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DOES COMPREHENSIVE GERIATRIC ASSESSMENT (CGA) HAVE A ROLE IN UK CARE HOMES?

ADAM GORDON, MB ChB MMedSci(Clin Ed) MRCP(UK)

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Abstract

UK care home residents are frail, dependent and multimorbid. General practitioners (GPs) provide their healthcare but there is evidence that existing provision fails to meet their needs. Comprehensive Geriatric Assessment (CGA) comprises comprehensive multidisciplinary assessment, goal setting and frequent review. This thesis considers a possible role for CGA in UK care homes through three research projects.

The Care Home Literature Review (CHoLiR) was a systematic mapping review of randomized controlled trials (RCTs) in care homes. It found no evidence supporting CGA as a whole but described some CGA components supported by RCTs: advanced care planning; interventions to reduce prescribing; staff education around dementia and end-of-life; calcium/vitamin D and alendronate in preventing fractures and osteoporosis; vaccination/neuraminidase inhibitors in preventing influenza; functional incidental and bladder training for incontinence; and risperidone/olanzapine for agitation.

The Care Home Outcome Study (CHOS) was a longitudinal cohort study recording dependency, cognition, behaviour, diagnoses, prescribing, nutrition and healthcare resource use in 227 residents across 11 care homes over six months. It reported high levels of dependency, cognitive impairment, malnutrition, multimorbidity and frequent behavioural disturbance. Polypharmacy and prescribing errors were common. Variability between homes and individuals was significant for most baseline and outcome measures.

Staff Interviews in Care Homes (STICH) was a qualitative interview study of 32 staff working with care homes including: GPs; care home managers and nurses; NHS community nurses and specialist practitioners. It described care defined by discontinuity and lack-of-anticipation; driven by communication failure, inadequate training and expertise in frail older patients, and arbitrary boundaries between care homes and the NHS which interfered with care.

Using the findings of these studies, the author proposes a model of care which is multidisciplinary, guided by comprehensive assessment, reinforced by frequent review and delivered by experts in the care of frail older patients: CGA has a role in UK care homes.

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Chapter 1 – Introduction

1.1. Care Homes and the prevailing model of healthcare

Care homes were defined in the UK Care Standards Act 2000 as "establishments providing accommodation, together with nursing or personal care, for persons who are or have been ill, who have or have had a mental disorder, who are disabled or infirm, or are or have been dependent on alcohol or drugs"[1]. Under the taxonomy outlined in this act, UK long-term care establishments were classified either as care homes (often called residential homes) or care homes with nursing (often called nursing homes). Only 8.6% of residents who live in care homes are under 70[2].

4% of people over 65 in the UK live in care homes[3]. The best-available evidence suggests that they represent a frail and dependent population with multiple co-morbidities. A 2004 census of 16,043 residents living across 244 UK care homes owned by BUPA, a large international corporate care home provider operating in the UK, reported 76% of residents to require assistance with their mobility or be immobile, 78% to have at least one form of mental impairment and 71% to be incontinent[2]. The same survey recorded the prevalence of 26 "admission diagnoses" – with the most prevalent being dementia, frailty, stroke and sight impairment, present in 36%, 25%, 22% and 13% of residents respectively. The year 2000 Health Survey for England[3] reported 75% of care home residents to be severely disabled.

Care home residents have become more dependent over the past 25 years. Data collected in 1982 revealed 43% of residents to be independently self-caring, 64% to be fully-continent and 49% to be fully oriented and aware[4]. These data came from 6947 residents of 175 homes, comprising the entire local authority care home provision of North Yorkshire, Derbyshire, Kirklees and Nottinghamshire and it is likely that they were broadly comparable with the BUPA study, given the consistency of methods applied. Postulated reasons for the increased dependency over this time were: the closure of National Health Service (NHS) long-stay inpatient beds for frail older patients, with the movement of these patients into care homes[5]; the advent of intermediate care services, meaning that increasingly frail patients could be accommodated within their own homes, potentially selecting out only the frailest members of society for care homes[6]; and the standardisation of NHS continuing care funding models, with the consequence that an increasing number of patients with complex health needs were funded by the NHS to be cared for in the private care home sector[7]. Over the same time-frame there was a gradual increase in average care home size, the proportion of care homes owned by the private sector and the proportion of private sector homes owned by large national or multinational corporate chains[7].

The demand for care home services is predicted to rise. The mean age of the UK population is increasing. National census data from 2006 showed 21% of the UK population to be aged over 65. This figure was projected to reach 28% by 2031, equating to a rise in the absolute number of over 65s from 13 to 20 million people[8]. Assuming no change in the prevalence of dependency, Wittenberg *et al*, on behalf of the Joseph Rowntree Foundation, predicted that the number of care home places in the UK would have to expand by 150% by 2051[9]. These predictions were conservative. Harwood *et al*[10] used data from the Global Burden of Disease Study on prevalence of 483 medical diagnoses around the globe and attached disability tariffs to these in order to project levels of physical dependency for the next 50 years. Their results suggested that prevalence of dependency in established market economies would increase by 31% over this time. Barring a significant change to the structure of health and social care in the UK, care homes will therefore be part – and probably a growing part – of UK long-term care provision for the foreseeable future. Given the magnitude of predicted demographic change, this is likely to happen regardless of policy initiatives by health and social care providers to attempt to provide care to more people in their own homes[11].

Although care homes have evolved significantly over the last 15-20 years, healthcare support for UK care home residents has remained largely unchanged. It continues to be provided predominantly by General Practitioners (GPs), with support from district nurses and a team of community based allied health professionals, as part of the General Medical Services (GMS) contract. There is, for the most part, little difference between the models of care provided to care home residents and to patients who live in their own homes[12].

Shortcomings with existing healthcare arrangements have been demonstrated. There has been evidence of poor prescribing. The Care Home Use of Medication Survey (CHUMS)[13] reviewed 256 residents across 55 homes in 2006-7, revealing the mean number of prescriptions to be 7.6 per person (more than four medications is recognised to be an independent risk factor for falls in older patients[14]) and identified one or more prescribing error in 70% of those studied. The rate of neuroleptic prescribing in care homes has been reported to be as high as 24-28%, which is much higher than would be expected[15], and is an indicator of practice deviating significantly from the recommendations of the UK Medicines and Healthcare Products Regulatory Agency (MHRA)[16]. There has been evidence of inequality of access to NHS resources to the disadvantage of care home residents. Steves *et al*[17] conducted a national survey of NHS Primary Care Trusts (PCTs) in 2008, in which 25% of trusts reported inequality of access to services for physiotherapy and occupational therapy and 35% for district nursing. There has been evidence that existing incentive frameworks for GPs don’t serve care home residents well. Shah *et al*[18], in 2011, used a large primary care database to compare how 10,387 care home residents and 403,259 community dwelling patients had the NHS Quality Outcomes Framework (QOF) applied. QOF is a scheme whereby GPs are paid financial incentives for achieving health promotion-related performance targets amongst their patients – payments are made when a pre-determined threshold of patients achieve the performance targets (examples being prescribing of beta blockers in coronary vessel disease or appropriate use of retinal screening in patients with type 2 diabetes). They reported a significantly higher incidence of exemption reporting – where GPs documented that QOF targets were inappropriate – and lower attainment of quality indicators for care home residents. These findings suggested that either QOF targets were less relevant in the care home population than in community-dwelling patients, or that they were appropriate but difficult to achieve.

Thus current arrangements are associated with high prescribing error rates and inequality of access to specialist services. The high incidence of QOF exemptions, meanwhile, either reflects a failure of existing models to deliver quality care to care homes, or suggests that QOF has little to offer in driving quality healthcare for care homes. It is perhaps unsurprising, in this context, that a 2010 survey of GPs by the "Pulse" magazine revealed that 61% believed current arrangements for the medical care of care home residents were inadequate[19]; a view supported by 40% of 330 geriatricians surveyed in 2011 by the British Geriatrics Society (BGS)[20]. These concerns have been mirrored by the Care Quality Commission (CQC) – which launched a special review investigating the issue of differential access to and quality of healthcare for care home residents in March 2010[21], the results of which are awaiting publication. Despite a lack of nationally co-ordinated policy for healthcare in care homes, it is clear that there are also widespread concerns regarding existing models of care within the NHS - 90% of NHS trusts surveyed in 2008 reported that they had launched initiatives to improve medical care in care homes[17].

1.2. Comprehensive Geriatric Assessment (CGA)

In 1943 Dr Marjorie Warren published her seminal paper on "Care of the Chronic Sick"[22 23] in which she used her experience as deputy medical superintendent of the West Middlesex Hospital to lay out some fundamental principles of geriatric medicine. These included methodical review of patients, separating out those who were ambulant and amenable to rehabilitation from those who were bed-bound and required long-term care, and those with cognitive impairment with or without behavioural and psychiatric disturbance. She made a case that older patients should be cared for in the general hospital, by experts rather than by novices, and that their care should be the focus of training for doctors and nurses. She argued that care should be holistic and multidisciplinary, with particular attention to nutrition, occupational therapy, mobility and environment. She suggested that, with such attention, many patients previously labelled "incurable" could be expected to show "some measure of improvement."

These principles espoused by Warren – thoughtful, comprehensive, multidisciplinary assessment to target rehabilitation interventions towards patients most likely to benefit – gradually evolved to form the central tenet of geriatric medicine, Comprehensive Geriatric Assessment (CGA)[23]. CGA has been defined as, "A multidimensional interdisciplinary diagnostic process focused on determining a frail elderly person's medical, psychological and functional capability in order to develop a coordinated and integrated plan for treatment and long-term follow-up."[24] The term is a misnomer, in that it is taken to encompass not just the assessment process but also the integrated care plan that emerges from it. In their systematic review of randomized controlled trials (RCTs) evaluating CGA, Ellis and Langhorne listed the constituent parts of the interventions studied, illustrating that – whilst assessment was the common feature of all programmes – most also incorporated components of goal setting for treatment. The other features common to most of the interventions evaluated were multidisciplinarity – the core multidisciplinary team (MDT) comprising geriatrician, nurse, physio- and occupational therapist, with or without supplementary team members including social workers, dieticians, speech and language therapists and psychologists; and regular meetings of the MDT[25] (see Table 1).

Table 1 - The Composition of CGA Interventions Studied by RCT - adapted from Ellis and Langhorne[25]

	Comprehensive assessment	**≥MDT1 weekly**	**Goal setting**	**Assessment tools**	**Protocols**	**Ward environment**	**OP follow-up**
Epstein[21]	●	●	□	●			
Fretwell[22]	●	●	□	●			
Gayton[23]	●	●	□				
Hogan[24]	●	●	□				
Hogan[25]	●	●	□				●
Naughton[26]	●	●	●				●
Reuben[27]	●	●	□	●			●
Saltz[28]	●	●	□	●			
Thomas[29]	●	●	□	●			
Winograd[30]	●	●	□				
Applegate[12]	●	●	●				●
Asplund[13]	●	●	●				
Cohen[14]	●	●	●	●			●
Collard[31]	●	●					●
Counsell[15]	●	●	●		●	●	
Harris[16]	●						
Landefeld[17]	●	●	●		●	●	
Nikolaus[18]	●			●			●
Rubenstein[19]	●	●	●	●			●
Saltvedt[20]	●	●	●		●		

□ = recommended only

Evidence of the effectiveness of CGA emerged almost from the point of its inception. Warren, for example, was able to rehabilitate and discharge large numbers of patients, whom it had previously been assumed would die in the infirmary, to the community – reducing the number of long-term inpatients from 714 to 240 and increasing bed-turnover three-fold in the process[26]. A large meta-analysis of randomized controlled trials (RCTs) of CGA, conducted in 1993, reviewed 28 studies including 4959 subjects allocated to CGA and 4912 to control[27] across a number of inpatient and outpatient settings. Regardless of setting, patients receiving CGA were more likely to be living at home and less likely to be functionally or cognitively impaired at 6 and 12 month follow-up respectively. A recent Cochrane review considered 22 trials of CGA in an acute hospital setting including 10,315 participants and found that patients receiving CGA were less likely to be institutionalised, suffer death or deterioration, and more likely to experience cognitive improvement at 12 month follow-up[28]. In the community setting, CGA has been shown to result in improved outcomes, over routine care, in the day hospital setting[29] and community hospital-based early supportive discharge[30].

The populations in which CGA has been shown to be successful are universally old – cut-offs vary from >65 years to >75 years – and usually frail[25]. Frailty comes with a number of definitions, but the two predominant definitions are of “a biologic syndrome of decreased reserve and resistance to stressors, resulting from cumulative declines across multiple physiologic systems, and causing vulnerability to adverse outcomes”[31]; or of a collection of accumulated deficits which place a person at increased risk of future adverse event[32]. Many geriatricians maintain, simply, that they “know it when they see it”. Regardless of the definition adopted, few would doubt, based upon the prevalence of disability and diagnoses stated above, that care home residents are frail – indeed, significantly frailer than the cohorts in which CGA has been shown to work. It is seems reasonable to assert, in this context, that CGA may have a role.

1.3. Models of healthcare to care homes apart from GMS

A number of alternative service models for providing healthcare to care homes have been described within the NHS. Four of these were singled out for special consideration by the Continuing Care Special Interest Group of the BGS in 2006[12].

The first of these linked a single GP practice with a single home, with an additional payment made to the practice in exchange for providing additional services – for example weekly visits and regular review. A second model allocated additional payments to all GPs who looked after care home residents but nominated one practice as a "lead practice" for each home, with a further additional payment reflecting this responsibility. Tied to the lead practice payment was the expectation that the practice would co-ordinate education and infection control for the home. A third model established a "care home practice" where a single practice was contracted to care exclusively for care home residents within a given catchment area. Patients were encouraged to migrate to the care home practice from their usual doctor. To facilitate its work with frail older patients, the practice also employed physio- and occupational therapists and specialist nurses. The fourth model established combined services – bringing together a GP, geriatrician and senior community nurse – which then provided exclusive medical care to homes within a specific catchment area. These models, when considered in this order, might be seen as ascending a hierarchy of CGA, with the former two interventions systematising care, without necessarily adding components of comprehensive assessment, goal setting or multidisciplinarity. The latter interventions, whilst they incorporated multidisciplinarity, did not specifically adopt detailed multidisciplinary assessment followed by goal setting and regular review. That is to say, although some were more comprehensive than others, all fell short of full-CGA based upon the descriptions published.

To find evidence of CGA in the care home setting, it is necessary to look outside of the UK. The most commonly cited example of CGA in care home practice is Evercare, a US Medicare-funded programme of care specifically designed to support nursing home residents – residents voluntarily opt-into the programme, with the remainder receiving standard Medicare-funded healthcare.

A report written in 2002 for the US Centres for Medicare and Medicaid Services (CMS)[33] evaluated the demonstration programme upon which Evercare was based. It reported that residents opting for Evercare received support from Nurse Practitioners (NPs) at a ratio of 1 nursing practitioner per 100 residents. NPs conducted comprehensive assessments, triggered appropriate referrals to allied health professionals and acted as case managers liaising with and between patients, their families, nursing home staff and primary care physicians. They averaged 20 minutes per patient per day and thus were able to frequently adjust and change management plans. They had the option of support from a geriatrician as required. They played a role in educating nursing staff. In addition to the NP, Evercare also modified the model of reimbursement for primary care physicians, such that they were reimbursed for family or multidisciplinary team meetings, which would not have been the case under routine Medicare arrangements. Evercare residents were reported to show a similar level of overall dependency to the wider US nursing home population but have a slightly higher prevalence of dementia[34].

A subsequent observational cohort study compared 664 residents receiving Evercare, with 885 controls from within the same homes and 1490 controls from homes where no resident received Evercare. Residents were followed for 18 months. Those receiving Evercare had significantly lower rates of preventable admissions by comparison with both control groups[35]. This was largely achieved by the implementation of “intensive service days” where the nursing home was provided with additional reimbursement in order to continue to support the resident in their home, rather than having them admitted to hospital. There was no difference in mortality between the two groups and no difference in measures of healthcare quality using the US care home Minimum Dataset. The cost-effectiveness of the intervention was not calculated.

Evercare, as described, had many of the features of CGA. It was defined by regular assessment, regular review, multidisciplinarity and frequent interactions between the disciplines involved. However, whilst it is clear that it had an important influence over admissions to hospital, it is not clear that it improved health outcomes for residents. It may simply have changed their venue of care, by diverting reimbursement from one care venue (acute hospital) to another (nursing home) – albeit that the venue to which reimbursement was diverted was cheaper.

The other commonly cited example of CGA in care homes comes from the Netherlands, which has a highly developed specialty of care home medicine – with a national association of care home physicians and more care home medics than geriatricians registered to practice[36]. Numerous articles have been published citing high quality care in Dutch care homes as a consequence of regular involvement of physicians, describing a process which incorporates comprehensive, frequent assessment and regular input from an expert multidisciplinary team[37 38]. Yet, because care home physicians and the MDTs which they lead have been a part of life in the Netherlands for four decades, their intervention has not been subjected to rigorous evaluation of the sort seen for Evercare. When the Dutch care model has been subjected to comparison with other countries where MDT involvement in management is not routine, it has not always been shown to deliver the best outcomes – an important example being the comparison in pressure ulcer prevalence between Dutch and German homes recorded using the Dutch National Prevalence Measurement in 2003, reporting a prevalence in the Netherlands 1.5 times greater than in Germany[39].

This latter study, however, raises an important point – that international comparisons of care homes are difficult because the long term sector is significantly different between countries. Depending on the country studied between 2% and 14.5% of people over the age of 65 years will live in care homes, whilst the funding, focus and day-to-day running of long term care facilities varies between nations[40]. Dutch care homes are large, averaging 173 residents per home, and each home has a permanent staff including doctors, physiotherapists, occupational therapists, speech and language therapists and psychologists[36]. 40% of those living in Dutch care homes are short-term residents, there for rehabilitation. This model of care is much more akin to the now discontinued model of NHS long-term care beds than it is to the current UK care home sector. In the USA, 86% of residents are cared for in homes with 100 or more residents[41], compared with an average home occupancy in the UK of 26 for residential homes and 44 for nursing homes[42]. There is also the consideration of the differing healthcare sectors with which homes must interact. That the UK and US healthcare economies, for example, are very different is well understood.

Thus the lessons to be learned from overseas, whilst important, should not be overstated. Evercare, despite its success, could not be imported into the UK as an “off-the-peg” solution because the care home population, the health service and models of remuneration and revenue flow in the UK are very different. A model of care home physicians, as seen in the Netherlands, could only be implemented in the

UK after comprehensive evaluation to consider how it would impact on a different cohort of residents and how it would integrate with, or replace, existing models of care. These are important, therefore, not as examples of services to be emulated, but because they illustrate that CGA has been successfully implemented in other countries and has been championed in both instances as delivering high quality care to frail older patients – it is both feasible and seems to make a difference to clinical outcomes.

1.4. Does CGA have a role in Care Homes?

So, care home residents have been shown to be complex and frail, and existing models of care have been shown to inadequately meet their needs. CGA has been demonstrated to deliver effective healthcare to frail older patients in other settings within the UK and to result in improved clinical outcomes. It has been shown to be feasible in long-term care facilities in other countries and has been championed as delivering high quality care in these settings. The NHS has engaged in a search for satisfactory models of healthcare for care homes – yet none of the models described in the literature so far have all the components of CGA.

There is some equipoise here. CGA has not worked in every cohort in which it has been tested. When tested in nurse-led intermediate care it failed to show any effect on objective clinical outcomes at 6 months[43]. When tested in therapist-led care home-based early facilitated discharge, it resulted in a shortened duration of acute hospital stay but increased the overall time spent away from home and failed to show any objective improvement in clinical markers[44]. The reason it may have failed to make a difference in both of these contexts is that they comprised “step-down” interventions, where many of the components of CGA might have taken place before residents reached the intervention, minimising the impact that could be made. Its failure, however, serves to emphasise the fact that the successful implementation of

CGA is context-dependent and a detailed understanding of the context in which it might be implemented is essential in considering its possible role.

CGA is a complex intervention. Complex interventions are defined by the UK Medical Research Council (MRC) as "those which comprise a number of separate elements which seem essential to the proper functioning of the intervention, although the 'active ingredient' of the intervention that is effective is difficult to specify"[45]. Evercare has been used as an example of a complex intervention by the MRC[46].

The MRC Framework for Design and Evaluation of Complex Interventions to Improve Health[45] breaks the evaluative process for complex interventions into discrete steps which, as illustrated in figure 1, have been defined to replicate the discrete phases seen when developing and evaluating a drug therapy.

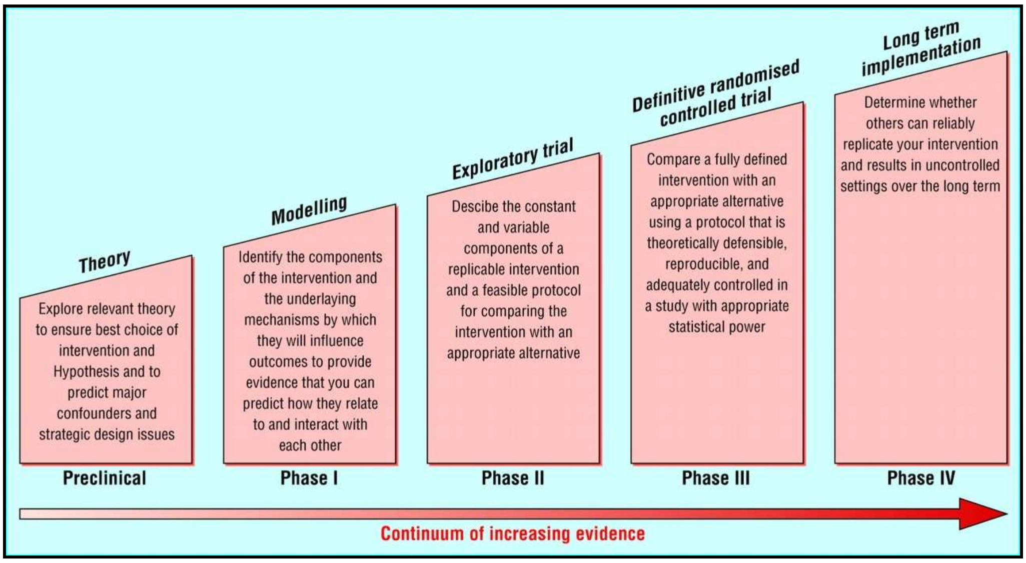


Figure 1 - The Medical Research Council Framework for Design and Evaluation of Complex Interventions, reproduced from Campbell *et al*[45]

The analogy with pharmaceutical trials emphasises the importance of preparatory work. Thus, where one would spend a long time in the laboratory developing, refining and conducting animal tests for a new drug compound, one must devote similar effort to ensure a sound theoretical basis for a complex intervention through, for example, recourse to the literature and gathering data about the context in which the intervention would be delivered.

CGA has already been comprehensively described and evaluated in a number of other settings. In considering whether CGA had a role in care homes, the uncertainty was less around what comprised CGA and more about whether it had relevance to the care home setting. The question was one of context.

