when they are ready to do so. At policy level, as noted above, the Alzheimer's Society report *Short Changed: Protecting People with Dementia from Financial Abuse*,²⁸⁷ to which this research contributed, has been a springboard for the Alzheimer's Society to take forward discussions with the financial services industry

Appendix 67 Chapter 6: Proposed data capture fields with definitions for primary care

Date of data extraction

GP name and contact details

Search register for:

Dementia syndrome	Suspected	(see below) Allows mild cognitive impairment capture
	Diagnosed	Diagnosis of dementia
	Subtype diagnosed	Subtype diagnosed under 'organic brain disorders', i.e. Alzheimer's disease, vascular, mixed, Lewy body, frontotemporal dementia, Parkinson's disease dementia, other
or Dementia symptoms	Presence of possible dementia symptoms	Presence of possible dementia indicators such as: st memory loss, memory loss, forgetfulness, behavioural change, disorientation, confusion, personality change, speech problems, deterioration, global deterioration, wandering
or Cognitive impairment indicator	MMSE score	Where MMSE score is not available from within the electronic medical record other psychometric tests indicative of cognitive impairment will be captured, e.g. 6CIT, AMTS, ADAS-cog, etc.

Then exclude:

Alcohol dependency	Alcohol dependency	Record of alcohol dependency is required as 'alcohol problem' may be insufficient as an exclusion criterion
and Opioid dependency	Opioid dependency	
and Diagnosis of psychiatric disorder	Diagnosis of major psychiatric disorder	Any diagnosis of major psychiatric disorder would be an exclusion criterion

From this modified subpopulation audit and report on:

Patient gender		Automatic
Patient age		Automatic
Patient contact details	<i>Residential status</i>	Ideally we could like to capture residential status, i.e. own home, sheltered accommodation, care home. However, we will be able to capture only the patient's address
	<i>Carer details</i>	Ideally it would be preferable to capture presence of a carer, marital status and carer strain score as a dependency indicator. However, we are unlikely to be able to routinely capture this data and a follow-up call for these details after initial selection criteria have been applied may be required
Comorbidities	Capture all active comorbidities	Automatically identified from active problem list
Medication	Capture all medications	The whole medication record can be extracted, this will allow checking for prescription of cholinesterase inhibitors and concomitant medications, such as antidepressants, psychotropics, etc.
Contact with secondary care	Professional contacts	List other professional contacts, such as memory clinics. This information will allow a quality assessment of secondary care databases and also give contact details if further information is required; reports may need to be followed up manually
Medical imaging		Indication of whether CT scans/MRI scans have been performed, date of scan and results where possible; reports may need to be followed up manually

ADAS-cog, Alzheimer's Disease Assessment Scale-cognitive subscale.

A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and depth.

EME
HS&DR
HTA
PGfAR
PHR

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