Against this background, this thesis describes a programme of research designed to address the question of whether CGA had a role in care homes by addressing the uncertainties about the context in which it would be implemented. It did so by conducting three pieces of research:

- The Care Home Literature review (CHoLiR) was designed to describe the research conducted using RCTs in care homes to establish whether an evidence base for CGA – or component interventions which might comprise part of CGA – had already been built. This is described in chapter 2.

- The Care Home Outcome Study (CHOS) was designed to comprehensively describe the health and functional status of care home residents, and how they use NHS resources. This is described in chapter 3.

- The Staff Interviews in Care Homes (STICH) study was designed to describe how care home staff and the healthcare professionals who work with them identify and respond to changes in residents' health. This is described in chapter 4.

Chapter 2 – The Care Home Literature Review (CHoLiR)

2.1. Introduction

The first step in considering a possible role for CGA in care homes was to look at whether it had already been evaluated in this setting. This was a relatively complex proposition since CGA is by definition an intervention comprised of multiple more focussed assessments and interventions[25]. Thus, it was necessary not only to establish whether an intervention correctly identified and described as CGA had been subjected to formal evaluation in a care home setting, but also whether component assessments and interventions had been evaluated, either together or in isolation, such that they might contribute to an understanding of the role of CGA in care homes.

A literature review was designed to collate randomised controlled studies (RCTs) already undertaken in care homes with the aim of describing existing research to establish whether some or all components of CGA had already been evaluated – and whether they had been evaluated in a combined form as CGA. Given the nature of CGA – comprising functional, physical, cognitive and behavioural assessments and establishing management priorities regardless of professional or specialty boundaries – it was clear that this review would require to be both broad and inclusive.

2.2. Aim

To describe the research conducted using RCTs in care homes to establish whether an evidence-base for CGA – or component interventions which might comprise part of CGA – had already been built.

2.3. Methodology

2.3.1. Why randomized controlled trials?

Randomized controlled trials (RCTs) are commonly held to represent a gold-standard in empirical evaluation of medical interventions[47]. They comprise, for example, the highest tier of medical evidence under the GRADE system, used in the evaluation of evidence for medical guidelines by the World Health Organization, the American College of Physicians, the American Thoracic Society, the Cochrane Collaboration, the Scottish Intercollegiate Guidelines Network and the UK National Institute of Clinical Excellence[48-50]. The rationale for this is well rehearsed, that randomization minimizes the effects of both confounding and selection bias and that the addition of blinding, where possible, minimises the potential for bias at multiple levels[51]. This position is well supported by empirical studies suggesting that randomization and concealment of treatment allocation reduces bias in trials of clinical interventions[52 53].

There are limitations to RCTs, several of which are particularly relevant in the care home setting. The multiple comorbidities which are common in frail older patients introduce confounding. The most appropriate response to this is to identify all confounding variables and appropriately power RCTs to take account of them – often resulting in very large studies. A less constructive – but relatively common – response is to avoid confounding by limiting studies to particular sub-cohorts of older patients and a consequent tension between the internal validity of RCTs and their generalisability to the older population is well recognized[54]. Many of the healthcare interventions commonly conducted in a care home setting, for example continence and falls prevention interventions, are complex – often involving multiple staff members from multiple agencies and targeting syndromes which are multifactorial and influenced by biological, psychological and social variables. The MRC Framework for Design and Evaluation of Complex Interventions to Improve Health[45], as already discussed, describes an approach to these problems which leans heavily on detailed mixed-methods preparatory work to define the intervention, its target population and appropriate outcome measures prior to conducting RCTs. Such preparatory work is complicated and the research paradigms it draws upon are relatively subjective, such that the target population or outcome measures adopted in a subsequent RCT may be flawed – with consequent failure to demonstrate the success of an intervention. True double-blind studies are difficult in complex interventions where no placebo is readily available[55] [56] – if consultant geriatrician review, for example, were to constitute the intervention in an RCT, then it would be impossible to blind participants to the fact that they had received the intervention. Even where participants are adequately blinded, the possibility of cross-contamination in a care home setting, where control residents might, either accidentally or intentionally, experience changes in practice as a consequence of the intervention, is considerable[57]. This has led to cluster randomization strategies, usually used as a means of avoiding contamination by diffusion (where the behaviour of staff or residents in the control arm is altered), which demand large sample sizes and, in themselves, run the risk of introducing bias by failing to identify key confounding variables at the whole-home level[58].

These concerns underline the limitations of RCTs and hence the importance of mixed-methods research in understanding healthcare interventions in care homes. They do not, however, mean that there is nothing of value to be gleaned from RCTs. Even the most extreme critics of RCTs – Bayesian statisticians have challenged the assumption that confounding can be satisfactorily accounted for through randomization[59] and interpretivists have challenged the very assumption of reality upon which positivistic experimentation is based[60] – have recognised the need for relatively robust evidence upon which clinicians can base critical healthcare decisions and that RCTs have a role in providing such evidence (even if they would prefer that Bayesian statistics, or qualitative paradigms such as critical realism, were brought to bear on RCT-derived data in addition to probability theory)[61 62].

Given that the aim of this review was to establish whether an evidence-base for CGA, or its component interventions, had already been established in care homes – a review of RCTs seemed both appropriate and defensible. The findings of these would, of course, have to be interpreted with caution given the various limitations described above.

2.3.2. Choosing a mode of literature review

The work of Grant and Booth[63] was consulted in considering which mode of literature review to adopt in order to most effectively fulfil the aims. In 2009, these authors conducted a series of scoping reviews and reviewed commonly applied terminology in conducting literature reviews, before categorising these according to a **S**earch, **A**ppraisa**l**, **S**ynthesis and **A**nalysis (SALSA) framework. Their resulting typology outlined 14 modes of literature review: critical, literature, systematic mapping, meta-analysis, mixed study, overview, qualitative systematic, rapid, scoping, state-of-the-art, systematic, systematic search and review, systematized and umbrella reviews. In deciding which approach to take here, their SALSA framework and accompanying descriptions[63] were reviewed and, from amongst the types described, a systematic mapping review was identified as most closely meeting the aims as stated.

The Institute of Education's Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI)[64] has published specific guidance on conducting systematic mapping reviews, which it calls systematic descriptive maps, in educational subjects. It defines them as describing, rather than scrutinising in-depth and critically appraising, the research – allowing reviewers to address a much broader field than is possible when conducting a narrower synthesis of research findings. In conducting a mapping review, studies are coded against a keywording strategy. EPPI provides an example of an educational keywording strategy which is not immediately transferable to a healthcare context but provides examples of the sort of domains recorded, including country and language of study, type and topic of study and study setting[65].

A key strength of the systematic mapping review has been the ability to identify gaps in the literature and focus on key research targets going forward[63], making it very well suited as a methodology to address the aims stated here. It was identified as a methodology which would allow a potentially very large number of research trials, encompassing not only CGA but also component interventions from across a number of disciplines, to be considered.

The gold standard methodologies for healthcare literature reviews are commonly held to be systematic review and meta-analysis (sometimes called quantitative systematic review). These seek to minimize confounding and bias through inclusive search strategies and careful evaluation of the quality of research before reporting – and, in the case of meta-analysis, pooling – the results of studies in a transparent manner designed to facilitate clinical decision making[66]. They have come to comprise a cornerstone of guideline preparation and clinical decision making and are integral to the work of the Cochrane Collaboration[67]. Systematic review was not adopted here because its key strength – the need to quality-assess articles for inclusion[66] – was felt to represent a shortcoming in this context. A consequence of rigorous quality assessment is that, whilst the resulting list of publications represents a comprehensive list of the studies in an area which meet specified quality criteria, the review does not effectively map all the work undertaken around a given topic. For this review, whilst it was important to capture large and methodologically rigorous studies which might effectively make (or dismiss) the case for CGA, it was felt to be unlikely that studies of such importance would exist and have gone largely unrecognised by the geriatric medicine community. It was therefore important, in addition, to map all work undertaken that might help, in summation, to consider the case for CGA or its component interventions, or build an overview of specific topics for research going forward. Systematic review would not achieve this as well as a systematic mapping review would. Meta-analysis, meanwhile, was clearly out of the question, given the wide-ranging nature of the literature surrounding CGA and the need for meta-analysis to focus around studies measuring a common treatment effect[68].

2.3.3. Choosing sources for the literature review

Electronic bibliographic databases are a common starting point for healthcare literature reviews. Medline, maintained by the US National Library of Medicine, is frequently the database of first choice for physicians and biomedical researchers, in part because of its ready accessibility through the free Pubmed interface[69]. It is recommended in the Cochrane handbook as a cornerstone of systematic review[70] and its centrality to effective literature searching is well recognised in the literature on methodology of systematic reviews, with other databases evaluated for their value as additions, rather than alternatives, to Medline[71].

Embase is a product of Excerpta Medical Ltd. and is comparable in size and depth to Medline. Both have broadly comparable sensitivity and specificity for correct identification of common article types[72]. The degree of overlap between Embase and Medline varies, depending upon the discipline studied, from 5.1%-87%[73-80]. Embase has more comprehensive coverage of the pharmaceutical literature[81] and is commonly cited as having broader international coverage than Medline[82-84]. It is commonly used as a standalone bibliographic database by clinicians working outside the US and UK[85]. Within the systematic review literature, however, Embase is more commonly considered as an augmentation than an alternative to Medline – with the recommendation being that decisions around its inclusion, or otherwise, in search protocols be framed in terms of the time and personnel resources available, traded against the potential gain in citation coverage from an Embase search[70 71 85].

Medline and Embase have a predominantly biomedical focus, however a significant number of healthcare interventions for care home residents are delivered by non-physicians, including occupational therapists, physiotherapists, psychologists, nurses and care assistants. These disciplines each have a literature-base which is covered to a greater or lesser extent by Medline and Embase[86-88]. Additional databases potentially contributing to literature searches in these disciplines are the **A**llied and complimentary **ME**dicine **D**atabase (AMED), the **C**umulative **I**ndex to **N**ursing and **A**llied **H**ealth **L**iterature (CINAHL), the **B**ritish **N**ursing **I**ndex (BNI) and the PSYCHinfo psychological abstracts database.

A series of articles used Bradford's law of scattering, an information science theory stating that "for any discipline, a relatively small core of journals can be expected to account for a disproportionate amount of the literature"[89], to identify a core body of literature relevant to nursing and allied health disciplines. This method involves selecting one or two leading journals in a discipline, then retrospectively searching the reference lists from these journals and recording all journals cited. The number of citations is then used to identify journals as "core", or zone 1, "next most relevant", or zone 2, and "unlikely to be of relevance", or zone 3. The coverage of articles in each zone can then be used to evaluate the relative contribution of bibliographic databases to literature searches in the discipline. Using this methodology, Wakiji[86] evaluated coverage of the physiotherapy literature by commonly-used electronic databases, identifying 14 zone 1 and 95 zone 2 journals and evaluating coverage of citations from these across Medline, Embase, CINAHL and AMED. Medline was found to provide 95-100% coverage of zone 1 and also to provide the most comprehensive coverage of zone 2. Of those journals not covered by Medline, CINAHL provided "some" coverage for seven, Embase for six, and AMED for five. AMED covered 11 core journals and 33 peripheral ones, whilst CINAHL covered 8 core and 20 peripheral. 57% of journals covered by CINAHL were also covered by AMED, although where a journal was covered by CINAHL its citation rate tended to be higher, with a mean citation index of 3.1 (indicating 50-74% coverage of citations from included journals) compared with 1.9 for AMED (indicating 25-49% coverage of citations from included journals). Reed[87] conducted a similar evaluation for occupational therapy citations across three zone 1 and 117 zone 2 articles, evaluating their coverage by MEDLINE, CINAHL and PSYCHinfo and demonstrating coverage of 71%, 52% and 46% respectively. It was noted that there were eight titles specific to occupational therapy which received comprehensive coverage only in CINAHL. Allen *et al*[88] led a programme of related research addressing the nursing literature across multiple sub-specialties and using a wider array of databases. Their main results are summarized in Table 2.

Table 2 - Citation coverage index for commonly used electronic bibliographic databases by nursing speciality - abridged from a table by Allen *et al*[88]

Nursing area of specialty	CINAHL	PubMed	Embase	PsychINFO
General Nursing: USA	2.78	3.41	1.78	0.27
Gerontological Nursing	0.51	3.29	1.76	1.27
Case Management Nursing	2.23	3.30	1.78	0.71
Nurse Practitioners	1.87	3.62	2.31	0.54
Community/Public Health Nursing	2.72	3.35	1.46	1.13
General Nursing: International	2.50	3.32	1.94	0.41
Rehabilitation nursing	2.52	3.25	2.07	1.15
Average scores for Zone 1 and Zone 2 in each study; based upon database coverage score: 5 (95-100%); 4 (75-94%); 3 (50-74%); 2 (25-49%); 1 (1-24%)				

For UK-based studies, the British Nursing Index (BNI) constitutes an important additional resource worthy of consideration. It is cited by its proponents as providing the most up-to-date bibliographic database for core UK nursing journals[90] and to contain material not cited in other commonly used bibliographic databases[91]. It has not been subjected to comprehensive evaluation along the lines described above, possibly due to it not being seen as a direct competitor to the other bibliographic databases due to its narrow geographical and disciplinary focus. Where it has been evaluated, it has been demonstrated to have higher precision but significantly lower sensitivity than CINAHL[92]. In a systematic review of hospital pharmacy in the UK it contributed 5.7% of citations, more than Embase, CINAHL or AMED (which contributed 5.3%, 3.2% and 0.4% respectively)[93], an important additional observation was that BNI generated relatively fewer articles than other databases – 81 compared with 2860 and 1034 for Medline and CINAHL respectively – indicating high citation yield from relatively little additional effort and supporting the conclusions drawn elsewhere about its high precision.

Clearly, a comprehensive search, involving all available bibliographic databases represents the gold standard but is unlikely to be achievable in the context of all but the most highly resourced studies. In the case of this review, it was clear that a multi-disciplinary focus was necessary and thus inclusion of CINAHL and AMED in addition to Medline was essential. Given the international variations in care home practice[40] and that the central drive of this thesis was to explore the role of CGA in UK-style care homes, the UK-oriented focus of BNI made its inclusion important.

All electronic bibliographic databases are limited to those journals which they choose to index, with selection criteria focussing around scope and coverage, scientific quality, quality of editorial, production quality, types of content, and geographic coverage[94]. These criteria vary between databases, resulting in the differential coverage of citations already discussed. One consequence of the selection criteria is a potentially large body of literature, often termed “grey literature”, which the databases fail to cover. The formal definition of grey literature is “information produced on all levels of government, academia, business and industry in electronic and print formats not controlled by commercial publishing, i.e. where publishing is not the primary activity of the producing body”[95]. It includes but is not restricted to theses, dissertations, guidelines, publications from government agencies and charitable organisations and newspaper articles. In the context of randomized controlled trials, the most commonly cited grey literature source is conference proceedings, which are often of sufficient quality in terms of conduct and reporting for inclusion in Cochrane systematic reviews[96]. Attempts to analyse these grey literature RCTs suggest that they differ from published articles predominantly through smaller magnitude of treatment effect and through smaller sample size[96]. The smaller treatment effect can influence pooled results and has been cited as a potent case for inclusion of grey literature RCTs in meta-analyses[96 97]. RCTs from the grey literature are, however, more likely to be methodologically flawed or report allocation concealment strategies inadequately[98].

Strategies for searching the grey literature have been developed including research registry searches, searching conference abstracts, hand-searching journal citations and using internet search engines[99]. These strategies vary considerably in their yield but are almost universally labour intensive. Given that the broad topic coverage already identified as key to addressing the research aims would already tax the limited time and personnel resources at the disposal of a PhD research project, and the uncertainty around the quality of RCT data yielded from the grey literature, it was difficult to justify conducting such a review for this thesis. As this was neither a formal systematic review nor a meta-analysis, the previously stated concerns about significant bias resulting from non-inclusion of grey-literature were of limited relevance.

2.3.4. Developing a search protocol

Because CGA is needs driven, holistic and multidisciplinary[25], it could comprise almost any intervention delivered to frail older patients. These interventions, when evaluated as isolated interventions might not be viewed or indexed as part of CGA. As such, a search strategy using clinical intervention as the index was impracticable – searches using CGA as a search term would risk missing large amounts of data from studies evaluating component interventions, whilst individual searches for all possible component interventions would be impossibly expansive.

In absence of being able to search studies by intervention, the next most obvious search was by locus of care. As outlined in the introduction, “care home” is a UK specific terminology and was not represented in the Medical Subject Headings (MeSH) for Medline. A search of MeSH yielded the corresponding terms “Nursing Home”, “Residential Facilities” and “Homes for the Aged”. The corresponding terms for CINAHL were “Nursing Homes”, “Residential Facilities”, “Skilled Nursing Facilities”, for AMED were “Nursing homes”, “Long term care” and “Residential facilities” and for the BNI were “Nursing Homes”, “Residential Care” and “Long-term care”.

Clearly such broad terms would yield a large number of results from long-term care institutions in other countries which would differ in several ways from the long-term care setting in the UK[40]. There are, however, sufficient commonalities between the frail older populations housed in long-term care settings across countries to believe that lessons learned from other countries might be applicable within the UK[37].

Further, it was impossible to be certain *a priori* what proportion of citations would be relevant and, within the framework of a systematic mapping review, inclusion of possibly irrelevant citations was preferable to a failure to build a comprehensive picture of the research conducted to date.

2.4. The research team

Recognising the significant amount of work to be undertaken, a research team was formed to comprise: Dr Adam Gordon (AG), an academic geriatrician; Dr Jon Mamo (JM), a trainee physician; Dr Calum Forrester-Paton (CFP), a trainee physician; Dr Rob Jones (RJ), an academic old age psychiatrist; Professor John Gladman (JG), a professorial-level academic geriatrician and PhD-supervisor for AG; and Dr Pip Logan (PL), an academic occupational therapist and second PhD-supervisor for AG.

AG designed the search protocol, led development of the keywording strategy, designed and maintained the Microsoft Access™ database for collation of results, conducted the initial search of electronic bibliographic databases and read the abstracts of all articles in full before identifying those articles to be included at final review. He sourced hard copies of articles, distributed articles for review and acted as first reviewer for 1/6 of articles shortlisted for full-review. He acted as second reviewer for all articles and conducted all analyses from the resulting database. JG and PL helped to develop the keywording strategy and also acted as first reviewer for 1/6 of articles short-listed for full-review. The remaining researchers: CFP, RJ and JM acted as first reviewer for 1/6 of articles short-listed for full review.

2.5. Methods

Medline (1950-June 2009) was searched using the terms “Nursing Home”, “Residential Facilities” and “Homes for the Aged”, combined using the “OR” command. Results were limited for English language and randomized controlled trials. CINAHL with full text (1978-June 2009) was searched for “Nursing Homes”, “Residential Facilities”, “Skilled Nursing Facilities”, results were limited for randomized controlled trials and Medline citations were excluded. The Allied and Complementary Medicine Database (AMED) (1985-June 2009) was searched for “Nursing homes”, “Long term care” and “Residential facilities” combined using the “OR” command and “Randomized controlled trial” using the “AND” command. The British Nursing Index and Archive (BNI) (1985-June 2009) was searched for “Nursing Homes”, “Residential Care” and “Long-term care” – it was not possible to limit the results from this database further as no filter for RCTs was available. Abstracts were reviewed by a single reviewer for descriptions of interventions evaluated using RCTs in residential, nursing or care homes. Those including such a description were included in the review; those which did not were discarded.

A keywording strategy, of the type described by EPPI[65], was developed by three researchers (AG/PL/JG) using an iterative approach and a random sample of 20 articles. The articles were reviewed repetitively and key descriptors of the article recorded at each review. The researchers met regularly to discuss the keywording strategy and the articles. This process was concluded when no new descriptors were identified on two subsequent reviews. The resulting framework described: year of publication, country of publication, individual or cluster randomization, stratified or non-stratified randomization, method of stratification, blinding strategy (patient/investigators/both/neither), target of intervention, intervention treatment, control treatment, number of subjects (total/intervention/control), number of clusters (total/intervention/control), outcome measures and results.

The remaining articles were then divided amongst six reviewers (AG, PL, JRG, JM, RJ, CFP) who acted as primary reviewers and were asked to classify them according to the keywording strategy. As a final measure, all articles were then read by the lead researcher (AG) who acted as second reviewer to ensure consistency of classification. Disagreements in classification were resolved by consensus.

Classifications against the keywording strategy were entered onto a Microsoft Access™ database, which acted as the basis of analysis. Data were analysed for publication rate by year, country of publication, type of randomization, blinding, type of intervention, target of intervention and study outcome. Those articles specifically considering CGA or case management in the elderly were selected out for more detailed narrative review, which was undertaken by AG.

2.6. Results

3226 unique articles were identified when the results from all databases were pooled. Based upon review of abstracts, 331 were identified as describing RCTs of interventions in care homes.

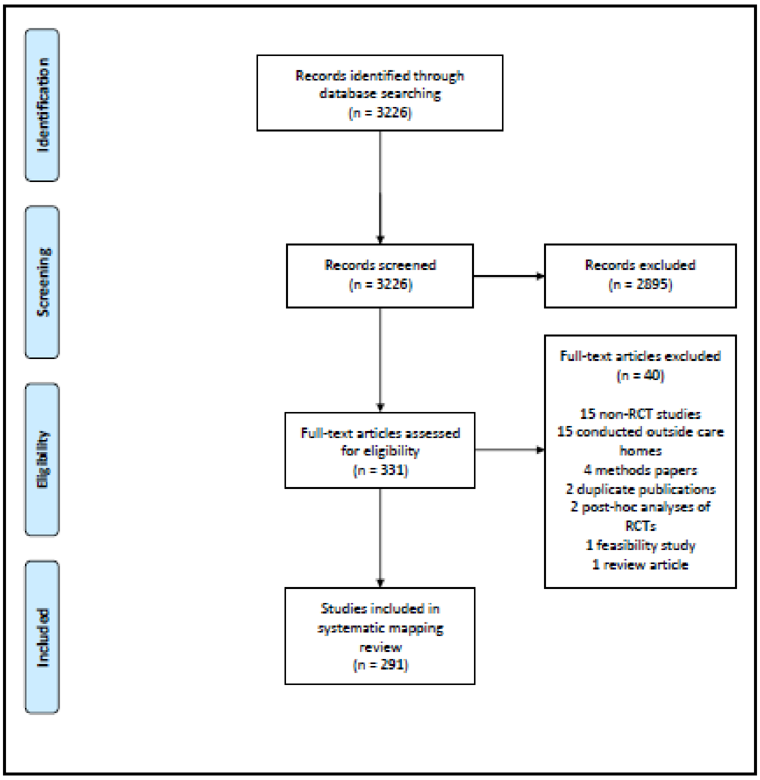


Figure 2 - PRISMA diagram for CHoLiR literature review

A further 40 articles were excluded at full review: 15 described studies which were not RCTs; 15 described research conducted in settings other than long-term institutional care (9 community-based; 6 hospital-based); 4 were methods papers; 2 were duplicate publications; 2 were post-hoc sub-analyses of RCTs; one was a feasibility study and one a review article. This left 291 articles which were considered in full. A PRISMA diagram is shown in Figure 2.

The number of articles published by each of the top 10 most prolific countries are shown in Table 3. The majority of studies were conducted in the United States. When grouped by continent, 161 articles came from North America, 87 articles from Europe, 23 from Asia, 16 from Australasia and 2 from South America. Only four articles were produced by international collaborations and only three of these by intercontinental groups.

Table 3 - Number of articles by country

Country	Number of articles
USA	145
UK	24
Netherlands	23
Canada	16
Australia	12
Japan	8
Sweden	7
China (H.K.)	7
Norway	6
France	6
Countries with 5 or fewer articles each were Germany, Belgium, Italy, Taiwan, New Zealand, Finland, Turkey, Spain, Australia, Austria, Chile, Israel, Denmark, Korea, Iceland, India, Mexico, Lithuania and Russia.	

Publication dates ranged from 1976-2009 with a mean article age of 8 years (median 6 years). The years with the most publications were 2006 and 2007. Publication rate by year is shown in Figure 3.

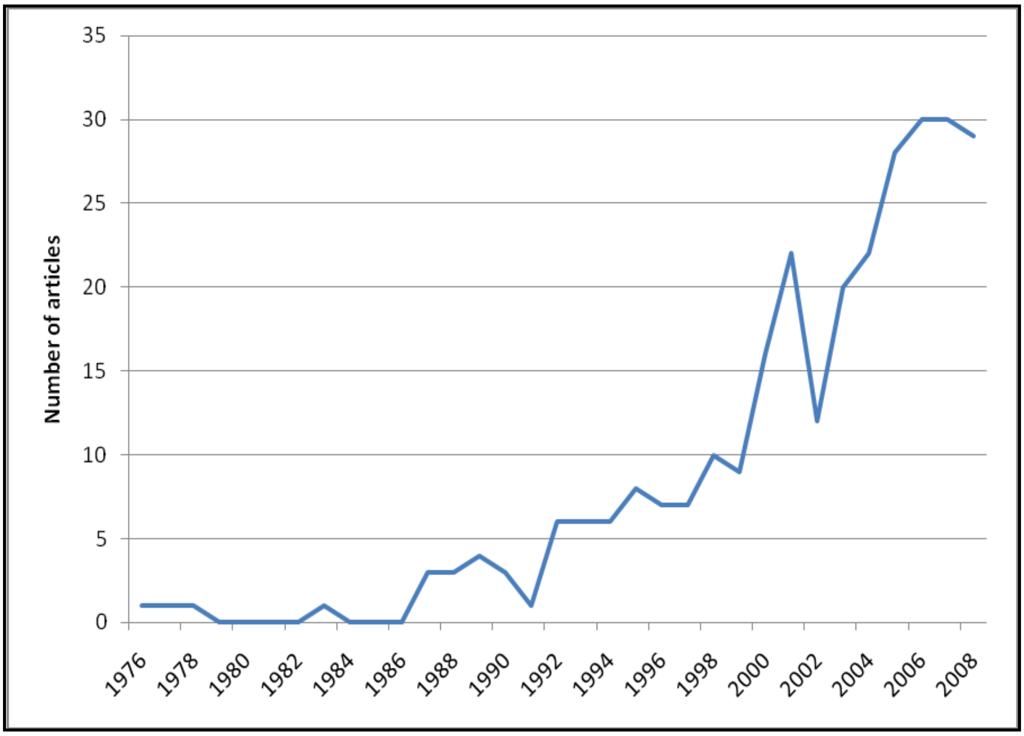


Figure 3 - Number of articles published by year

The randomization strategies used are outlined in Table 4. The most common strategy was non-stratified individual randomization. There were 43 stratified individually randomised trials. Crossover designs were infrequently employed but used more commonly for individually randomized than cluster randomized trials.

Table 4 - Randomization strategies used

Design	Stratified	Non-stratified
Cluster	23	45
Cluster Crossover	2	7
Individual Patient	42	149
Individual Patient Crossover	1	23

In cluster randomized controlled trials, the median number of clusters was 13 (range 2-223) and the median number of participants per cluster was 22 (range 1.18-177.79). A scatter plot of cluster number and size is shown in Figure 4.

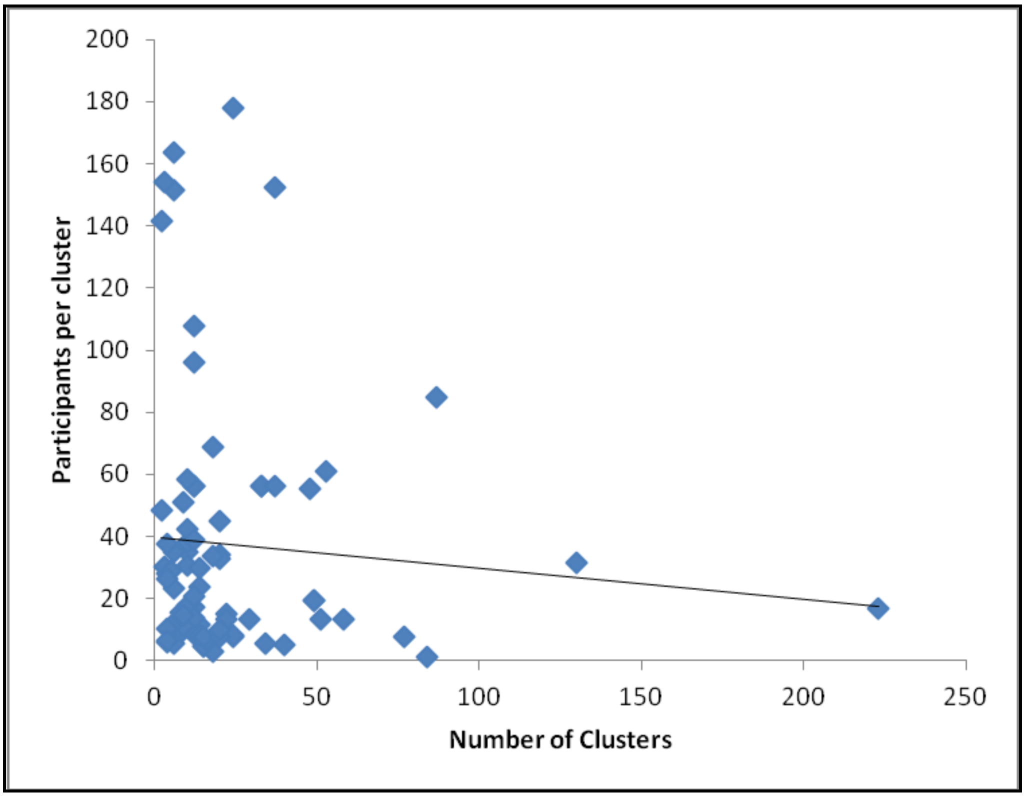


Figure 4 - Scatterplot of cluster number vs size

Where stratified randomization was used, the variables used for stratification in individual and cluster randomized studies are shown in Table 5 and Table 6 respectively. In the case of individual stratified randomization, 12/43 (28%) studies used two or more variables for stratification, whilst for cluster stratified randomization, 13/25 (52%) used two or more variables. No study used more than 3 stratification variables and the average number of stratification variables per study was 1.53.

Table 5 - Variables used for stratification of individual randomization

Variable used for stratified randomization	Number of studies
Clinical features of residents	27
Care home	10
Age	8
Care home attributes	5
Gender	5
Ethnicity	1
Source of recruitment	1

Table 6 - Variables used for stratification of cluster randomization

Variable used for stratified randomization	Number of studies
Care home size	12
Geographical location	6
Type of home (residential vs. nursing)	6
Proprietary status (private vs state vs charitable)	4
Aspects of residents' medical care (rate of drug prescribing/catheterisation)	4
Quality of care markers	3
Organisational characteristics of the homes	2
Age of residents	1
GP	1

Blinding strategies employed are shown in Table 7.

Table 7 - Blinding strategies used

Blinding Strategy/Type of Intervention	Number of studies
Double blind	85
Pharmacological	57
Vaccine	10
Dental and oral health	5
Nutritional	4
Physical therapy	3
Education of Staff	2
Case Management/Comprehensive Geriatric Assessment	2
Home administration	1
Psychological of behavioural therapy	1
Outcome assessor blinded only	72
Physical therapy	25
Occupational therapy, aids and appliances	15
Education of staff	13
Pharmacological	5
Psychological or behavioural therapy	4
Case Management/Comprehensive Geriatric Assessment	3
Nutritional	2
Home administration	2
Nursing interventions not covered elsewhere	1
Dental and oral health	1
Vaccine	1
Participant blinded only	7
Pharmacological	3
Nutritional	2
Physical therapy	1
Dental and Oral Health	1
Unblinded	128
Physical therapy	23
Occupational therapy, aids and appliances	23
Pharmacological	18
Nutritional	12
Education of staff	12
Home administration	12
Psychological or behavioural therapy	9
Nursing interventions not covered elsewhere	5
Dental and Oral Health	5
Case Management/Comprehensive Geriatric Assessment	5
Vaccine	3
Aromatherapy	1

The types of intervention investigated are shown in Table 8. The proportion (%) cluster randomized is also included as a possible marker of methodological quality, which is considered in depth in the discussion. Several studies combined interventions in more than one domain, for example pharmacological with physical therapy. Where this was the case, the study was counted for all relevant domains.

Table 8 - Types of intervention studied at RCT

Type of Intervention	Number of studies	Number (%) cluster randomized
Pharmacological	87	7 (8%)
Physical therapy	56	8 (14%)
Occupational therapy, aids and appliances	45	13 (29%)
Education of staff	32	25 (78%)
Nutritional	21	6 (29%)
Psychological or Behavioural therapy	15	1 (7%)
Home administration	15	9 (60%)
Dental and oral health	14	1 (7%)
Vaccine	14	1 (7%)
Case Management/Comprehensive Geriatric Assessment	10	4 (40%)
Nursing interventions not covered elsewhere	6	2 (33%)
Aromatherapy	1	0 (0%)

These are now considered in turn.

2.6.1. RCTs of Pharmacological interventions

This heading included RCTs evaluating drugs, their combinations and routes of administration, as well as trials of drug cessation and changes to prescribing, dispensing and drug management. This included trials of vitamin therapies where the primary target was not malnutrition.

71 studies were trials of drug therapies, the most commonly evaluated therapies being antipsychotics, vitamin D supplementation and neuraminidase inhibitors for treatment or prophylaxis of influenza (see Table 9).

Table 9 - Studies evaluating pharmacological interventions

Type of drug	Number of studies	Total Number of subjects
Antipsychotic[100-112]	13	2155
Vitamin D[113-120]	8	8447
Antibiotic/antibacterial[121-127]	7	360
Hormones	7	800
Megestrol[128-130]	3	189
Melatonin[131-133]	3	579
Oestrogen/progesterone[134]	1	32
Other vitamins and minerals	8	2695
Multivitamins[135-137]	3	1963
L-arginine[138 139]	2	58
Vitamin E[140]	1	551
Vitamin A[141]	1	109
Ferrous gluconate[142]	1	14
Neuraminidase inhibitors[143-148]	6	2390
Antidepressants[149-152]	4	176
Donepezil [153-155]	3	480
Anticholinergics[156 157]	2	113
Laxatives[158 159]	2	264
Paracetamol[160 161]	2	64
Bisphosphonates[113 162]	2	358
Others[163-168]	7	595

A further seven trials were of drug cessation, predominantly in neuroleptics (see Table 10).

Table 10 - Studies evaluating drug cessation

Class of drug stopped	Number of studies	Total number of subjects
Neuroleptics[169-172]	4	156
Antidepressants[173]	1	70
Benzodiazepines[174]	1	37
Dopaminergic therapy for Parkinson's disease[175]	1	11

Nine studies evaluated changes to the prescribing or dispensing of medications, of which the most commonly evaluated intervention was medication review by a pharmacist (see Table 11).

Table 11 - Studies evaluating changes to prescribing or dispensing

Intervention evaluated	Number of studies	Total number of subjects
Medication review by pharmacist[176-179]	4	4301
Team prescribing meetings[180]	1	1854
Protocol for antibiotic prescribing[181]	1	4267
Pharmacy outreach visits to care homes[182]	1	715
Education on drugs management[183]	1	675
Pharmacy discharge co-ordinator from hospital[184]	1	110

2.6.2. RCTs of Physical therapy interventions

This included RCTs of physiotherapy as defined by the UK Chartered Society of Physiotherapy[185], including exercise therapy, manipulation and electrotherapy, as well as other physical therapies, such as light therapy. Therapies included here might be delivered by physiotherapists or other professional groups.

Table 12 - Studies evaluating physical therapies

Intervention evaluated	Number of studies	Total number of subjects
Exercise therapy	34	3758
Generic[186-203]	18	2199
Functional incidental Training[204-213]	10	1200
Seated exercise[214-217]	4	250
Wheelchair Bicycling[218 219]	2	109
Light therapy	11	811
Bright light therapy[132 133 204 213 220-225]	10	766
Ultraviolet light therapy[226]	1	45
Physiotherapy as a service[227 228]	2	309
Massage therapy[229 230]	2	86
Tai Chi[231]	1	139
Ultrasound therapy[232]	1	88
Yoga[233]	1	50
Vibration therapy[234]	1	42
TENS[235]	1	34
Reflexology[236]	1	21
Cervical mobilization therapy[237]	1	15

2.6.3. RCTs of Occupational Therapy, Aids and Appliances

This included RCTs of Occupational Therapy as defined by the World Federation of Occupational Therapists[238]. It incorporated a wide range of interventions which share the common goal of maximising social and societal participation for residents, including aids, environmental modification, recreational therapy, multifaceted interventions for falls, continence and ADLs.

Table 13 - Studies evaluating OT, Aids and Appliance

Intervention evaluated	Number of studies	Total number of subjects
Aids	19	11471
Hip protectors[202 239-246]	10	9761
Pet therapy[247 248]	2	182
Mattresses and cushions[249 250]	2	116
Toothbrushes[251 252]	2	51
Spectacles[253]	1	142
Bathing systems[254]	1	29
Continence aids[255]	1	24
Recreational or vocational therapy[256-265]	10	461
Falls prevention[202 215 266-269]	6	1798
Bladder training or other continence intervention[207 270-273]	5	497
Goal-oriented, ADL-targeted therapy[274-277]	4	916
Occupational therapy as a service[227 278]	2	233

2.6.4. RCTs of Educational Interventions

This included RCTs of educational interventions delivered to care home staff, residents or healthcare professionals.

Table 14 - Studies evaluating educational interventions

Intervention evaluated	Number of studies	Total number of subjects
Dementia management education[262 279-283]	6	2065
Education around falls prevention/bone health[188 267 268 284 285]	5	7675
Education around communication[286-289]	4	1757
Education around palliative care[290-293]	4	1166
Education around prescribing[177 294 295]	3	3738
Others[277 296 297]	3	805
Education around physical restraint[298-300]	3	758
Education around oral healthcare[301 302]	2	632
Interpersonal skills training for staff[182 303]	2	43

2.6.5. RCTs of Nutritional Interventions

This included interventions aimed at preventing or correcting malnutrition, including vitamin supplementation and dietary fortification. Where vitamin supplements were used for an alternative indication, such as modulating immune function, treating osteoporosis or improving muscle strength, they were included under pharmacological treatments above.

Table 15 - Studies evaluating nutritional interventions

Intervention evaluated	Number of studies	Total number of subjects
Nutritional supplementation[186 304-314]	12	1053
Organisation of mealtimes[315-318]	4	520
Bran in diet[319 320]	2	42
Probiotics[321]	1	209
Flavour enhancers[322]	1	93
Low-lactose diet[323]	1	51

2.6.6. RCTs of Psychological and Behavioural Interventions

This included RCTs of therapies which used psychological or behavioural strategies.

Table 16 - Studies evaluating psychological and behavioural interventions

Intervention evaluated	Number of studies	Total number of subjects
Emotion-oriented care[153 274 324-328]	7	502
Behavioural therapy[329-331]	3	195
Self-worth therapy[332 333]	2	160
Reality orientation[153 334]	2	47
Cognitive behavioural therapy[335 336]	1	21

2.6.7. RCTs of interventions in home administration

This included studies where the main focus was a change to care home governance through implementation of new policies, protocols or systems.

Table 17 - Studies evaluating interventions in care home administration

Intervention evaluated	Number of studies	Total number of subjects
Quality improvement initiatives[182 236 337-343]	9	12530
Changes to family role/visitation[344-347]	4	276
Others[348 349]	2	541

2.6.8. RCTs of dental and oral health interventions

This incorporated interventions designed to either improve, or prevent deterioration in, oral health. It included interventions delivered by dentists, care home staff and the residents themselves.

Table 18 - Studies evaluating dental and oral health interventions

Intervention evaluated	Number of studies	Total number of subjects
Oral care/toothbrushing[186 251 252 303 350]	5	321
Fluoride therapy[351-353]	3	148
Oral healthcare education for carers[301 302]	2	632
Chlorhexidine mouthwash/gum[354 355]	2	138
Advanced restorative dentistry[356]	1	162
Denture care[357]	1	24

2.6.9. RCTs of vaccines

RCTs of vaccines were classified separately from drugs because of their differing mode of action (immunological as opposed to pharmacological).

Table 19 - Studies evaluating vaccines

Intervention evaluated	Number of studies	Total number of subjects
Influenza vaccination[358-370]	13	5314
Pneumococcal vaccination[371]	1	118

2.6.10. RCTs of interventions in case management/ CGA

This heading included RCTs where CGA, case or disease management was evaluated as a single intervention. CGA was defined according to the Ellis and Langhorne[25] and Stuck[27] definitions and case and disease management according to the NHS long-term conditions framework[11].

Table 20 - Studies evaluating interventions in case management/comprehensive geriatric assessment

Interventions evaluated	Number of studies	Total number of subjects
Psychogeriatric case management[279 329 372-376]	6	673
Disease management[377 378]	2	203
Comprehensive geriatric assessment[379 380]	2	187

2.6.11. RCTs of nursing interventions not covered elsewhere

This included studies of interventions delivered by nursing or care staff which did not fit under any of the other headings – although clearly many interventions described under other headings might also be delivered by nursing staff.

Table 21 - Studies evaluating nursing interventions

Intervention evaluated	Number of studies	Total number of subjects
Barrier nursing methods[381]	1	283
Pressure ulcer care[382]	1	235
Continence interventions[383]	1	80
Comfort touch[384]	1	45
Bathing interventions[385 386]	2	57

2.6.12. Targets of interventions

In the context of CGA, which builds interventions around the needs of patients regardless of professional or disciplinary boundaries, the targets of interventions were arguably more important than the discipline by which they were provided. These are summarised in Table 22.

Table 22 - Targets of interventions

Target of interventions	Number of studies
Behaviour	44
Prescribing	20
Malnutrition	20
Influenza	19
Quality of Life	19
Depression	18
Mobility	14
Oral Health	13
Falls	12
Quality of Care	12
Urinary incontinence	12
Cognitive performance	11
Sleep	10
Fractures	8
Immunity	8
Physical Function	8
Decubitus Ulcers	7
Osteoporosis	7
Pain	7
Constipation	5
Respiratory infection	5
Physical Restraint Use	3
Skin Health	3
Vitamin D deficiency	3
General health	2
Swallowing	2
Compliance with OT	1
COPD	1
Cough Reflex Sensitivity	1
Dehydration	1
Dementia	1
Faecal Incontinence	1
Hypertension	1
Interpersonal skills	1
Microbial colonization	1
UTI	1

Given that targets are a logical means by which to classify studies when considering CGA - a comprehensive summary of interventions, outcome measures and study findings, grouped by target, was compiled. Due to the length of the resulting table, this can be found in Appendix 2.

2.7. Discussion

An explosion of interest in care home research was evident from a doubling of the publication rate over 10 years (Figure 3). Much of this activity had taken place in the USA. There were some caveats, which are discussed in section 2.7.5, around possible biases introduced by the literature search methodology which could have resulted in over-representation of studies from Anglophone countries in general, and North America in particular. It is, however, unlikely that these could fully explain the clear lead established by North American researchers. The US predominance reflects, to some extent, the picture seen across all medical disciplines represented in the published literature which has been attributed, in part, to the higher levels of funding-support available to US researchers[393]. It may also reflect widespread professionalization in the long-term care sector in the US – where physicians, including statutorily appointed medical directors, have had an integral role in providing nursing home care[394] and administrators are certified and licensed[395]. The emergence of the Journal of the American Medical Directors Association (JAMDA) as the 7th highest impact factor journal in the Gerontology and Geriatrics category of the Thomson Reuters Journal Citation Index in 2009[396] was an example of the growing influence of this sector in the US over the preceding 10 years. In the UK, by comparison, over the same period long-term care was only beginning to be recognised as a healthcare sector in its own right and no special certification was available to, or required of, doctors, nurses or administrators to work within it[397]. Whether the larger role played by doctors, a group traditionally associated with professional enfranchisement, in the US long-term care sector played a role in its professionalization is unclear. It is, however, worth noting that the Netherlands had a care home article publication rate per head of capita 3.5 times greater than the UK over the period studied and that the long term care sector in the Netherlands has been defined by the prominent leadership role played by its physicians[37].

As discussed earlier, differences in the organisation, funding and resident mix between US and UK care homes[40] over this period were such that it might be anticipated that few of the findings reported here would be applicable in the UK setting. However most were. The exceptions were studies considering quality assurance measures based around the US Minimum Data Set (MDS) [339 342], which was not routinely used in the UK during the study period, and those evaluating medications not licensed in the UK[111 122 126 144 145]. Others seemed initially to have limited relevance to the UK setting, an example being those studies which investigated educational programmes to reduce the use of formal physical restraints[298-300] not widely used in the UK[398]. However on further consideration, for example when these were considered in the context of the prevalent use of less formal restraints, such as cot sides or tray tables[399], clear lessons were identifiable.

Considering the central question of this thesis, around the role of CGA in care homes, those articles specifically focussing on CGA and case management in care homes which were selected out for narrative review are considered first. Lessons from the broader literature concerning component interventions which might comprise part of CGA are then discussed. Finally, methodological issues identified through the review, which might be important to future research evaluating the role of CGA in this setting, are presented.

2.7.1. Trials evaluating CGA and case management

Of the ten studies classified under this heading, one was a trial of disease management for COPD in the care home setting[377]. The remaining nine considered comprehensive geriatric assessment, comprehensive psychogeriatric assessment, or case management as their primary intervention and are reviewed here.

2.7.1.1. CGA/case management targeting behaviour

Three studies considered the role of CGA in treating behavioural disturbance in care home residents with dementia.

Opie *et al*[373] evaluated individually targeted psychosocial, nursing and medical interventions delivered by a team comprising a psychologist, psychiatrist and nurses in 99 Australian nursing home residents. Their research design was governed by resource limitations and somewhat complex. Participating homes (n=42) were asked each to identify two residents with behavioural disturbance. Where more than two residents were identified in a home, those with the most frequent and severe behaviours – seemingly based upon staff accounts – were selected for participation. Participants were cluster randomized at a whole home level (n=2 per cluster) to receive either early or late intervention, the late participants acting as the control group. The rationale for this design was based upon the anticipation that homes would refuse to participate if only offered a control intervention. They delivered a mean number of interventions of 4.6 per resident with 46 receiving input from all three disciplines in the team, a further 47 receiving interventions from two team members and six receiving monodisciplinary input. The types of intervention used are illustrated in Table 23.

Table 23 - Summary of interventions undertaken in context of Comprehensive Psychogeriatric Assessment by Opie *et al*[373]

Description of intervention	*n*
Medical	93
Commence psychotropic	15
Change type/dose/timing of psychotropic	7
Change pain management	18
Request test/medical treatment	8
Nursing	141
Timing/approach to ADL (e.g. Bathing)	50
Communication, aggression management	31
Comfort (e.g. Seating)	18
Rest periods	16
Snack foods	12
Other (e.g. Removing restraint)	14
Psychosocial	213
Radio, audiotapes	29
Environmental change	23
Behaviour modification	21
Regular walks	19
Touch/massage	14
Aromatherapy	14
Books, pictures	14
Personalized activity	11
Reminiscence	11
Social interaction	10
Staff cultural kit	9
Companion resident	9
Other	29

It is worth noting that the taxonomy applied by Opie *et al* differed from that applied in this review, so that interventions which would be regarded as occupational therapy (environmental modification) or physical therapy (massage) in the context of this review were regarded as psychosocial by Opie. That such interventions took place, albeit under the auspices of different professions than in a medical MDT, underline that the intervention here represented CGA.

The results were not convincingly positive, with a failure to demonstrate significant difference between groups for either Behaviour Assessment Graphical System (BAGS) or the Cohen Mansfield Agitation Inventory (CMAI), although there were some differences between groups in more generic staff reports of behaviour (arguably irrelevant as staff were unblinded to the treatment allocation). The authors attributed this, in part, to a complex study design which introduced a "Hawthorne effect" – a significant improvement in outcome measures in both groups over time, triggered by positive behaviours associated with being observed[400]. A more likely explanation for the failure to demonstrate a treatment effect, not mentioned by the authors, was that the time-lag between intervention for the early and delayed treatment arms was one week. In the context of behavioural modification, this left very little time for treatments to be initiated or take effect. This suggests a possible failure to understand the mechanism of CGA, which requires for the prescribed interventions to both be instituted and take effect before any treatment effect can be measured.

Cohen-Mansfield *et al*[330] considered the role of a behavioural case management programme in 167 residents of 12 US nursing homes. Homes were cluster randomized at an individual home level to receive either: detailed assessment led by a geriatrician in conjunction with care home staff, coupled to commencement of tailored interventions which included pain management but predominantly comprised activity-oriented therapies such as doll therapy, music therapy, or provision of videos or books; or a control intervention comprising education for care home staff around syndromes of agitation, their aetiologies and non-pharmacological treatments. The components of the intervention were not detailed. The intervention period lasted 10 days with behavioural observations conducted within four designated hours of the first and last three days of the intervention using the Agitated Behaviours Mapping Instrument (ABMI) for agitation and an observational measure of positive and negative affect developed and validated *de novo* by the study group. They reported a reduction in the number of observed aggressive behaviours and an increase in the number of behaviours suggestive of positive affect in the treatment arm. A major caveat, however, as for the Opie study, is the short latency of follow-up which means that many behavioural interventions would not have had time to become established – in which light the positive outcome is somewhat difficult to explain.

Brodaty *et al*[376] evaluated a comprehensive psychogeriatric evaluation in 86 subjects from 11 Australian nursing homes, the targets of the intervention being abnormal behaviour and/or depression in the context of dementia. The intervention incorporated physical and psychiatric examinations and involved psychiatrists, psychiatric nurses and nursing home staff. Although the assessment was quantified, the nature of the resulting interventions was not. Participants underwent individual randomization, stratified by care home size, to receive either comprehensive psychogeriatric assessment, a conventional psychogeriatrician only consult, or usual care. Although the psychiatric morbidity of participants in all three arms improved significantly there was no difference between groups on a battery of indices including the Even Briefer Assessment Scale for Depression (EBAS-DEP), Hamilton Rating Scale for Depression (HAM-D), Cornell Scale for Depression in Dementia (CSDD), Geriatric Depression Scale (GDS), Neuropsychiatric Inventory (NPI), SAD faces, Behavioural Pathology in Alzheimer's Disease Rating Scale (BEHAVE-AD), Scale for the Assessment of Positive Symptoms (SAPS) and clinical interview. The outcome assessor was blinded for the interview data only. The duration of follow-up in this study was more appropriate at 12 weeks, however the other systematic failures, namely failure to cluster randomize and to adequately blind outcome assessors draw the findings into question.

2.7.1.2. CGA/case management targeting depression

Two studies considered the role of case management in treating depression, the first of these by Brodaty *et al*[376] has been discussed already. The second, by McCurren *et al*[372], randomized 85 US nursing home residents with a GDS > 10 and a Folstein Mini-mental State Examination (MMSE) > 19 to receive either comprehensive assessment and care planning by a specialist nurse practitioner, or usual care. Randomization was stratified by GDS (mild vs. severe depression) at baseline using block permutation. All participants received once weekly visits by the nurse and twice weekly visits by a team of volunteers, who were trained and supervised by the nurse. Outcome assessors were blinded. The intervention was designed in response to individual needs but was universally based around talking therapies, without reference to either physical comorbidity or prescribing. It continued for 24 weeks, with outcome assessments (GDS, the mood subset of MDS, MMSE, Salamon-Conte Life Satisfaction in the Elderly Scale (LSES) and functional ability) measured at 12 and 24 weeks. The treatment group had a significantly lower GDS at follow-up both by comparison with baseline and the control group. However, although a successful intervention, with components of case management, this study doesn't contribute much to the understanding of CGA in this setting due to the narrow focus of both the assessment and the intervention.

2.7.1.3. CGA/case management targeting quality of life

Kotynia-English *et al*[374] took the somewhat different approach of an intervention which conducted a comprehensive psychogeriatric assessment routinely on patients admitted to care homes in the area around Perth, Australia. 106 new admissions to 22 homes were given a battery of tests incorporating the GDS, Health of the Nation Outcome Scale for over 65s (HoNOS 65+), MMSE and NPI and were then randomized without respect to the outcome of these baseline variables. Those in the treatment arm with significant psychiatric morbidity were referred to mental health services, whilst those in the control arm received usual care. The group found no difference in the average number of medical contacts, self-rated health, use of psychotropic or

PRN medication, use of physical restraint, mortality, or mental health outcomes, as measured by the GDS-15, HoNOS 65+ and NPI between groups at 12 month follow-up. They concluded that screening did not significantly augment the mechanisms already in place to support and treat psychiatric morbidity in the cohort. Alternative interpretations are that the screening tools used were insufficiently sensitive and specific to identify treatable psychiatric morbidity in this cohort, or that the treatments instituted by the mental health team, which were not quantified in the research article, were ineffective in modifying outcomes.

Orrell *et al*[378] recruited 24 UK care homes in pairs matched for size, locality and registering body. 11 residents were selected at random from all residents with dementia within each home. One home in each pair was then allocated at random to treatment or control. Residents in both the treatment and the control arms underwent a comprehensive needs assessment at baseline and 20 week follow-up using the Camberwell Assessment of Needs Questionnaire (CANE) – a comprehensive tool which identifies individual needs and encompasses medical, social, psychological and environmental domains. Intervention homes were supported by an MDT comprising a mental health nurse and clinical psychologist who had access to the CANE results and used these to build individualised care plans, whilst control homes received usual care. The MDT visited intervention homes for 2 hours every fortnight to ensure that the individualised care plans progressed as intended. The intervention did not have any effect on either unmet needs measured using CANE or quality of life measured using the Quality of Life in Alzheimer's Disease Scale (QoL-AD).

With this intervention, although the focus of the CANE was admirably wide, the narrow skill range of the MDT employed, which again focussed on a psychiatric skill-set at the expense of somatic domains, may have adversely influenced the impact of the intervention and the results can be taken to have only passing relevance to CGA in its broader sense.

2.7.1.4. CGA/Case management targeting pain

Kovach *et al*[378] conducted an RCT of an intervention targeting unmet needs in dementia in residents of US nursing homes which had many features of CGA even though it was delivered predominantly by nurses. The procedure, called a serial test intervention (STI) comprised multiple stages which incorporated behavioural, physical and affective assessments before escalating through non-pharmacological measures for discomfort, onto analgesics and then psychotropic therapies. Specialist help was enlisted using prompts within the STI tool at appropriate intervals. 114 residents across 14 homes were cluster randomized to receive either the intervention or a control intervention comprising an unrelated educational programme for staff. The geographical isolation of the homes and the nature of the control intervention were such that double blinding was possible. Outcomes were measured using the Discomfort Scale for Dementia of the Alzheimer’s type (DS-DAT) and BEHAVE-AD, with DS-DAT demonstrating significant reduction in discomfort in the intervention arm. No corresponding change in behaviour was seen. Although apparently a robust analysis of a CGA-like intervention, the study did not seem to account for clustering in either its power calculation or analysis of outcomes, thus almost certainly over-estimating treatment effects and underestimating the size of confidence intervals. The results must therefore be treated with caution.

Chapman *et al*[379] evaluated CGA delivered by Advanced Illness Care Teams (AICTs) in US nursing homes. AICTs comprised doctors, nurses, physio- and occupational therapists, social workers and psychologists. They conducted a holistic assessment at baseline and implemented individualized treatment plans based upon this over an 8 week period. Although the intervention was reported as a generalized holistic intervention, it is clear from the outcomes measured – CMAI; Face, Legs, Arms, Crying and Consolability pain scale (FLACC); CSDD; Pain in Advanced Dementia scale (PAINAD) – that the primary targets were pain and psychiatric morbidity. It was an individualised partial-crossover study, with the randomization and cross-over mechanisms reported in oblique terms that made them difficult to fully comprehend but, by the time of analysis, 57 residents had been seen by the AICT and 61 had received routine care only. The study was reported as double blind – although quite how double blinding was maintained in the context of a multi-disciplinary intervention delivered at the individual level within an institutional setting is unclear. The only test to demonstrate a difference between groups difference was CMAI, which showed a significant reduction in physically non-aggressive behaviour only. Although the intervention tested here was clearly a variant of CGA, the methodological issues surrounding the study are such that this does not inform the debate around CGA in care homes to any great extent.

2.7.1.5. CGA/case management targeting general health

Cavalieri *et al*[380] evaluated physician-led CGA, with support from an MDT comprising nursing, physio- and occupational therapy, in a nursing home setting. 69 residents were individually randomized to receive either CGA or usual care in an unblinded study. They recorded significantly greater use of outpatient health services but a significantly lower average number of prescriptions in the CGA group. There was no difference in hospital admissions or longevity between groups. There is a face validity to these findings, however the fact that this was a statistically underpowered, unblinded study means that it can be taken, at most, as a spur to further research.

2.7.2. Trials evaluating components of CGA

Considering the table in Appendix 2, a number of clinically relevant outcomes were identified which are summarised here.

For interventions targeting behaviour, results of drug studies were mixed. Most evidence was available for risperidone[100 105 107 109 110 401] and olanzapine[103 108], both of which were shown to be effective in correcting behavioural and psychiatric symptoms in dementia (BPSD) against behavioural scales including NPI, BEHAVE-AD and the Clinical Global Impression Scale (CGI). Adverse events were recorded including extra-pyramidal gait symptoms, gait disorder and somnolence and were more frequently recorded in risperidone studies (although it should be noted that no direct comparison between olanzapine and risperidone had been undertaken in this setting). These findings come with significant caveats, given the UK Medicines and Healthcare Products Regulatory Agency (MHRA)'s recommendation against prescribing risperidone and olanzapine in the elderly[16]. They do, however, provide evidence upon which to base practice on the rare occasions when specialist prescribers feel there is a clear indication for antipsychotics[402]. In the context of the MHRA recommendations, it is important that two small studies suggested that antipsychotic therapy could be safely withdrawn without significant adverse events[171 172].

Although reports were mixed and treatment effects typically small, there was some evidence to suggest a role for non-pharmacological behavioural management in care homes. A study of physical activity in 134 care home residents showed no improvement in behaviour despite significant improvement in physical performance parameters[193], however when a physical activity programme was coupled to guidelines surrounding psychotropic medication and regular educational rounds, a reduction in agitation and physical restraint were witnessed[262]. It is not clear what proportion of the treatment effect in this latter study can be attributed to exercise and what to the changes in prescribing. Three small studies of music therapy suggested a possible role in reducing agitated behaviours[260 261 264]. Staff education[280 286 288 293] around communication in dementia led to a reduction in the prevalence of agitated behaviours in several small studies. Under the heading of psychological and behavioural therapies, an RCT in 92 residents comparing a psychomotor activation programme with usual care demonstrated improvements in both agitation and group behaviour[263]. Lavender aromatherapy demonstrated significant improvements in both NPI and CMAI scores in a study of 70 residents when compared with sunflower oil (placebo) aromatherapy[388]. A small study suggested that towel bathing and person-centred showering may have a positive effect on agitated behaviour when compared with usual care[386]. For most of these interventions, there was sufficient evidence to suggest some merit in further, more comprehensive, evaluation but insufficient evidence to support immediate widespread adoption.

Seven studies targeting prescribing looked at incorporating pharmacist review, with or without physician involvement, into clinical pathways either on or after admission to care home[176-179 182 184 389]. Five of these reduced[176 177 179 184 389] and two had no effect upon[178 182] the number of drugs prescribed per resident. For the most part this was without either harm or clinical benefit[176 177 389], although one study did report a reduced readmission rate[184] and another reduced falls rate[179]. One study reported an increase in aggressive behaviour measured using the CRBRS following reduction in number of prescriptions[176]. Other, more targeted interventions suggested it was safe to withdraw hypnotics[174], neuroleptics[169 170], anti-depressants[173] and even anti-Parkinsonian[175] therapy in selected cohorts – although these findings all come from studies which were small and underpowered to detect the type of adverse events they claimed to dismiss.

The influence of care home staff over prescribing was evident from three studies which evaluated educational packages delivered to care home staff around psychopharmacology and which demonstrated significant reductions in the number of antipsychotics prescribed per resident in intervention homes[183 282 292]. Similar effects were shown for NSAIDs following an educational package around pain management[294].

For interventions targeting nutrition the most convincing, clinically meaningful outcomes (improvements in body weight and/or anthropometric measurements) were demonstrated for nutritional supplementation using vitamins and/or minerals[307 309 312 313] and protein-energy supplementation[186 310 311 314]. Although these were predominantly small studies, the consistency of interventions applied and results yielded were convincing. Given the homogeneity of intervention and outcome measures, these studies might be appropriate for future meta-analysis. Other interventions to demonstrate clinically meaningful positive outcomes were the use of family-style dining arrangements[316 317] and the provision of feeding assistance[315]. Although there were 20 studies targeting malnutrition, and several of these interventions would have been expected also to have affected dehydration, only one study[312] used an outcome measure (fluid intake) which would allow meaningful conclusions to be drawn about hydration status. Only one study specifically targeted dehydration, demonstrating that a prompted preferred beverage programme can significantly improve fluid intake and lower blood urea nitrate[277].

For interventions targeting depression, drugs tested in this setting showed no benefit[149-152], with the caveat that studies were small and therefore likely to be statistically underpowered. Studies of physical therapies including light therapy[224], exercise therapy[218 219 336] and yoga[233], although also small in size, were more positive. A trial of self-worth therapy in 63 Taiwanese care home residents showed a significant reduction of depressive symptoms in the treatment arm[332]. One caution with such small trials is that they may be underpowered to detect adverse outcomes, even though they show a small treatment effect. These findings suggest that further research activity might be legitimately focussed around either pharmacological or non-pharmacological management but none of these studies is sufficiently powerful, in isolation or combination, to drive clinical management. Case management studies targeting depression in this setting were mixed and are discussed under CGA/case management above.

In studies focussing on influenza, prophylaxis studies, although mixed, suggested a likely role for zanamavir or oseltamivir in prophylaxis of influenza in care home settings[143 144 148]. Most of the vaccine studies, meanwhile, compared different preparations or doses of influenza vaccine[360 361 363 365 367-369]. Where influenza vaccination was compared to placebo, either in the context of resident or staff vaccination, it was shown to be effective[358 359 390]. Comprehensive reviews of this literature are published elsewhere[403].

Several studies targeted quality of life with positive outcomes including: physical therapy – tai chi, back rubs [230 231]; occupational therapy, aids and appliance focussed interventions – spectacle correction of eyesight, engagement in teaching activities and pets[247 253 256]; psychological therapies – self-esteem counselling and life-review programmes[325 333]; and staff training in end of life care and dementia[281 290]. However, there are difficulties with measuring quality of life in the care home setting – discussed in section 2.7.4. – which mean that these results come with significant caveats. The challenge to these findings is not whether a measurable change occurred but what the measured change actually means – is it really an objective measure of quality of life or a multi-dimensional measure, which is actually detecting changes in psychiatric or physical morbidity or cognition? Much of the work targeting quality of life going forward will require to focus on reliable quality of life measures in care home residents before further effort is expended on interventions to improve these.

A number of physical and occupational therapy interventions had positive effects on outcomes including measures of postural stability, flexibility and gait[187 192 195 197 200 202 208 210 216 217 234]. These challenge the assertion that care home residents might be “beyond rehabilitation” and are further supported by the positive outcomes for physio- and occupational therapy when used to target physical function[203 227 228 278]. As a group of articles they represent a legitimate target for more detailed review, possibly including meta-analysis, given the homogeneity of interventions and outcomes measures across studies.

Studies targeting falls, fractures and osteoporosis are perhaps best considered together, given the considerable clinical overlap between these domains. The literature studied suggested that calcium and vitamin D had a role in preventing falls and fractures[116] and that bisphosphonates had a role in osteoporosis[162]. Reports from trials of RCTs of falls prevention programmes were mixed with some reporting a reduction in falls[188 266] and others reporting only a trend towards this[267 268]. A fracture-preventative effect from hip protectors was not shown in this cohort[240 243].

Several trials evaluating various aspects of oral health and the impact of dentistry showed positive outcomes in terms of measures of oral hygiene[121 302 350 353]. No convincing effect on wider health status was demonstrated.

Most striking amongst the interventions targeting quality of care were those focussing on end-of-life care where a large study evaluating staff training around death and dying demonstrated improvements in attitudes towards dying patients[290], whilst an advanced directive support programme[343] and interviews assessing appropriateness for hospice care[236] were able to influence the number of inappropriate admissions to hospital and transfer to hospice care respectively. These latter two studies were large and, although unblinded, used objective outcomes (number of admissions, venue of care) that were unlikely to be significantly influenced by observer bias.

Regarding incontinence, none of the drug-based interventions studied were shown to be effective[125 134 156 157]. Non-pharmacological therapies, including functional incidental training, bladder training and mobility interventions demonstrated more positive outcomes[270-273 292]. For functional incidental training and bladder training the studies were sufficiently large and well designed to consider these treatments effective.

In studies targeting cognition, some medium-sized RCTs evaluating drugs had mixed results but probably showed no benefit overall[154 155 167]. A number of small studies evaluating physical and behavioural therapy interventions were positive but were insufficiently homogenous in terms of interventions or outcome measures to either steer clinical decision making or inform systematic review and further research in these areas is clearly merited[153 198 203 263 331].

Regarding sleep, several drug, physical therapy and nursing studies failed to show much benefit[131 133 163 204-206 213 220 223], however the studies were small and statistically underpowered. A conceptual challenge to research in this area seems to have been the realisation that positive outcomes are more likely when multiple interventions are combined. Further research evaluating combinations of drugs (predominantly melatonin), physical therapies (predominantly light and exercise) and nursing interventions (predominantly sleep hygiene and daylight stimulation) have been proposed[404].

2.7.3. Trials of CGA and its components – a summary

To draw the key findings on CGA and its components together:

- CGA had not been well tested as a whole intervention in this setting. Studies either showed significant methodological flaws or tested focussed models of case management – predominantly focussing on psychological parameters – that didn’t address the hypothesis that holistic, comprehensive, multidisciplinary assessment and subsequent management planning could change management and patient outcomes.

- Some components of CGA were shown to work. This was the case for: advanced care planning; pharmacy interventions to reduce prescribing; staff education around prescribing, dementia and end-of-life care; calcium and vitamin D in preventing fractures; alendronate in preventing osteoporosis; influenza vaccination; oseltamivir or zanamivir for influenza prophylaxis; functional incidental training and bladder training for incontinence; and risperidone and olanzapine for agitated behaviours in carefully selected patients under expert guidance.

- One component of CGA – hip protectors – was shown not-to-work in this setting.

- Some groups of studies were sufficiently homogenous, both in terms of intervention and outcome measures applied, to merit more detailed systematic review and/or meta-analysis. This was the case for nutritional supplementation and interventions targeting mobility.

- For most other domains there was an equivocal body of evidence, with small, diverse, or methodologically unsound, studies which failed to provide a robust evidence to drive clinical practice. Further research would be required to provide this.

2.7.4. Methodological issues in care home research

A number of methodological issues affecting the conduct of research in care homes were identified. These are relevant to the central argument of this thesis in so much as they would influence how research to evaluate CGA in this setting might be designed.

Considering the outcome measures shown in Appendix 2, the majority of studies used resident, proxy or observer completed questionnaires. Although a detailed interrogation of the metrics of these is beyond the scope of this thesis, several of the resident response measures have shortcomings at the extremes of cognitive or physical frailty which mean that they almost certainly represent inadequate tools for describing the care home population. To provide some examples: the GDS, used as an outcome measure in 29 studies here, has been shown to be less sensitive and specific in the care home population than in the wider community and alternative diagnostic cut-offs have been suggested[405] which were not used in any of the studies reported here; the Hospital Anxiety and Depression Scale (HADS), used in two studies, is not designed for application in the care home setting and has not been evaluated in advanced dementia[406]; and the 28-item General Health Questionnaire (GHQ-28), used in two studies, becomes largely unusable in advanced dementia due to the complex cognitive constructs employed[407].

Of greater concern than the selection of inappropriate measures for studies, however, was the use of measures which, even though well validated in the care home setting and advanced cognitive impairment (for example NPI[408], CSDD[409], CMAI[410], BEHAVE-AD[411]), were entirely dependent on observations or proxy accounts for their completion. Such observations and proxy accounts came predominantly from care home staff, whose reliability as proxies is uncertain. Kane *et al*[412] considered the effectiveness of staff as quality of life (QoL) proxies for care home residents by comparing responses of 50 communicative care home residents to questionnaires summarising QoL and emotional wellbeing with proxy responses from staff and family members. Notably, from a study where the authors had sought to exclude poorly communicative participants, they were able to obtain meaningful responses from only 60% of residents. The correlation of staff responses with those of residents was low for QoL domains (Pearson's r=0.131-0.365) and non-existent to low for emotional domains (r=0.071-0.176). Family members performed consistently better than staff but only just so. Lum *et al*[413] compared MDS measures of ADL performance in 3385 care home residents with data recorded at interviews with residents, family and staff members, demonstrating poor-moderate agreement between all interviewees and MDS observations. Agreement was calculated using Fleiss' kappa – a statistic widely used to assess inter-observer variability[414] – and was, at best, fair for each of residents (κ=0.25-0.48), staff (κ=0.29-0.50) and family members (κ=0.31-0.52). The reliability of proxy measures in those residents unable to communicate is even less certain and convincing solutions as to how to measure outcomes in these residents have not yet been developed.

The role of blinding in a trial becomes particularly important where subjective outcome measures, such as the proxies already described, are employed. Wood *et al*[415] conducted a meta-epidemiological analysis comprising 146 meta-analyses of 1346 trials to investigate the association between inadequate blinding and biased estimates of treatment effect. They used a ratio of odds ratios as a measure of bias and reported this to be 0.75 (95%CI 0.61-0.93) for subjective outcome measures and 1.01 (0.92 to 1.10) for objective outcome measures. Given this, it is worrying that 128 (44%) of the studies reviewed here were unblinded. Only 85 (29%) were double-blind and, in the absence of double-blinding, only 72 (25%) blinded the outcome assessor. As expected, most of the double-blind studies evaluated drugs or vaccines, these interventions being readily amenable to patient blinding. Non-pharmacological interventions, predominantly in physical and occupational therapy, comprised the majority of single outcome-assessor blinded studies and also the bulk of unblinded studies.

The difficulties of blinding participants to rehabilitation interventions are well documented[55 56] – whilst placebo interventions are available for some physiotherapy interventions, such as seated exercises in lieu of weight-bearing exercises[197], it can be difficult to blind participants to all aspects of rehabilitation, for example whether they have received walking aids from a therapist. This can introduce performance bias – changes in the way in which participants are dealt with influenced by knowledge of their treatment allocation[416]. However of far greater concern, particularly when subjective outcome measures are employed, is ascertainment bias

– where outcome assessors are influenced in their measurements by knowledge of treatment allocation[417]. In this context, blinding of outcome assessors becomes an imperative if the RCT methodology is to be of use at all[416].

The picture may not be as bad as it initially seems. Montori *et al*[418] reviewed 200 articles from five leading journals in 2002 and found less than 25% to explicitly report their blinding status. The Consolidated Standard of Supporting Trials (CONSORT) group continue to consider the reporting of blinding to be grossly inadequate[417]. So the failure may be in reporting, rather than conduct. However, the failure to adequately report blinding perhaps indicates a naivety about its importance in this context.

Very few of the articles reviewed considered the numerous possible sources of unblinding for outcome assessors in the context of care homes where they have to come into contact with staff, residents, family members and a built environment all of which may be effected by the intervention. These issues are compounded in cluster randomization, where accidental unblinding of a single participant can unmask treatment allocation for an entire cluster.

Table 4 shows that 77 (26%) studies employed cluster randomization, the majority of these being RCTs of non-pharmacological interventions relating to education of staff, home administration, occupational and physical therapy. The use of cluster randomization in these topic areas is perhaps unsurprising given the nature of such interventions and the stated aims of cluster randomization as: avoiding cross-contamination by staff providing aspects of the intervention to participants in the control arm; and allocating trial interventions in a way which simulates how they would be delivered in clinical practice (i.e. at a whole home level)[419]. However, as shown in Table 8, 48% of the studies in these topic areas were not cluster randomized even when in some instances, such as continence interventions[273 420] or inclusion of physical exercises into daily routines (functional incidental training)[205 213 421-423], cross-contamination by staff might be expected. This implies that either the benefits of cluster randomization were not universally agreed or understood, or more likely that the cumbersome methodological considerations associated with cluster randomization are a deterrent. At the forefront of these are the difficult statistics which need to be undertaken to adequately power and appropriately analyse cluster randomized RCTs and the prohibitively large sample sizes which may be required to allow such statistical analysis[424].

That is not to say that, where conducted, cluster randomization was always done well. Whilst this review did not include a detailed analysis of randomization methodology for each study, some useful overarching points can be made by considering the number and sizes of clusters as illustrated in Figure 4. Sample size calculation for cluster randomization is notoriously complex as it must determine both an optimum number and size of clusters, which in turn depends upon the presence of identified pretest co-variables and the amount of inter-cluster correlation (sometime expressed in terms of between cluster variance)[425]. Whilst this makes it difficult to comment upon the size and number of clusters recorded per trial, it is worth noting in the context of care homes that there is likely to be a fair degree of intra-cluster correlation for many important variables such as dependency, cognitive impairment, levels of prescribing and comorbidities – as all of these are affected by institutional policies around client selection and day-to-day management, which are also likely to differ between homes. A rule of thumb is that the higher the intra-cluster correlation, the higher the number of clusters required to achieve statistical precision (see Table 24).

Table 24 - Effect of intra-cluster correlation on sample size in cluster randomized trials assuming a constant cluster/person cost ratio, derived from Raudenbush[425]

Intracluster correlation (ρ)	Number of participants per cluster	Number of clusters	Sampling variance (γ_1)
0.01	14	31	0.0103
0.05	6	61	0.0133
0.1	4	80	0.0156
0.2	3	104	0.0186
0.5	1	146	0.0233*
*A $\gamma_1 \geq 0.0225$ is regarded as lacking sampling precision for the purpose of this analysis.			

The number of clusters in the reviewed articles ranged from 2-223. At the lower end of this spectrum, where a single coin toss determines the treatment allocation of all trial participants, the trials were unlikely to have any properties of randomization. The cluster-size ranged from 1-177. Although small cluster size does not generate statistical problems per se, one has to question the rationale for using cluster methodology, with associated loss of statistical power, in a situation where there is just over one participant per cluster. It should be noted from Table 24 that there is an inverse relationship between the optimum size and number of clusters required and that this is not the relationship demonstrated in Figure 4, where most studies have both a small average size and number of clusters. Taken cumulatively, these data would tend to suggest that, although the rationale for cluster randomization is sound, the methodology is imperfectly applied in practice – probably because of the technical difficulties encountered in doing so.

Stratification, where participants are separated into strata which are randomized separately, is used as a means of preventing unequal distribution of important co-variables which may confound the outcome measure across treatment and control arms[417]. It can be a useful mechanism to control for confounding, particularly in small studies where the likelihood that key co-variables might be unequally distributed between treatment and control arms is high. Although formulae exist to calculate the maximum parsimonious number of strata appropriate for an RCT based upon sample size, the general rule regarding their use is the fewer strata used the better[426]. Overstratification results in failure to fill permuted blocks, with the consequence that less relevant stratifying variables may cloud the effects of important ones[427]. In this context it is reassuring to note the low mean number of strata (1.53) across the articles reviewed and that no study exceeded 3 stratifying variables. The variables chosen by researchers for stratification provide some insights into what they regard as important confounding variables in the care home setting, with organisational features of care homes (type, size, geographical location, proprietary status) featuring highly. This further underlines the complex interaction between home and individual which must be allowed for in evaluating all but the most simple interventions in this setting.

One disadvantage of stratification is that it requires block-permuted randomization to make it work[417]. This is both more complex than simple randomization and more predictable, running the risk of loss of allocation concealment unless further complex safeguards, such as variable size block-permuted randomization, are used. Given that many of the stratification variables chosen in the reviewed articles focussed around care home organization, i.e. care home cluster level variables, an alternative strategy would be to account for confounding by appropriately powered cluster randomization. Some studies reviewed chose to use stratified cluster randomization but, given the technical difficulties exemplified in the reviewed literature, it is tempting to suggest that adopting one strategy and doing it well is preferable to doing both inadequately – unless there was a grossly compelling case to use both.

To summarise the findings around methodology. Pharmacological and vaccine related studies were most likely to be double-blind and physical and occupational therapy studies to be unblinded. Many of the outcome measures used were subjective, raising concerns with trials where outcome assessors were not blinded. In addition, the wider reliance on proxies draws into question the robustness of many of the findings reported. Cluster randomized studies were most likely to be related to education, home management, or occupational or physical therapy – however, almost half the studies in these areas were not cluster randomized, raising issues around cross-contamination. Cluster randomization was imperfectly executed, with many studies having clusters which were too small or too few. Stratification was conducted parsimoniously with a tendency to select variables focussed around care home structure and organisation.

Considering these, one can start to propose some rules for conducting an RCT in a care home setting:

- Subjective outcome measures should be avoided.
- Where the use of such measures is unavoidable (and often no alternative will be available), blinding of both participants and outcome assessors is preferable.
- Where double-blinding is impossible (and for many rehabilitation interventions it will be), then blinding of outcome assessors is essential.

- Where an intervention is such that contamination by diffusion is unlikely (such as a drug or vaccine based study) then individual randomization is most straightforward and to be preferred.
- Where contamination by diffusion is likely, as in rehabilitation, management or educational interventions, cluster randomization is to be considered but power calculations must be conducted in a manner that allows for clustering.
- Stratification of randomization, particularly cluster randomization, should only be used where there is reason to believe that a study will be significantly biased in its absence. Where it is used it should be used parsimoniously. It may be that adequately powering a cluster-randomized trial is preferable to introducing additional complexity with block-permuted stratified randomization.

These rules highlight the huge technical challenges of conducting methodologically sound RCTs in a care home setting. It is clear that in some instances, for example when adequately powered cluster-randomization results in an impossibly large sample or when blinding of outcome assessors is impossible, that they will be difficult to follow. The dilemma then is between performing a methodologically unsound RCT, or accepting the limitations of the RCT in the care home setting and opting for an alternative research design when the research question cannot be addressed by these means.

Some of the most convincing trials conducted in the care home setting to date have not been RCTs. The Evercare study[35], as discussed in Chapter 1, is an example of a case-control observational study, which incorporated large numbers of participants, collected meaningful and objective outcome measures and yielded believable, clinically relevant outcomes which have both reinforced practice within the US and spurred practitioners elsewhere in the world to reconsider their own practices. It would have been an enormous technical and political challenge to have conducted this study within the framework of an RCT, with randomization of customers away from an intervention they wanted to buy and randomization of homes away from an intervention they wanted to deliver as part of their business model. Within the context of the US healthcare system, where the primacy of patient choice over healthcare is often asserted to be a central tenet[428], it may even have been unethical to subject it to RCT.

An alternative standpoint, which may be true for many research questions in the care home setting, is that the RCT will be the correct research methodology in the future but that further developmental work is required before methodologically-sound RCTs can be run. Consider, for example, the central question for this thesis of whether CGA has a role in the care home setting. For this to be evaluated by RCT the possible components of CGA in the care home setting would have to enumerated and described, so that they could be counted, and outcome measures which capture the treatment effect of CGA would have to be identified. It is not clear what these outcome measures could be: an objective measure of quality of life, which is validated in the care home setting, is not yet available[429 430]; resident satisfaction measures, although available, have not been convincingly evaluated at the extremes of cognitive impairment[431]; time to death is likely to be a blunt statistical tool in a population with a short life expectancy and is challenged by the, albeit controversial, standpoint that there may be measurable health states which are worse than death[432]; recording healthcare admissions, or healthcare contacts, as outcome variables raises the challenge of separating appropriate and desirable resource use from inappropriate resource use which is harmful to the resident. Thus whilst an RCT might, feasibly, be a way to address the issue of CGA in this setting, a considerable amount of developmental work is required before such a trial could be conducted in a robust fashion.

When considered in this context, the question may be whether the MRC framework for the evaluation of complex interventions has been sufficiently adopted in care home research. The analogy to drug development might be used as justification for much more time and thought to be expended in the pre-RCT phases. The average time spent on phase I-II of new drug development, the phases during which safety is verified, optimum dose established and outcome measures developed, is 47.3 months, at an average cost of $23.5 million[433]. Over half of new drugs tested fail to make it past phase two, having been found to be unsafe or ineffective[434]. The time and financial resources made available for development of complex interventions are both smaller and less flexible – an NHS National Institute of Health Research Programme Grant, for example, comprises £2 million over five years, during which there is a expectation that a team of investigators would, at least, reach the end of phase II in the MRC framework[435]. Perhaps in this context, the pragmatic RCT is one never undertaken.

So to the above rules one must add a preface:

- Consider whether an RCT is the correct methodology for the research question.
- If an RCT is the correct methodology consider the following:
    - Is the research intervention adequately described?

  - Are objective outcome measures available and are these validated in the care home setting?

- If the answer to either of the above is "no", then further developmental work is required before moving to RCT.

2.7.5. Limitations and strengths

CHoLiR had a number of weaknesses. It was a systematic mapping review and, as such, provided an overview of the topics covered and broad issues raised by the literature available, with only a superficial assessment of quality of the research undertaken or its reporting. It focussed only on RCTs and the significant shortcomings of RCTs in this setting mean that potentially important pieces of research conducted using other methodologies will have been overlooked – the Evercare study being an example.

Another possible limitation is highlighted by the predominance of Anglophone countries - the top five most published countries amongst articles retrieved were either Anglophone (US, UK, Canada, Australia) or have a strong tradition of publishing in English-language journals (the Netherlands)[436]. This might represent a bias introduced by limiting the Medline search to English language journals – researchers from Asian countries, in particular, have been noted to publish less frequently in these[393] – which may have been further compounded by the decision to exclude Embase from the search. Data from Elsevier in 2010 reported that 51% of Embase citations came from Western Europe, 30% from North America and 5% from Asia, compared with 41%, 44% and 3% for the same regions in Medline[84]. However, given these stated differences in coverage, it seems unlikely that database selection, even if it introduced some bias, could have fully explained the US predominance amongst articles retrieved. A different but related question is whether the exclusion of foreign-language articles could have substantively changed the clinically relevant findings. A NIHR Health Technology Assessment conducted by Egger *et al*[98] in 2003 evaluated the effect of inclusion of "hard to find" studies in systematic reviews. It identified potential reasons for studies being hard to find as not being published, coming from non-Pubmed indexed publications and being published in languages other than English. By considering meta-analyses with "hard to find" studies included and excluded, the authors concluded that non-English non-Pubmed indexed publications showed larger treatment effects. Whilst missing such studies is of less importance in the context of a systematic mapping review than meta-analysis, there is no doubt that some strongly positive studies could have been missed in this way.

The failure to include allocation concealment as a variable in the keywording framework was a potentially important oversight. CONSORT regard allocation concealment during randomization as central to effective conduct of the RCT[417] and, where broad value judgements have been made about the quality of the studies retrieved on the basis of other methodological variables such as blinding and randomization strategy, it seems potentially remiss not also to have reviewed this. Allocation concealment during randomization is, however, methodologically straightforward and there is no reason to anticipate that the methodology applied would be substantively different for randomization in the care home setting than in other settings. The failure to record explicitly in the keywording framework whether stratified randomization was associated with blocking (given that it does not work without[417]) is another potentially important oversight in this respect. However, this was a systematic mapping review with the primary aim of identifying overarching methodological themes and key clinical lessons and, as such, detailed appraisal of the quality of the retrieved literature was beyond its remit. Indeed, having attempted to do this with the resources available would probably have made the review impossible to complete.

The review had two main strengths. Firstly, it was unique in drawing together all the RCT literature from care homes around the world and therefore allowed the question of whether CGA, or its component interventions, had been trialled in care homes to be addressed with some degree of confidence. Secondly, it used the bounded methodology of a systematic mapping review to describe diverse literature retrieved against a specific keywording framework, allowing articles to be described and compared, without there being any need to try to evaluate them collectively. The pitfalls of applying alternative literature review methodologies in this context is clear from the previous work of Peet *et al*[437], who attempted in 2004 to combine 58 papers from 37 randomised and non-randomised controlled studies across diverse interventions in the care home setting using meta-analysis and found it difficult to derive meaningful conclusions from the summed results of such heterogeneous research.

2.8. Conclusions

There was no evidence that CGA had been satisfactorily evaluated in care homes. The RCTs which were identified as evaluating CGA-type interventions either focussed on relatively narrow, predominantly psychogeriatric, interventions, or suffered significant methodological flaws that served to undermine their conclusions.

Several component parts of CGA had, however, been effectively evaluated at RCT and shown to work – these were advanced care planning; pharmacy interventions to reduce prescribing; staff education around prescribing, dementia and end-of-life care; calcium and vitamin D in preventing fractures; alendronate in preventing osteoporosis; influenza vaccination; oseltamivir or zanamivir for influenza prophylaxis; functional incidental training and bladder training for incontinence; and risperidone and olanzapine for agitated behaviours in carefully selected patients under expert guidance. Only one component of CGA, the use of hip protectors, had been shown conclusively not to work. For a number of other components, the literature was inconclusive, in part due to the methodological shortcomings of a significant proportion of the RCTs reviewed.

RCTs clearly have a role in care homes and, where they represent the correct methodology for the research question, as in the large trials of staff influenza vaccination or pharmacist-led medication reviews reported here, they have delivered clinically meaningful outcomes. There are, however, significant methodological challenges in adequately randomizing and blinding care home residents to interventions at RCT and the literature reviewed here suggests that the research community has so far failed to meet these. Such is the extent of the challenges and the manifest failure to accommodate them that RCT methodology might, at times, be best abandoned. On other occasions, it may be best postponed. One reason why RCTs should be postponed is the shortcomings of many of the outcome measures currently applied in the care home setting, many of which are unacceptably objective when applied in the context of respondents with advanced cognitive impairment, whilst others simply have not been validated in this setting.

Coming back to the question of CGA, the literature reviewed – whilst it supported the use of many components of CGA – left a number of gaps. Allowing for these, the breadth of interventions evaluated and the relatively broad spectrum of targets for which effective interventions were identified, suggest that evidence-based healthcare for care home residents would require to be multidisciplinary: with expertise required in exercise therapy, continence management, prescribing in older patients, management of behavioural and psychiatric symptoms of dementia and end-of-life care. It seems logical to suggest that such broad-ranging expertise would be most effective when informed by comprehensive assessment and co-ordinated by regular interdisciplinary communication, as are inherent in CGA. A number of the gaps in our understanding of how to care for care home residents might be filled by RCT data collected from older, frail cohorts in other settings such as the community, or acute hospitals. It would be likely that, by doing so, additional components of CGA could be considered in this setting. It is, however, impossible to work out which data, from which alternative settings, should be applied in care homes without first describing in some detail the health and functional status of care home residents and how they interact with health services to receive healthcare. These will be described in Chapters 3 and 4. The question of whether, and how, the existing evidence might inform the case for CGA in care homes will be revisited in Chapter 5.

Chapter 3 – The Care Home Outcome Study (CHOS)

3.1. Introduction

Chapter 2 demonstrated the lack of an evidence base for CGA in care homes when considered as a whole intervention. It did, however, highlight a number of components of CGA which were supported by RCT findings. It concluded by stating that evidence generated in other settings, including acute and community healthcare, might be extrapolated to fill the gaps in understanding about a role for CGA. This would depend upon the extent to which care home residents resembled, or differed from, frail older patients seen elsewhere.

Building a detailed understanding of the health and functional status of care home residents was a logical next step, partially to address the issue of cross-applicability of evidence from other sectors as already described and partially to address the more basic question of whether care home residents were a cohort in which a cogent case for CGA could be made on the basis of need.

Several research studies had already described health and functional status in care home residents but were either out-of-date, had been designed to address issues other than the routine delivery of healthcare or suffered methodological shortcomings.

The Office of Population and Census Studies (OPCS) survey of disability in Great Britain[438], conducted in 1988, sampled one in 13 long-term care establishments at random and gathered data from permanent residents, defined as those living in institutions for more than 6 months. Researchers interviewed one in four residents from smaller establishments and one in 12 residents from larger establishments. It collected comprehensive data on disability in locomotion, reaching and stretching, dexterity, seeing, hearing, continence, communication, personal care, behaviour, intellectual functioning, consciousness and digestion directly from the resident, or a proxy when the resident was unable to provide answers. These findings were cited to summarise the prevalence of disability in care homes as recently as the Laing and Buisson 2009 UK Market Survey of Care Homes[7]. However, as described in Chapter 1, there have been significant changes in healthcare provision for frail older patients, which have resulted in increased dependency in the care home population, over in the intervening period. In this context, data which was over 20 years old was likely to have significant limitations and was unlikely to be sufficiently contemporaneous to build a case for CGA.

More recently, Bebbington *et al*[439], working on behalf of the UK Personal and Social Services Research Unit (PSSRU), conducted a detailed 42-month longitudinal cohort study, concluding in the year 2000, which evaluated length of stay, life expectancy and total lifetime costs of care for care home residents from the time of admission. They reviewed all local authority-funded admissions from 20 local authorities selected for representativeness of the wider UK population on the basis of socio-economic group, population sparsity and migration rate. They found a median survival of 19.6±0.9 months, 11.9±0.9 months and 26.8±1.0 months for the whole sample, nursing homes and residential homes respectively. Amongst their cohort, 18% were totally dependent (Barthel score 1-4), 23% had severe dependency (Barthel score 5-8), 24% moderate dependency (Barthel score 9-12), 21% low dependency (Barthel score 13-16) and 13% very low dependency (Barthel score ≥ 17). Using the Minimum Data Set Cognitive Performance Scale 34% had severe confusion, 46% mild confusion and 20% intact cognition. Medical diagnoses, although considered, were reported only in broad terms under the headings dementia, depression, cardiovascular, respiratory, malignancy and stroke. Diagnoses were used as variables in regression analysis, as predictors of changes in functional and residential status, and their raw prevalence was not reported.

Netten *et al*[440] conducted a follow-up survey considering 921 self-funding residents across 292 homes which replicated the distribution of purposive sampling variables recorded by Bebbington. They found self-funded residents to have higher levels of physical and mental functioning than the publicly-funded residents, but to be older. They also reported significant differences in the prevalence of disease between their cohort and that of Bebbington. They attributed this to a reporting bias because their survey responses came from care home managers and those of Bebbington from social workers. The fact that survey responses for both Bebbington and Netten came from social care providers without access to healthcare records draws into question the accuracy of the diagnostic prevalences recorded, although it is less likely to have affected the data around functional and cognitive status and time to death.

A more health-focused approach was undertaken by Bowman *et al*[2] who undertook a census of the residents of UK care homes comprising part of the BUPA chain in 2004, recording data from 15483 residents across 244 homes. These findings were already touched upon briefly in chapter 1. They reported 50% of residents to have dementia, 76% to be immobile and 27% to be immobile, confused and incontinent. They also recorded the prevalence of 26 “admission diagnoses” – with the most prevalent being dementia, frailty, stroke and sight impairment, present in 36%, 25%, 22% and 13% of residents respectively. There were, again, issues around reporting bias because data were derived from forms completed by care home managers without access to residents’ medical records. In addition, responses were subjective, with managers being asked to respond without clear definitions of what comprised dementia, immobility and incontinence. There were similar issues with the list of 26 “admission diagnoses” which encompassed syndromes with vague diagnostic criteria, such as “frailty” and “family/social reasons” not fully agreed by specialist geriatricians, let alone by care home staff.

Taken in summation, the findings of Bebbington and Netten suggested care home residents were disabled, cognitively impaired and near the end-of-their lives – perhaps a cohort in whom CGA might reasonably be applied. Bowman’s work built the case for CGA further, by suggesting that syndromes (incontinence, confusion and immobility) and diagnoses (dementia, frailty, stroke and sight impairment) which had been shown in other settings to be appropriate targets for CGA, were prevalent in care homes. None of the studies, however, provided sufficient detail to make a robust case for comprehensive multidisciplinary assessment and planning.

Looking back at Chapter 1, the assertion that CGA might have a role to play in improving care from care home residents was borne less out of observations about the prevalence of frailty, dependency and particular diagnoses in care homes, as it was out of a recognised failure of existing models of healthcare to treat residents equitably and appropriately. Thus any consideration of a possible role for CGA would be incomplete without considering how care home residents used NHS resources. Data on this was limited largely to the work by Steves *et al*[17] and Shah *et al*, already discussed in Chapter 1.

Against this background of incomplete data on the health and functional status of care home residents, and how they used NHS resources, it was impossible to robustly establish, or refute, a role for CGA. To fill this gap, the Care Home Outcome Study

(CHOS) set out to build a more comprehensive understanding of the health and functional status of care home residents and to describe their use of NHS resources.

3.2. Aim

To comprehensively describe the health and functional status of care home residents, and how they use NHS resources.

3.3. Methodology

3.3.1. Choosing a longitudinal cohort study design

Given that the stated objective was to describe the care home population in detail and there was no identified intervention, an observational – rather than experimental – cohort modality was adopted. The description of health status of a cohort required that detailed cross-sectional "snap-shot" data be collected. However, to measure healthcare resource use and to investigate its association with baseline health status, longitudinal follow-up was required. Taking these factors together, an observational longitudinal cohort study with comprehensive cross-sectional data collection at two data-points, one at baseline and one at conclusion, was proposed (see Figure 5).

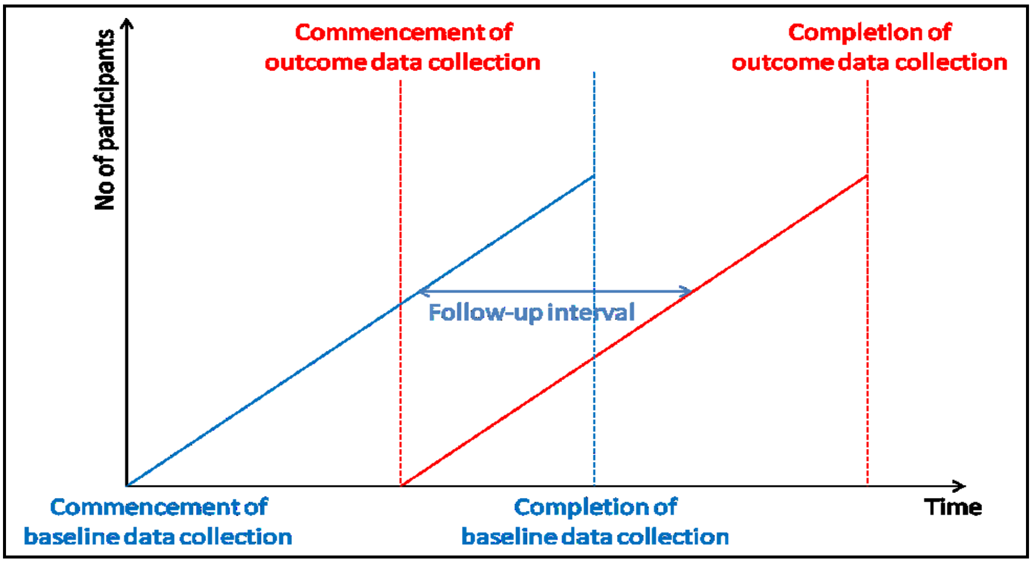


Figure 5 - An observational longitudinal cohort design

3.3.2. Defining "health"

The World Health Organisation (WHO) defines health as a state of complete physical, mental and social wellbeing, not simply the absence of disease or infirmity[441]. Beyond the apparent simplicity of this definition, however, the conceptualization of health status becomes increasingly complex. The WHO offers two complementary, yet largely exclusive, conceptual frameworks against which health status can be described. The International Classification of Diseases, currently in its 10th iteration (ICD-10) is designed to "describe the general health situation of population groups"[442] and yet does so by classifying medical diagnoses – rather than more generic wellbeing – in detail, subcategorized by organ system and pathological process. The International Classification of Functioning, Disability and Health (ICF)[443], by contrast, eschews diagnostic criteria in favour of describing health against domains comprising: body function and structure, activity, participation and environment. Reconciling these two conceptual models is difficult. In an attempt to the operationalise them for the World Health Survey, the WHO identified 16 health domains and 4 health-related domains[444], which comprised elements of both ICD-10 and ICF (see Table 25).

Table 25 - Health domains used in the World Health Survey

Health domains	Health related domains
Vision	Self care
Hearing	Usual activities
Speech	Social functioning
Digestion	Participation
Bodily excretion	
Fertility	
Sexual activity	
Skin and disfigurement	
Breathing	
Pain	
Affect	
Sleep	
Energy/Vitality	
Cognition	
Communication	
Mobility and Dexterity	

Many of the clinical and research tools used to record health status measure domains of the ICF or ICD-10 but have been developed using conceptual frameworks different from those of the WHO. These have often been derived pragmatically based around what can be measured and seems clinically meaningful. An example of this would be the Folstein Mini-Mental State Examination (MMSE), commonly used in clinical practice as a measure of cognitive status and derived pragmatically[445]. It also operates, however, within the “cognition” domain of the World Health Survey, the “function” domain of the ICF and the “mental and behavioural disorders” domain of the ICD-10.

In building a comprehensive overview of health status, it was important that the measures chosen were clinically-meaningful but also described all domains of health as described by the WHO. The rationale for choosing individual measures is covered in sections 3.3.2.1-3.3.2.3 below, whilst a summary of how these mapped to the ICD-10 and ICF as operationalised in the World Health Survey is outlined in Table 26.

Table 26 - How indices chosen for CHOS summarised WHO-defined health and health-related domains

Health domains		Health-related domains	
Vision	ICD-10 diagnoses	Self care	BI EQ-5D
Hearing	ICD-10 diagnoses		
Speech	ICD-10 diagnoses		
Digestion	ICD-10 diagnoses MNA		
Bodily excretion	ICD-10 diagnoses BI CI	Usual activities	BI EQ-5D GHQ-12
Fertility	ICD-10 diagnoses		
Sexual activity	ICD-10 diagnoses		
Skin and disfigurement	ICD-10 diagnoses		
Breathing	ICD-10 diagnoses CI	Social functioning	BI EQ-5D GHQ-12
Pain	ICD-10 diagnoses EQ-5D		
Affect	ICD-10 diagnoses NPI GHQ-12 EQ-5D		
Sleep	ICD-10 diagnoses NPI GHQ-12		
Energy/Vitality	GHQ-12 EQ-5D	Participation	EQ-5D GHQ-12
Cognition	ICD-10 diagnoses MMSE NPI CI		
Communication	ICD-10 diagnoses NPI		
Mobility and Dexterity	BI EQ-5D		

3.3.2.1. Describing physical wellbeing

Against the WHO definition, physical function was considered in its broadest sense and it seemed reasonable, therefore, to start with measures of functional status. Functional status can be measured by careful recording of individual physical and mental functions – for example measures of grip strength, walking speed and short term memory – but is more commonly measured in clinical practice using Activity of Daily Living (ADL) scales. These measure either basic ADLs (such as indoor mobility and self care), more advanced instrumental ADLs (such as walking outdoors or cooking food), or both. Given the high levels of recorded disability in surveys of the care home population[2 3], it was felt likely that instrumental ADL scales would score consistently low and therefore suffer from a significant floor effect (where a significant proportion of the variability seen is below the lowest extreme of the score and hence not recordable) and hence a basic ADL score was sought.

The most widely used basic ADL score in UK clinical practice is the Barthel Index (BI)[446], which includes domains in continence, feeding, grooming, bathing, dressing, transferring, mobilising and the ability to climb stairs. Originally scored out of 100, it was modified by Collin and Wade[447] in 1988 to be scored out of 20, with some changes to scoring guidelines to take account of identified uncertainties. It has good test-retest and inter-rater reliability[448].

The BI has two main shortcomings: firstly, it is an ordinal scale, where numerical values do little to reflect severity of functional impairment – a patient with a Barthel score of 7, for example, is not twice as functionally impaired as one with a score of 14; secondly, it suffers from a significant ceiling effect – thus a patient with a maximum Barthel score of 20 may still be significantly disabled, despite being able to perform all of the basic ADLs outlined in the score[449]. Despite these shortcomings, it is recommended by the British Geriatrics Society[450] and Intercollegiate Stroke Working Party[451] for use in frail older patients and patients with stroke, largely because the core aspects of dependency measured by the Barthel index are important both to patients and to health and social service providers, who need to arrange for physical dependency to be met.

Given the predominance of the BI in UK clinical practice, any ADL measure chosen over it would have to have very clear advantages. Commonly-cited alternatives are the Functional Independence Measure (FIM) and Katz ADL scale[452]. The FIM[453] was developed specifically to address the deficiencies of the BI. It is bidimensional, with physical and cognitive subdomains, and can be weighted such that it behaves as an interval scale[454] – where points are equal and equate directly to physical function – with possible increased utility in long term follow-up. Despite these apparent advantages, head-to-head trials of the BI and FIM show little difference in sensitivity, specificity or responsiveness to change[455] [456]. The Katz ADL scale[457] is less comprehensive than the BI and has at its core a hierarchy of physical functions (based on expectations of the order that these would recover following rehabilitation) which is not universally accepted[458 459]. Although well-validated[460 461], it is supported by incomplete reliability data with no published data on test-retest reliability[452]. Given that neither the FIM nor the Katz ADL score had clearly demonstrable superiority over the BI, they were rejected as alternatives.

Medical morbidity is an important determinant of physical wellbeing and it was therefore important to describe this in detail. This was done using the ICD-10. As illustrated in Table 25, the ICD-10 – because of its comprehensive nature and because it lies at the heart of much of the WHO's operationalisation of what it means to be healthy – is an intuitive place to start when measuring medical morbidity. An additional advantage is that medical data in the UK is coded against health resource group (HRG) codes which are based upon the ICD-10 - making it technically quite straightforward to code health-record entries against it.

It is rare for the type of frail older patients seen in care homes (as described by Bowman *et al*[2]) to have just one diagnosis and whilst comorbidity, defined as co-occurrence of multiple diseases in one person[462], can be described using a simple list of active medical diagnoses, a number of indices have been developed which weight diagnoses according to their prognostic importance. The rationale for using such indices is that they can provide, on the basis of a raw score, the means of selecting patients for clinical interventions or research programmes – something which one might struggle to do simply on the basis of a list of ICD-10 codes. De Groot *et al* conducted a systematic review of the available co-morbidity classifications in 2003 and concluded that four – the Cumulative Illness Rating Scale (CIRS), Kaplan index, Index of Co-existent Disease (ICED) and the Charlson Comorbidity Index (CI) – had undergone adequate validation for use in clinical studies[463]. Of these, the CIRS and CI have been modified to account for the effects of age[464 465] – an important consideration in care homes.

The CIRS scores 13 body systems according to level of impairment, where 0 = no impairment and 4 = life-threatening impairment – with scores being made against guidelines in the CIRS user manual[466]. A modified manual, the CIRS-Geriatric (CIRS-G) manual, has been produced to take accounts of differing prevalence of illnesses in older patients[464].

The CI records the presence or absence of 19 conditions which were chosen and weighted according to how strongly they predict mortality. The weightings were based on longitudinal follow-up of 685 patients over 10 years in New York during the 1970s and 80s[467] but have been validated in numerous other populations since[463]. The CI has also been modified to take account of the effects of age on comorbidity – producing a combined age-morbidity index[465].

The main criticism of the CI is that the weightings applied to conditions, based upon how strongly they predict mortality, do not hold true for all populations – with liver disease, HIV positivity and metastatic cancer being demonstrated as over-weighted in the CI by estimates from subsequent studies[468]. Of particular concern here is the weighting of HIV, since survival following diagnosis of HIV increased four-fold in the

10 year period following publication of the CI[469] and has continued to improve since. Given, though, that HIV is not routinely seen in UK care home practice, this was not important in the context of CHOS.

Both the CIRS-G and CI have good inter-rater[470 471] and test-retest[472 473] reliability. The CI is easier to use than the CIRS-G because no interpretation of disease severity is required and – given that CHOS proposed to use a battery of tests and therefore minimising assessment burden was important – it was chosen for inclusion on this basis.

Digestion and bodily excretion are factors of nutrition and it therefore seemed reasonable to include a nutrition index. In addition malnutrition is recognised to be a prevalent problem in care homes[474] and is recognised to be a risk factor for mortality in older patients[475]. Nutritional assessment measures are a relatively recent development and have not yet generated as extensive a literature base as some of the other measures described. The Mini-Nutritional Assessment (MNA) was chosen for inclusion on the basis that it had been validated in the elderly and shown to be predictive both of future functional status and mortality[476]. It asks questions about a patient's appetite, eating habits, recent weight loss and uses measurements of arm and calf circumference[477] – these can be used as a proxy for body mass index, which is important as weight can be difficult to record in frail, dependent patients.

3.3.2.2. Describing social wellbeing

Social wellbeing is a difficult concept with which to contend although, within the context of the WHO definition of health, it is clearly an individual phenomenon and separate from societal wellbeing. When those domains obviously related to physical or mental wellbeing are removed from Table 25, those remaining – self care, usual activities, social functioning and participation – map very well to descriptors of health-related quality of life (HRQoL). Indeed, when trying to quantify the social domain of health for the World Health Survey, the WHO used the WHO Disability Assessment Scale (WHO-DAS) which – despite some largely unresolved debate over whether measures of disability and HRQoL indices are measuring similar, overlapping or discrete domains[478 479] – is broadly accepted to be a generic HRQoL measure[480].

The HRQoL measure most commonly used in evaluation of healthcare interventions in the UK is the EQ-5D. This measures five health-related dimensions – mobility, self-care, pain/discomfort, usual activities and anxiety/depression – across three levels of utility – no problems, some problems, severe problems. This results in a system which can describe up to 243 health states[481]. The reason for the pre-eminence of the EQ-5D in the UK is primarily that it has been chosen for cost-utility evaluations by the National Institute of Clinical Excellence (NICE) and therefore lies at the centre of NHS policy[49 50].

The predominance of the EQ-5D over other measures in UK health policymaking might be taken as adequate justification alone for its inclusion in the study. The EQ-5D does, however, compare favourably to other measures. A Health Technology Assessment review comparing the EQ-5D to other HRQoL measures including the Quality of Well-Being Scale (QWB), Rosser's disability/distress scale, the Health Utility Index (HUI; mark I to III) and the 15D found the EQ-5D to be briefer than other measures, to have better test-retest reliability, and to be broadly equivalent in terms of descriptive and empirical validity[482]. A more recent paper by the UK Department of Health[483] suggested that EQ-5D had less descriptive power than more detailed indices, such as the short-form 36 (SF-36) and HUI, but that it had broadly equivalent discriminant and predictive validity and measurement reliability. These authors also suggested that the relative brevity of the EQ-5D led to higher completion rates, making it more appropriate for use in older populations which have constitutively lower completion rates for multi-attribute utility indices. The relative brevity also gives the index intuitive appeal when used as part of a battery of evaluations, as was the case for CHOS. The trade-off for brevity is what Cieza and Stucki referred to as “loss of bandwidth”[484]. They mapped the domains of the EQ-5D, SF-36, WHODAS, World Health Organisation Quality of Life Assessment (WHOQoL-BREF), Nottingham Health Profile (NHP) and Quality of Life index (QL-I) to those of the ICF, indicating that all HRQoL measures were operationalisations of the international classification, with the EQ-5D being the briefest but also the measure with the narrowest focus.

3.3.2.3. Describing mental wellbeing

The GHQ-12[485] is the 12 point version of the General Health Questionnaire (GHQ), a self-completion measure of mental health. It has been show to be as sensitive and specific as longer versions of the GHQ[486 487] and can be delivered within 2 minutes to a co-operative and cognitively intact participant. The GHQ-12 screens for “caseness” – that is the likelihood that a patient is a “psychiatric case”. It is a feasible and useful screening tool in mild-to-moderate cognitive impairment and can be administered verbally, rather than as a written questionnaire, in this group[407 488].

A particular issue with the GHQ-12 is that its sensitivity and specificity, and hence its cut-off scores for caseness, vary between populations[407 489]. This is, in part, explained by the effects of language, educational-level and age on test performance, but has not been fully explained. Physical illness confounds longer versions of the GHQ but not the GHQ-12 because it contains no somatic domains[490].

Alternatives to the GHQ abound. The Hospital Anxiety and Depression Scale (HADS) is a 14-item self-completion questionnaire, with 7-item anxiety (HADS-A) and

Depression (HADS-D) subdomains[406], initially designed for use in a hospital outpatient population. Head-to-head comparisons of the GHQ-12 and HADS show them, with a few exceptions, to be roughly equivalent in terms of sensitivity, specificity, positive and negative predictive value[490 491]. HADS has not been evaluated in cognitive impairment – which is a significant disadvantage in the care home population.

The Cornell Scale for Depression in Dementia (CSDD) is validated in more severe dementia and is administered predominantly to the caregiver, with a short patient interview afterwards[409]. This renders it considerably more time-consuming than the GHQ-12. The 15-item Geriatric Depression Scale (GDS-15) is similar in length to the GHQ-12 and has similar sensitivity and specificity for caseness when compared to it. However both CSDD and GDS-15 are unidimensional and screen only for depression (the CSDD contains one question on anxiety and one on agitation but is still primarily a depression rating scale).

Given the high prevalence of dementia anticipated in care home residents, the role played by dementia as leading cause of mental morbidity and the potential for cognitive impairment to explain or confound other measures, it was important to measure cognitive function. The Mini-Mental State Examination (MMSE) is the most-commonly used short-questionnaire to measure cognitive function[492]. It was initially described in 1975 as a screening test for cognitive impairment[445] and has since been well validated and has good inter-rater and test-retest reliability[493]. A significant shortcoming is its high false-positive rate in people with low education if a universal cut-off score for dementia is used[494].

Alternative measures to the MMSE have been developed. The Modified Mini-mental State Examination (3MS)[495] added four additional questions and provided altered scoring guidelines, demonstrating increased sensitivity for mild dementia and otherwise close correlation with the MMSE[496 497]. The Cambridge Cognitive Examination (CAMCOG) has similar sensitivity to and better specificity than the MMSE[498] but is still affected by age and educational level[499]. However, neither is as commonly used in clinical practice or has sufficient advantages over the MMSE to be used in preference.

A significant proportion of the morbidity in dementia comes from behavioural and psychiatric symptoms of dementia (BPSD). BPSD is an umbrella term which covers a number of non-cognitive manifestations of dementia – wandering, aggressive behaviour, withdrawn behaviour, sexual behaviour, disinhibition – which patients and carers find distressing and which are increasingly the focus of attention for old age psychiatrists and psychiatric nurses[500]. Clearly such symptoms have significant implications for measurement of morbidity and could be significant baseline predictors of high NHS resource use – and therefore these required to be measured as part of this study. Several scales are used to measure BPSD - of these, the Neuropsychiatric Inventory (NPI) and Behaviour Rating Scale for Dementia (BRSD) have both been developed exclusively for use in dementia and both attempt to measure symptoms comprehensively[501]. Both are completed at interview with a carer since BPSD sufferers are unreliable witnesses to their own symptoms, particularly as their dementia progresses. The BRSD consists of 48 items, recording the severity of symptoms in each domain, and takes approximately 25 minutes to complete[502 503]. The NPI consists of 10 items, recording severity and frequency of symptoms in each domain, and is considerably briefer than the BRSD. The NPI has excellent internal consistency, good inter-rater reliability and moderate-to-good test-retest reliability[504]. No direct head-to-head comparison of the NPI and BRSD has been undertaken, apart from the Korean versions of both measures, which were evaluated in 99 carers of patients with dementia, showing a high degree of correlation between the two[505]. Thus, given the broad equivalence of the two measures and the relative brevity of NPI, it was chosen for inclusion.

3.3.3. Describing healthcare resource use

NHS healthcare resource use is increasingly recorded on electronic databases. A number of NHS databases existed which could possibly describe healthcare resource use in our cohort. These were managed by separate organisations and contained complementary but overlapping datasets. Work to integrate outputs from these was part of the broader programme of work taking place around CHOS but proved very complex and it quickly became clear that it would be most appropriate to work only with those covering acute inpatient care.

The rationale for focussing on these databases was that they had been designed with ready data accessibility in-mind, enabling easy collation of service use data, and had robust research and development governance frameworks in place which made approval for data collection relatively straightforward. In addition, much of the policy agenda driving innovation in healthcare delivery to care homes (as outlined in chapter 1) had focussed on avoidance of acute inpatient admissions. This approach had some limitations – namely that the relationship between primary and secondary care, and somatic and mental health, resource use could not be interrogated. It was, however, the only approach manageable within available resources.

3.4. The research team

It was clear that a large sample of care home residents from a number of homes would be required to address the research aims and a team of researchers was convened to enable timely recruitment and follow-up. The core team comprised Dr Adam Gordon (AG), an academic geriatrician; Professor John Gladman (JG), a professorial-level academic geriatrician and first-PhD supervisor for AG; Dr Pip Logan (PL), an academic occupational therapist, and second-PhD supervisor for AG; and Lucy Bradshaw (LB), a medical statistician studying for her own PhD. AG designed the research protocol based-upon a research-funding proposal previously submitted by JG, designed all study proformas, obtained ethical approval for the study, recruited the 11 participant homes, collected data from 110 participants at baseline and 108 patients at follow-up, commissioned and supervised the design of the Microsoft Access™ database for the study, supervised primary data entry, conducted second data entry and conducted the analysis of data and reporting of findings. JG designed the research-funding proposal on which the study protocol was based and helped to recruit the participant homes. JG and PL between them provided supervision to AG at all stages of design, data collection, analysis and reporting in keeping with their role as PhD supervisors. Both JG and PL collected data from a small number of residents in order to understand the processes involved. LB helped with sample-size calculations and provided statistical support throughout data analysis. A number of other researchers – largely enlisted through the NHS Primary Care and Mental Health Research Networks – helped with data collection for the patients not seen by AG, these were: Claire Litherland, Elizabeth Andrews, Mick Bachner, Philip Clissett, Yadiki Jayakumar, Isabella Robbins. Claire Forster, a trainee doctor in General Practice, worked with AG on the STOPP-START subsection of the analysis.

3.5. Methods

3.5.1. Defining a sample and the sample-size considerations

3.5.1.1. The purposive sampling matrix

The Care Quality Commission (CQC) care home database was searched for all care homes within Nottinghamshire and a ten-mile radius of the University of Nottingham Medical School, as it was felt these were the homes that could be pragmatically involved in the study. This returned 131 homes with 4952 beds and an average number of beds per home of 35. All care homes on the list were approached by direct mail – 16 responded saying that they wanted to be involved in the study.

To ensure representativeness of the wider care home population, a purposive sampling matrix was developed. A meeting of researchers from the Medical Crises in Older People programme – the NIHR-funded research programme of which this study was part – was convened to consider this. The group comprised a consultant geriatrician, old age psychiatrist, occupational therapist, social worker, qualitative health services researcher, health economist and statistician. A list of possible variables which might bias outcome measures and therefore be relevant to purposive sampling was identified during the discussions as listed in Box 1.

Proprietary status – private/state-owned

Corporate status – large or medium-sized corporate chain/single home or small corporate chain

Building type – custom-built/renovated property

Size of home – bottom/middle/top tertile

Registration status – nursing/residential

Specialist registration – dementia/physical disability/older patients

CQC rating – excellent/good/average/poor

Number of general practitioners per home – bottom/middle/top tertile

Box 1 - Possible confounding variables for inclusion in a purposive sampling matrix

Based upon a 60% recruitment rate, it was anticipated that 21 residents could be recruited per home and based upon the time and resources available for the study it was felt that 10-12 homes, (210-252 residents) could be recruited over the time of the study. The ideal purposive sampling matrix would therefore have only 10-12 categories, limiting the number of variables that could be included. Through a process of iterative exclusion, the following variables were felt to be essential:

- Nursing/residential status – on the grounds that identified need for nursing input would be likely to predict for a higher prevalence of health problems and therefore to influence both baseline health status and healthcare resource use.

- Dementia registration – on the grounds that the need for specialist dementia input would be likely to predict for a higher prevalence of mental health problems and therefore to influence healthcare resource use. It was also felt that a high prevalence of residents lacking mental capacity in some homes might influence how healthcare was accessed in these settings.

- CQC rating – on the grounds that this would provide a broad index of quality of care in homes and therefore would be likely to influence how homes interacted with the NHS and accessed healthcare resources.

Using the CQC care home database, the prevalence of these variables in Nottinghamshire care homes within a 10 mile radius of the Nottingham University Medical School was calculated as shown in Table 27. Homes recently opened and therefore not yet classified by the CQC were excluded.

Table 27 - Nottinghamshire care homes within a 10 mile radius of the University of Nottingham Medical School

		CQC Rating			
		Poor	Adequate	Good	Excellent
		No of Residents (% of total)	No of Residents (% of total)	No of Residents (% of total)	No of Residents (% of total)
Dementia Registered	Without nursing	88 (2.7%)	291 (9.1%)	480 (15.0%)	228 (7.1%)
	With nursing	146 (4.6%)	217 (6.8%)	226 (7.1%)	138 (4.3%)
Non-dementia Registered	Without nursing	114 (3.6%)	60 (1.9%)	315 (9.9%)	113 (3.5%)
	With nursing	109 (3.4%)	88 (2.8%)	493 (15.4%)	59 (1.8%)

The number and size of volunteer homes were such that a truly representative sample of homes could not be produced – the best sampling fit achievable was with 11 of the volunteer homes and is shown in Table 28. This clearly undersamples from the “adequate” CQC rating and oversamples from the “excellent” and “poor” categories – although arguably this was a reasonable trade-off, with the opportunity to sample from the highest and lowest quality providers compensating for the loss of data from the middle-ground. The most prevalent category in the wider care home setting, that of good-rated non-dementia registered homes with nursing, could not be sampled at all, as no home in that category had volunteered.

Table 28 - Best fit sample from volunteer care homes

		CQC Rating			
		Poor	Adequate	Good	Excellent
		No of Residents (% of total)	No of Residents (% of total)	No of Residents (% of total)	No of Residents (% of total)
Dementia Registered	Without nursing	25 (6.4%)		46 (11.7%)	38 (9.7%)
	With nursing			30 (7.7%)	68 (17.3%)
Non-dementia Registered	Without nursing	40 (10.2%)		49 (12.5%)	
	With nursing	40 (10.2%)	55 (14.1%)		

Using these attributes a sample was therefore chosen to include 11 homes: 3 dementia registered residential homes, 3 dementia registered nursing homes, 3 non-dementia registered residential homes, 2 non-dementia registered nursing home. A summary of each of these homes is provided in Table 29.

Table 29 - Description of individual homes enrolled in study

Care Home ID	Registration Status	CQC rating*	Residents (n)
1	Non-dementia registered nursing home	Adequate	55
2	Dementia registered residential home	Good	46
3	Dementia registered nursing home	Excellent	41
4	Dementia registered residential home	Excellent	38
5	Non-dementia registered residential home	Good	24
6	Non-dementia registered residential home	Poor	40
7	Dementia registered nursing home	Excellent	24
8	Dementia registered residential home	Poor	25
9	Non-dementia registered residential home	Good	25
10	Dementia-registered nursing home	Good	30
11	Non-dementia registered nursing home	Poor	40
*CQC rating at the outset of the study.			

During the study it became clear that CQC ratings were very labile amongst the study homes, with 5/11 homes changing their rating category during the 6 month follow-up. The sample distribution after removal of CQC ratings is summarised in Table 30. This, in fact, showed a closer match than the initial sampling matrix from Table 28.

Table 30 - Sample distribution with CQC-rating removed

	Proportion of Sample	
Type of home	All Nottinghamshire Homes	Sample
Dementia Registered/Without Nursing	33.9%	27.8%
Non-dementia Registered/With Nursing	23.4%	24.7%
Dementia Registered/With Nursing	22.8%	25%
Non-dementia Registered/Without Nursing	18.9%	22.7%

3.5.1.1. Sample-size considerations

Based upon this framework and the anticipated 60% recruitment rate, it was anticipated that 231 residents would be recruited from 11 homes. Unpublished data provided by Nottinghamshire County Primary Care Trust suggested that the number of emergency admissions to hospital locally at the time of commencing the study was 2 per care home per month – and as acute trust healthcare resource use was one of the proposed outcome measures this provided a reasonable means by which to test the statistical appropriateness of the sample size.

The sample size for the study was based on the precision to which the rate of emergency admissions could be estimated using a 95% confidence interval. Given 231 residents, 11 care homes and 2 residents per month, various lengths of follow-up were evaluated. 6 month follow-up provided a satisfactory compromise between feasibility and statistical accuracy. The supporting calculations were as follows:

- If 231 people were followed up for 6 months then the total amount of follow-up time in person months would be 231x6 = 1386 person-months.

- If the rate of unscheduled emergency admissions was 2 per care home per month and 11 homes were in the study for a period of 6 months then 2x11x6 = 132 unscheduled emergency admissions would be expected in this period.
- The approximate standard error of an incidence rate is √(number of events in follow-up time)/total follow-up time = √(132)/1386 = 0.008.
- To calculate half the width of the approximate 95% confidence interval for the incidence rate of unscheduled emergency admissions, the standard error was multiplied by 1.96, providing the following calculation 1.96x√(132)/1200 = 0.019 or 0.02 to 2 decimal places.

Therefore 231 people followed for 6 months would provide an estimate of the rate of unscheduled emergency admissions accurate to 0.02 per person per month, or roughly 0.5 per care home per month, suggesting that the proposed sampling framework was statistically appropriate to describe the chosen outcome measures.

3.5.2. Recruitment and Consent

Care home managers were asked to make the initial approach to residents and relatives and were provided with information packs to distribute on request.

The care home manager was asked to determine which residents would have capacity to consent to participation. Capacity was defined against the criteria specified in the Mental Capacity Act, 2005[506] - it is essential for managers to have a working knowledge of this act for their day-to-day practice and, although it was offered, none of the managers requested additional training to make these assessments. Residents with capacity were approached individually by a researcher, the study explained to them and an information sheet provided. Consent took place either immediately, or within 24 hours if the resident wished to consider their involvement at greater length. Researchers verified the care home manager's assessment of capacity before obtaining consent. For residents without capacity it was necessary, under the stipulations of the Mental Capacity Act, to find a consultee to inform the researcher of the potential-participants' attitudes to research. Where consultees were in favour of proceeding, residents were enrolled.

The aim was to recruit all residents in all homes in order to ensure a representative sample. Refusal to participate at any point, or to obtain consultee approval in those without capacity, excluded potential participants from further involvement. Potential participants were also excluded where no consultee was identified, if they were non-English speaking and no suitable translator was available, if they were felt by the manager to be in the last days of life or were receiving short term respite care. A recruitment algorithm is shown in Figure 6.

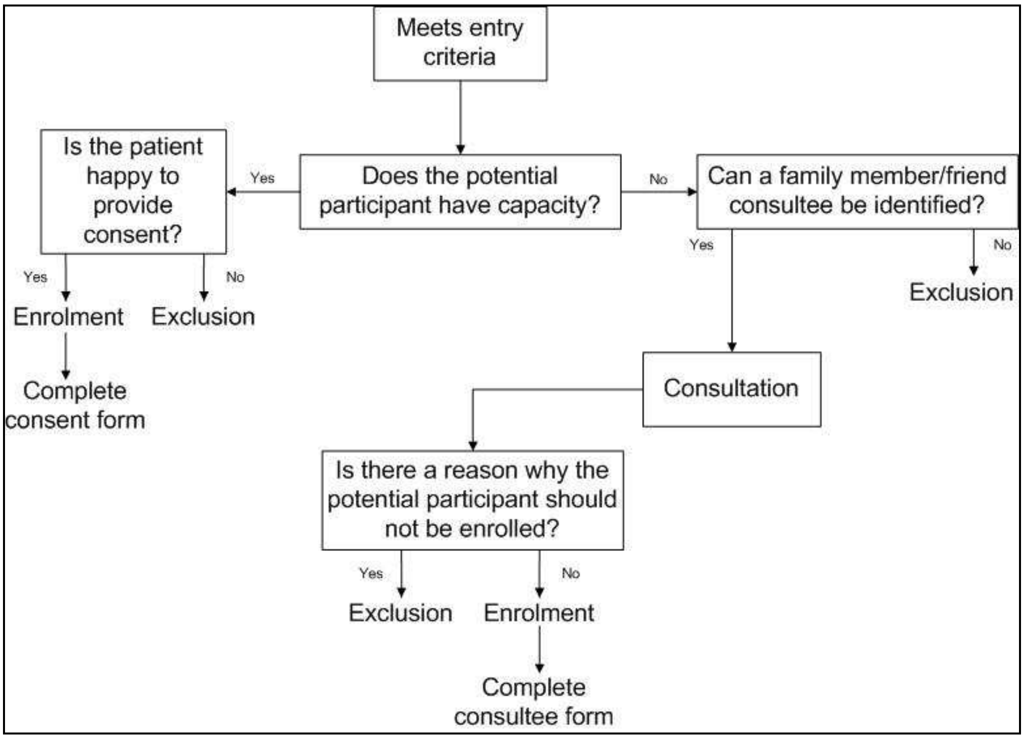


Figure 6 - CHOS recruitment algorithm

3.5.3. The questionnaires

A baseline questionnaire was developed based around the indices discussed in section 3.3.2. Similar items from different scales, for example eating questions from the BI and MNA, were grouped together to aid the logical flow of data collection and minimise repetition. Questions were then divided into an interview schedule, containing those questions that only the participant could answer, and a data schedule, containing those questions which could be answered from care home or medical records, or by proxy response from a member of staff or next-of-kin. The eventual composition of these two documents is outlined in Box 2 and Box 3.

Box 2 - Contents of CHOS data schedule

1. Name, Care Home and GP contact details
2. Demographics: age, gender, marital status
3. Medications Prescribed
4. Health conditions: List and Charlson Comorbidity Index
5. Barthel Index
6. Resource use (inventory of any regular care arrangements over and above that provided by the care home, e.g. district nurse visits, community physiotherapy visits, support from continence nurse specialists, etc.)
7. Psychiatric morbidity: The Neuropsychiatric Inventory (NPI)

Box 3 - Contents of the CHOS interview schedule

1. Physiological frailty and nutritional measures: height, weight, mid arm circumference measured in centimetres (required to complete MNA)
2. Cognitive function: MMSE
3. Quality of life: EQ5D
4. Psychological well being: GHQ-12

Outcome questionnaires were developed to include EQ-5D, GHQ-12, NPI and BI – as it was felt that these variables might change significantly over the follow-up period and that changes, if they occurred, might significantly affect healthcare resource use, morbidity or mortality. All outcomes were measured at 180 days (6 months).

3.5.4. Health conditions

In addition to collating data on health conditions from the care home records, GP records were also consulted. This was done either by a researcher directly accessing the GP database under supervision of a member of practice staff or by collecting copies of anonymised paper records from practices. All diagnoses were coded against the ICD-10 and entered onto the study database by a consultant geriatrician. Where discrepancies existed between the care home and GP records, both diagnoses were listed to establish the most comprehensive record of the participants' medical conditions. Where direct conflict existed between the GP and the care home record, the GP record was regarded to be the more reliable document.

3.5.5. NHS resource use

Acute NHS resource use was recorded over the 6 month follow-up period using data from the NotIS database at Nottingham University Hospitals and the ICE database at Sherwood Forest Hospitals Foundation NHS trusts. These recorded inpatient stays, outpatient consultations, day case visits and investigations requested through these providers. These hospitals represented the principal acute inpatient healthcare providers for all care homes involved in the study and their databases therefore provided comprehensive data on acute secondary and tertiary-level healthcare resource-use by the cohort – with the exception of private consultations, which it was assumed would be uncommon amongst care home residents. Where patients died, date of death was recorded from the care home records.

3.5.6. Data analysis

Data from the study proformas were entered into a Microsoft Access™ database held in duplicate on a secure sever at the University of Nottingham. Full double-entry of data was used as a quality control measure to ensure accuracy.

Data were analysed in PASW statistics™ (formerly SPSS™) version 18.0.0. Descriptive statistics were used to describe the overall population and their outcomes, with differences between residential and nursing homes explored using: the student's t-test for continuous and normally distributed variables; the Mann-Whitney U test for continuous and non-normally distributed or ordinal variables; the Chi-Squared test for categorical variables; and McNemar's test for paired categorical variables. Differences between individual care homes were explored using analysis of variance (ANOVA) for continuous and normally distributed variables and Kruskal Wallis non-parametric ANOVA for non-normally distributed or ordinal variables. Type I error was avoided when conducting multiple tests by using the Bonferroni correction.

The extent of care home level clustering of baseline and outcome variables was explored using intra-cluster correlation coefficients (ICC). ICC provides a means of describing the variance in individuals within a cluster (in this case a care home) by comparison with the variance across the sample as a whole[507]. It was calculated as described by Smeeth and Ng[508] using the outputs from a one-way ANOVA, which were inputted into the ICC equation as follows:

$$\mathrm{ICC} = (\mathrm{MS_b} - \mathrm{MS_w}) / (\mathrm{MS_b} + (m-1)\mathrm{MS_w})$$

Where MSb and MSw represented the mean squares from the ANOVA table for between and within clusters respectively and *m* was the average size of the cluster.

Standard error of the ICC was calculated on the basis that SE = √(variance), where variance was derived using the equation:

$$\text{variance}_{\text{ICC}} = 2(1\text{–ICC})^2[1+(n\text{-}1)\text{ICC}]^2/n(n\text{-}1)k$$

Where n was the harmonic mean of the number of participants per cluster and k was the number of clusters.

Medications and diagnoses were analysed separately in Microsoft Excel™. Descriptive data on medications was compiled by categorizing drugs into chapters and subchapters according to the British National Formulary[509] – the authoritative reference used for prescribing in the UK. A secondary analysis was conducted using the Screening Tool of Older Person's Prescriptions and the Screening Tool to Alert doctors to Right Treatment (commonly co-administered as the STOPP-START) tool – a clinical guideline which encourages doctors to consider stopping unnecessary or dangerous medications and starting those which are evidence-based for the treatment of older patients[510]. It has been validated in a number of older populations across Europe[511]. For this part of the analysis, the STOPP-START tool was applied independently by a GP and geriatrician, with differences resolved by consensus. Diagnoses were counted but also categorised according to ICD-10 section and subsection.

3.6. Results

3.6.1. Recruitment

Baseline recruitment commenced on 19/1/2009 and completed on 16/12/2009. There were 391 bed places across the participating homes, however subtotal bed-occupancy meant that there were only 323 residents, from which 227 (70%) subjects were recruited. Reasons for non-recruitment are shown in Table 31, with the most common issue being residents lacking capacity to consent to participate and having no consultee to inform their participation.

Table 31 - Reasons for non-recruitment to CHOS

Condition	No. of Residents
No consultee or consultee did not respond	61
Declined to participate	23
In hospital	6
In respite	3
Palliative care	3

A recruitment graph is shown in Figure 7.

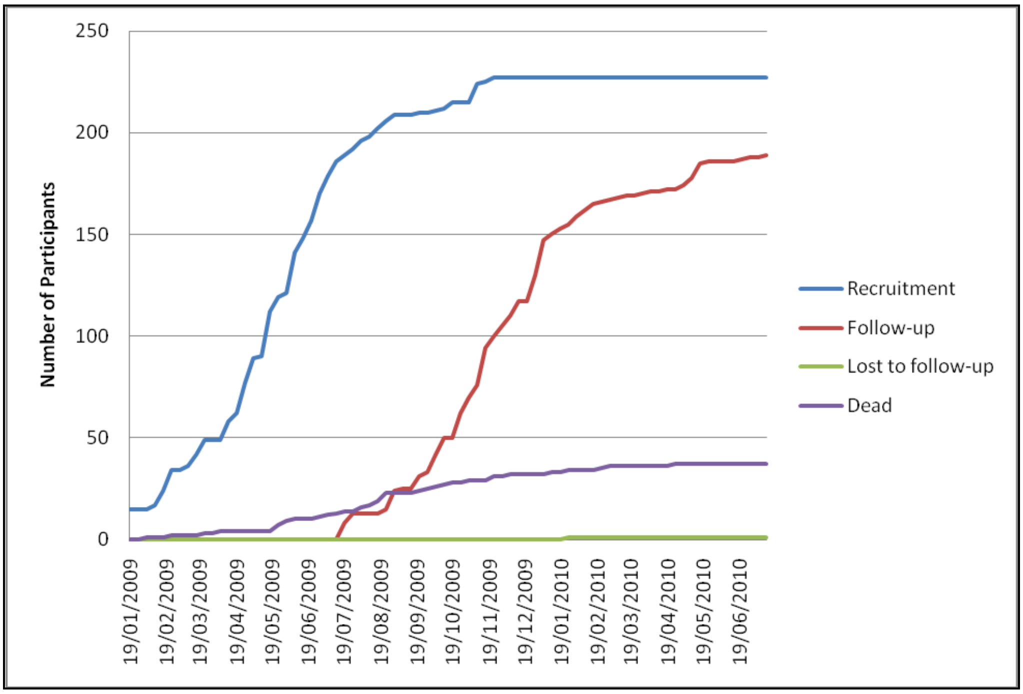


Figure 7 - Recruitment graph for CHOS

37 patients died during the 6-month follow-up period. 1 patient was lost to follow-up, having left the Nottingham area with no forwarding details. The mean number of days to follow-up was 185.6 (SD 22.4), the range of days of days to follow-up 177-292, with a small number of outliers taking a longer period to follow-up due to unavailability at the time of scheduled data-collection, predominantly due to hospital admission at the time of proposed data collection.

3.6.2. Missing data

174 discrete variables were recorded from 227 residents at baseline and 191 patients at follow-up. 114 of these were baseline variables and 65 were follow-up variables. Allowing for the 37 deaths and 1 withdrawal, 129 variables were complete, with no missing data. 17 variables had less than 5% missing data (data missing from between 1 and 10 respondents) and were unlikely to be significantly biased as a consequence. These are summarized in Table 32.

Table 32 - Variables with <5% data missing

	N		
	Valid	Missing (Corrected for deaths)	Percentage missing
Height	217	10	4.4%
Grip strength (right)	219	8	3.5%
Grip strength (left)	219	8	3.5%
Mid-arm circumference R	219	8	3.5%
Nutrition question	220	7	3.1%
Mid-arm circumference L	221	6	2.6%
Outcome EQ-5D pain	186	5	2.6%
MNA full meals	223	4	1.8%
MNA fruit	223	4	1.8%
MNA neuropsychological	223	4	1.8%
MNA dairy	224	3	1.3%
MNA eggs	224	3	1.3%
MNA meat	224	3	1.3%
MNA food intake	225	2	0.9%
MNA fluid	225	2	0.9%
MNA weight loss	226	1	0.4%

33 variables had 5% or more data missing, these are summarized in Table 33. All missing data for the pension credit variable was a consequence of non-response to this question at face-to-face interview. Most residents did not know whether they received the benefit, hence the high non-response rate. Where residents did respond, it was often in terms of “I think so” or, “maybe, yes”. The median MMSE was 11.5 for non-respondents and 16 for respondents to this question ($p<0.01$ Mann-Whitney U).

Table 33 - Variables with >5% data missing

	N		
	Valid responses	Missing data (Corrected for deaths)	Percentage missing
Do you receive pension credit	87	140	61.7%
BMI	149	78	34.4%
GHQ-baseline worthlessness	152	75	33.0%
Weight	154	73	32.2%
GHQ-12 baseline difficulties	158	69	30.4%
GHQ-12 baseline ADLs	160	67	29.5%
GHQ12-baseline decisions	161	66	29.1%
GHQ-12 baseline strain	161	66	29.1%
GHQ-12 loss of confidence	161	66	29.1%
GHQ-12 baseline problems	162	65	28.6%
GHQ12-baseline depressed	162	65	28.6%
GHQ-12 baseline sleeplessness	163	64	28.2%
GHQ-12 baseline usefulness	163	64	28.2%
GHQ-12 baseline concentration	164	63	27.8%
GHQ-12 baseline happiness	164	63	27.8%
GHQ-12 outcome usefulness	143	48	25.1%
GHQ-outcome difficulties	144	47	24.6%
GHQ-12 outcome decisions	145	46	24.1%
GHQ-12 outcome strain	145	46	24.1%
GHQ12-outcome problems	145	46	24.1%
GHQ12-outcome worthlessness	145	46	24.1%
GHQ-12 outcome confidence	146	45	23.6%
GHQ-12 outcome ADLs	147	44	23.0%
GHQ-12 outcome depressed	147	44	23.0%
GHQ-12 outcome happiness	147	44	23.0%
GHQ-12 outcome sleeplessness	149	42	22.0%
GHQ-12 outcome concentration	150	41	21.5%
Are you well off?	185	42	18.5%
EQ-5D baseline anxiety	187	40	17.6%
Level of education?	192	35	15.4%
Do you talk to your relatives often?	198	29	12.8%
EQ-5D outcome anxiety	175	16	8.4%
EQ-5D baseline pain	209	18	7.9%
ED-5D outcome self-care	177	14	7.3%
EQ-5D outcome ADLs	177	14	7.3%
EQ-5D outcome mobility	178	13	6.8%
Demispan	213	14	6.2%
Calf circumference R	214	13	5.7%
Calf circumference L	215	12	5.3%

94% of the missing BMI data was a consequence of missing weight data, 6% was explained by missing height or demispan data. All weight data was collected from care home records. 88% of the missing weight data came from only four homes (Table 34) – with widely fluctuating practices evident regarding the recording of weight. One home did not routinely record weight, whilst one home recorded weight in 94.4% of respondents.

Table 34 - Missing weights by home

Care Home ID	Weight missing (N)	Weight missing (% of respondents from that home)
6	23	57.5%
2	20	40.8%
16	12	100.0%
4	10	37.0%
1	6	27.3%
3	2	7.7%
5	2	14.3%
7	2	10.5%
14	1	5.6%

MMSE scores did not differ significantly for those with missing weights, however Barthel (BI) scores were significantly lower, with a median BI of 5 in those with missing weights and 10 in those with data available ($p<0.01$, Mann-Whitney U), suggesting physical inability to weigh the patient as an important contributor to non-response in this domain.

The low-response to individual variables had knock-on effects for two of the summary scores – GHQ-12 and EQ-5D. This effect was most marked for GHQ-12, with 27.8-33% non-response to component variables at baseline and 21.5-25.1% at follow-up, resulting in only 44% of respondents providing complete GHQ-12 responses at both baseline and follow-up. Non-respondents had a lower median MMSE and BI ($p<0.01$; Mann-Whitney U).

Individual EQ-5D variables, by contrast, had quite high response rates. This was achieved through the use of care home staff or family members as proxy respondents, where care home residents were unable to answer for themselves. Data on which questions were completed by residents and which by proxies were not collected. Staff and family members frequently stated, however, that they were unable to answer the question which asked whether residents were anxious or depressed. This was incomplete in 17.6% and 8.4% of respondents at baseline and follow-up respectively, resulting in complete EQ-5D data being available only in 140 (74%) respondents. Non-respondents were, again, more likely to have a lower MMSE and BI ($p<0.01$; Mann-Whitney U), with the effect most marked for MMSE (Figure 8).

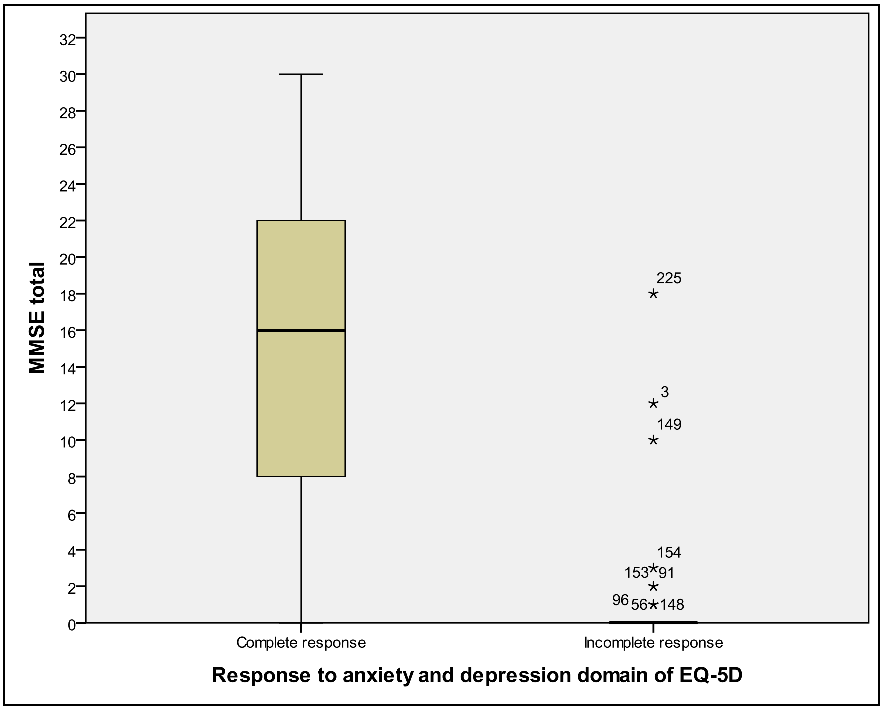


Figure 8 - MMSE for EQ-5D responders vs. non-responders, extreme outliers marked by *

Given the low completion rates for GHQ-12 and EQ-5D and likely significant bias introduced by non-response amongst the most disabled participants, these variables were not included in subsequent analyses.

3.6.3. Baseline measurements

The results for summary variables collected at baseline are outlined in Table 35. The median (IQR) BI for the cohort as a whole was 9 (3.5-14.5), indicating moderate dependency. Nursing home residents were significantly younger, more dependent, more cognitively impaired, more malnourished, had lower grip strength, had fewer diagnoses and were more behaviourally disturbed.

Table 35 - Summary variables collected at baseline, overall and by care home type

Variable	Whole Cohort	Residential homes	Nursing Homes
Number of participants	227	124	103
Mean Age (SD)	85.2 (7.5)	86.8 (7.3)	83.2 (7.3)**
% of residents who are female	78.9	80.6	76.7
Mean no of GPs per home (SD)	4.63 (2.73)	5 (2.60)	4.2 (3.11)
Median no. of days since admitted to home (IQR)	79 (5-153)	68 (0-147)	94 (28-160)
Mean body mass index (SD)	23.8 (5.9)	24.5 (5.9)	22.8 (5.7)
Median Barthel Index (IQR)	9 (2.5-15.5)	11 (7-15)	5 (1.5-8.5)**
Median MMSE (IQR)	13 (4-22)	16 (8.5-23.5)	10 (1-19)**
Median MNA Score (IQR)	20 (16.8-23.3)	21.5 (19.3-23.8)	17.5 (14-21)**
Median grip strength in PSI (IQR)	4 (1.5-6.5)	5 (3.8-6.3)	3 (0-6)**
Median Charlson Score (IQR)	2 (0.5-3.5)	2 (1-3)	2 (0.5-3.5)
Mean no of diagnoses (SD)	6.2 (4)	6.9 (3.1)	5.5 (2.4)**
Median no of medications (IQR)	8 (5.5-10.5)	7 (4.5-9.5)	8 (5.5-10.5)
Median NPI score (IQR)	3 (0-7.5)	2 (0-4.5)	6 (0-13)**
**Significant difference between residential/ nursing homes (p<0.01)			

The prevalence of specific dependencies from the BI is reported by home type in Table 36. This shows significantly higher dependency amongst nursing home residents in all domains of the BI apart from stair-climbing and bathing. These differences persisted after correction for multiple testing.

Table 36 - Prevalence of specific dependencies from the BI by home type

Specific Dependencies from BI	Whole cohort		Residential Homes		Nursing Homes		*p*-value*
	N	%	N	%	N	%	
Incontinent of urine (regularly)	129	56.8	53	42.7	76	73.8	<0.01
Incontinent of faeces (regularly)	95	41.9	35	28.2	60	58.3	<0.01
Need help to wash/brush hair	135	59.5	56	45.2	79	76.7	<0.01
Need at least some help to use the toilet (help on off; wiping)	170	74.9	78	62.9	92	89.3	<0.01
Need at least some help with eating (food cutting; spreading)	103	45.4	37	29.8	66	64.1	<0.01
Need help of two people to transfer to bed/chair	87	38.3	23	18.6	64	62.1	<0.01
Have no mobility	82	36.1	23	18.6	59	57.3	<0.01
Need at least some help to walk or wheel indoors	139	61.2	65	29	74	33	<0.01
Need to be dressed (unable to do half the task unaided)	119	52.4	51	23	58	26	<0.01
Unable to manage stairs	183	80.6	96	77.4	87	84.5	0.12
Needs help with bathing	213	93.8	114	91.9	99	96.1	0.15
* Calculated using Chi-square for difference between residential and nursing homes							

66% of respondents had evidence of BPSD as defined by at least one positive domain within the NPI. NPI results were further analysed for prevalence of any behavioural symptoms by domain. To further evaluate the relative severity and frequency of symptoms in each domain, the prevalence of severe behavioural symptoms – defined as the proportion of patients with symptoms of moderate to high severity – and frequent behavioural symptoms – defined as the proportion of patients with symptoms once weekly or more often – was calculated. These results are presented in Table 37 in descending order of prevalence. For any given domain, frequent symptoms were more prevalent than severe ones. Agitation, nervousness and irritability were the three most common symptoms, with severe irritability and agitation manifesting in over a third and severe nervousness in over a quarter. There was no significant difference between baseline and follow-up using McNemar's test after corrections were made for multiple testing.

Table 37 - Prevalence of NPI domains - any symptoms, severe symptoms and frequent symptoms at baseline and follow-up

	Number (%) of respondents					
	Any Behavioural Symptoms		Severe Behavioural Symptoms		Frequent Behavioural Symptoms	
	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up
Agitation	86 (37.9)	85 (37.4)	38 (16.7)	33 (17.4)	58 (25.6)	55 (24.2)
Nervousness	76 (33.5)	77 (33.9)	25 (11)	26 (13.7)	57 (27.1)	48 (21.1)
Irritability	69 (30.4)	71 (31.3)	35 (15.4)	20 (10.5)	48 (21.1)	41 (18.1)
Depression	52 (22.9)	64 (28.2)	19 (8.4)	23 (12.1)	39 (17.2)	35 (15.4)
Difficulty sleeping	46 (20.3)	34 (15.0)	12 (5.3)	12 (6.3)	32 (14.1)	25 (11.0)
Appetite disturbance	39 (17.2)	37 (16.3)	26 (11.5)	19 (10)	34 (15.0)	28 (12.3)
Motor behaviour	38 (16.7)	36 (15.9)	25 (11)	20 (10.5)	30 (13.2)	28 (12.3)
Apathy	31 (13.7)	38 (16.7)	17 (7.5)	25 (13.2)	25 (11)	31 (13.7)
Disinhibition	30 (13.2)	23 (10.1)	23 (10.1)	11 (5.8)	21 (9.3)	15 (6.6)
Delusions	20 (8.8)	28 (12.3)	13 (5.7)	13 (6.8)	16 (17)	22 (9.7)
Hallucinations	18 (7.9)	16 (7)	8 (3.5)	9 (4.7)	13 (5.7)	12 (5.3)
Elation	6 (2.6)	17 (7.5)	4 (1.8)	10 (5.3)	4 (1.8)	8 (3.5)

3.6.4. Differences in baseline measurements by care home

The practice of individual care homes might either select for particular types of patient within a home– for example by selecting patients with advanced dementia – or might modify the health and social status of the cohort over time (for example by particular practices which influence the incidence or prevalence of frailty). To explore this, the differences between baseline variables for individual care homes were explored using ANOVA. Those where statistically significant variability was demonstrated are summarised in Table 38. Significant variability between individual homes persisted for the same variables when nursing homes and residential homes were analysed separately.

Table 38 – Baseline variables analysed by individual care home IDs

	p for difference between individual care home IDs
Mean Age$^{\tau}$	<.01
Barthel Index$^{\tau\tau}$	<.01
MMSE$^{\tau\tau}$	<.01
MNA score$^{\tau\tau}$	<.01
Grip strength$^{\tau\tau}$	<.01
No of diagnoses$^{\tau}$	<.01
No of medications$^{\tau\tau}$	<.01
NPI$^{\tau\tau}$	<.01
$^{\tau}$Tested using one-way ANOVA; $^{\tau\tau}$Tested using Kruskal-Wallis non-parametric ANOVA;	

The differences between individual care homes for these variables where significant inter-home variability was identified are shown in box plots in Figure 9.

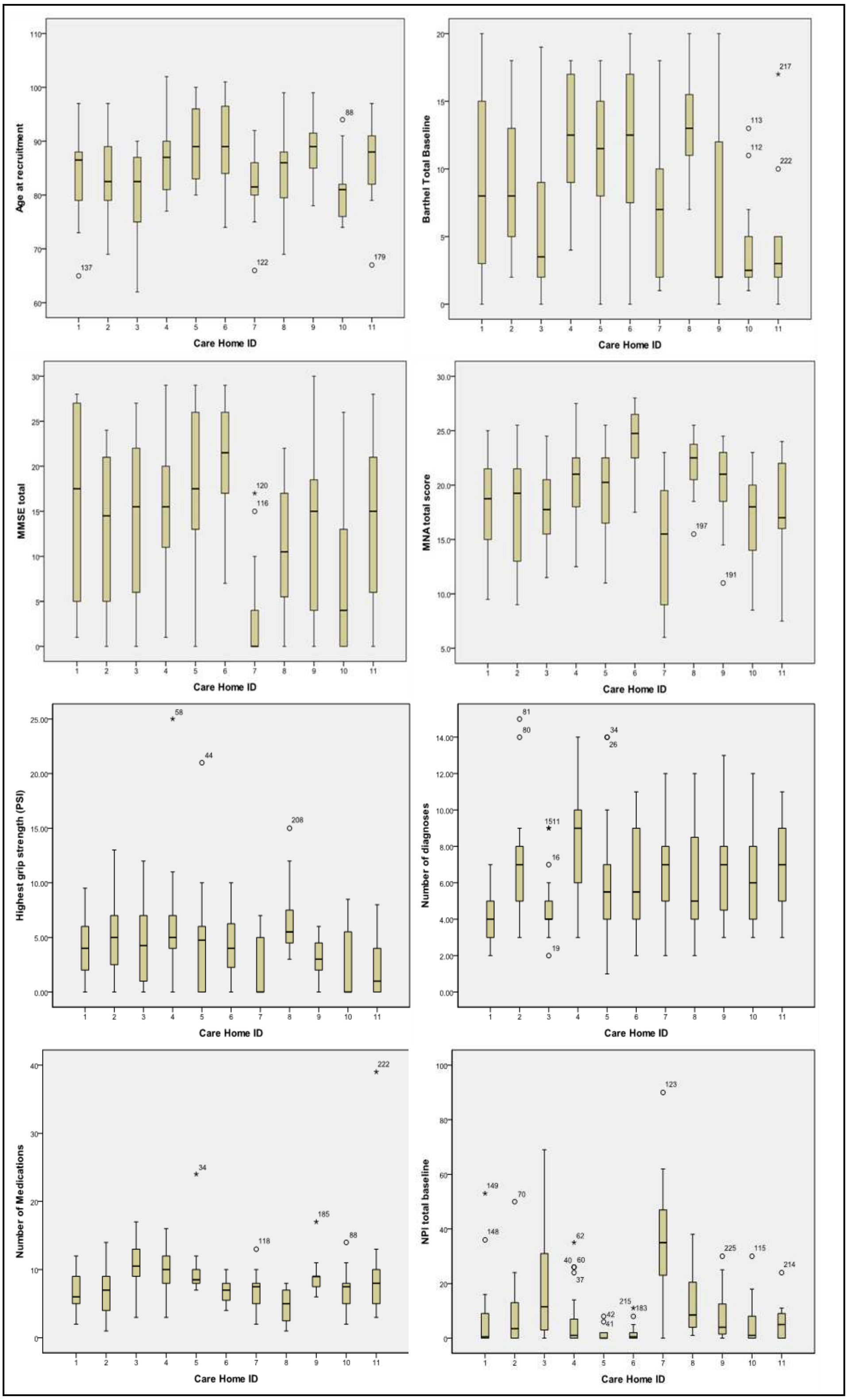


Figure 9 – Box plots for baseline variables which have significant variability by care home ID, with outliers marked by ⁰ and extreme outliers by * - numbers denote outliers' study ID

The ICCs and their standard errors (SE) for baseline measures are summarised in Table 39. The negative value for the Charlson index, although improbable, was checked on multiple occasions and using different statistical packages. It suggests that no clustering by care homes was evident for the Charlson and that residents were as alike between homes as they were within them. An explanation of how ICC's express clustering is given in section 3.7.7. of the discussion. These ICCs and those in table 50 were the main reason that no regression analysis was undertaken to explore connections between baseline and outcome variables, since such analysis would have required to take account of clustering and the study was inadequately powered to do so.

Table 39 - Intraclass Correlation Co-efficients (ICC) and Standard Errors (SE) for baseline measures, listed in order of descending magnitude of correlation

	ICC	SE
NPI	.343	.11
BI	.288	.01
MNA score	.222	.09
MMSE	.216	.09
No of medications	.167	.08
No of diagnoses	.159	.07
Grip strength	.136	.07
Age	.086	.05
BMI	.035	.04
Days since admission	.018	.03
Charlson Score	-.028	.01

The number of GPs per care home is summarised in Figure 10. Three homes had 1:1 relationships with GPs (IDs 3, 5 and 7). All of these were rural homes, with the consequence that the number of GPs within acceptable distance of the home able to provide cover was limited, however all three also had policies which encouraged residents to select a preferred local practice over other alternatives.

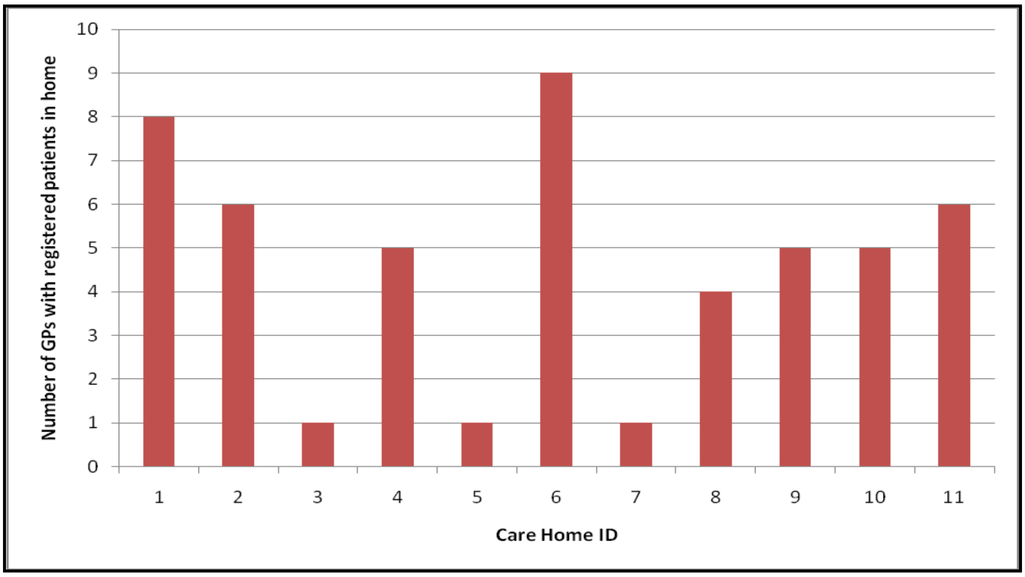


Figure 10 - Number of General Practitioners per care home

3.6.5. Nutritional Status

BMI and MNA results by category are shown in Table 40 and Table 41. Data for BMI were less complete than for MNA as a consequence of the missing weight data. Of those with weights recorded, just over a quarter of residents were underweight on the basis of BMI, compared with 30% of residents who were malnourished and a further 56% at risk of malnutrition on the basis of MNA scores.

Table 40 - BMI results by category

BMI categories	N(%)
Underweight	42 (28)
Normal Weight	50 (34)
Overweight	35 (23)
Obese	14 (9)
Morbidly obese	8 (5)

Table 41 - MNA results by category

MNA categories	N(%)
Normal nutritional status	29 (14)
At nutritional risk	113 (56)
Malnourished	61 (30)

Patients were more likely to be underweight as the severity of their malnutrition assessed using the MNA increased. However, 40% of the patients identified by the

MNA as malnourished and 82% identified as at risk were of normal weight or above. MNA categories are cross-tabulated with data on weight loss in Table 42. This allows separation of those who would require immediate dietetics intervention (highlighted in red) on the basis of the MNA algorithm, from those for whom only observation (amber) and no action (green) would be required. Thus using the MNA, 77 residents would be referred for dietetic input, as opposed to 38 residents if a referral criterion of being underweight according to BMI were adopted.

Table 42 – Cross-tabulation of MNA categories with recent evidence of weight loss

		MNA categories			
		Malnourished	At risk of malnutrition	Normal nutritional status	Total
Weight lost	No weight loss	23	97	28	148
	Weight loss	38	16	1	55
Total		61	113	29	203

3.6.6. Diagnoses at baseline

The top 20 most common diagnoses recorded at baseline are listed in Table 43. Circulatory diseases predominated and hypertension was the most prevalent diagnosis within this category. Musculoskeletal diseases were also common due to the high prevalence of osteoarthritis and osteoporosis. The high prevalence of mental and behavioural disorders was explained almost entirely by dementia, with the third most common diagnosis in this category, depression, recorded in only 33 participants.

Table 43 - Top 20 most common diagnoses by ICD-10 category

Diagnoses (n)	ICD-10 Code	ICD-10 Category
102	I10	Essential (primary) hypertension
83	M15.0	Primary generalized (osteo)arthrosis
77	F03	Unspecified Dementia
45	M80	Osteoporosis with pathological fracture
38	I64	Stroke, not specified as haemorrhage or infarction, Tabular list and Index
35	G30	Alzheimer's disease
35	N18	Chronic renal failure
34	E11	Non-insulin-dependent diabetes mellitus
33	F33	Recurrent depressive disorder
33	I67.9	Cerebrovascular disease, unspecified
31	I48	Atrial fibrillation and flutter
30	I25	Chronic ischaemic heart disease
29	F01	Vascular dementia
26	H90	Conductive and sensorineural hearing loss
23	H25	Senile cataract
22	D50	Iron deficiency anaemia
22	G40	Epilepsy
21	G81	Hemiplegia
21	H35.3	Degeneration of macula and posterior pole
19	E78.0	Pure hypercholesterolaemia

3.6.7. Prescribing

1795 prescriptions were recorded. The top ten most commonly prescribed categories summarized in Table 44.

When considered against STOPP-START criteria, there were 320 STOPP and 252 START indications. The mean number of STOPPs per resident was 1.41 (range 0-8; SD 1.53) with the most common indications being duplicate prescription, opioids in dementia, proton pump inhibitors at high dose and aspirin without an indication (60, 37 and 35 STOPPs respectively – see Table 45). The mean number of STARTs per resident was 1.11 (range 0-6; SD 1.20) with the most common being antihypertensives, beta-blockers for angina and calcium/vitamin D for osteoporosis (41, 28 and 28 STARTs respectively – see Table 46**)**.

Table 44 – Top ten categories of medication by BNF chapter

Prescriptions (n)	Drugs by BNF chapter	Prescriptions (n)	Drugs by BNF chapter
196	1.6 Laxatives	93	4.3 Antidepressant drugs
111	Stimulant laxatives	53	Selective serotonin reuptake inhibitors
75	Osmotic laxatives	35	Tricyclic antidepressants
6	Bisacodyl	5	Mirtazapine
4	Bulking agents	91	1.3 Antisecretory drugs and mucosal protectants
2	Co-danthromer	85	Proton pump inhibitors
2	Stool softeners	6	H_2-antagonists
1	Phosphate enema	75	2.2 Diuretics
182	4.7 Analgesics	46	Loop diuretics
127	Paracetamol	16	Thiazide diuretics
25	Compound paracetamol/ opioid preparations	7	Co amilofruse
15	Weak opioids	6	Aldosterone antagonists
7	Tramadol	70	13.2 Emollient and barrier preparations
3	Oral morphine	59	2.12 Lipid-regulating drugs
2	Gabapentin	58	Statins
1	Fentanyl patches	1	Ezetimibe
1	Meptazinol	46	2.5 Hypertension and heart failure
1	Sumatriptan	36	Angiotensin converting enzyme-inhibitors
121	2.9 Antiplatelet drugs	6	Angiotensin receptor blockers
108	Aspirin	3	Doxazosin
10	Dipyridamole	1	Co-approvel™
3	Clopidogrel		

Table 45 - Top 20 STOPP indications for cohort

STOPP Code	Indication for drug cessation	N
J	Any regular duplicate drug class prescription e.g. two concurrent opiates, NSAID's, SSRI's, diuretics	60
I3	Long-term opiates in those with dementia unless indicted for palliative care or management moderate-severe chronic pain	37
C4	PPI for peptic ulcer disease at full therapeutic dosage for > 8 weeks	35
A13	Aspirin with no history of coronary, cerebral or peripheral arterial symptoms or occlusive arterial event	29
A2	Loop diuretic for dependent ankle oedema only i.e. no clinical signs of heart failure	24
B8	Long-term (i.e. > 1 month) neuroleptics as long-term hypnotics	16
B1	Tricyclic antidepressants (TCA's) with dementia	14
A3	Loop diuretic as first-line monotherapy for hypertension	12
A8	Calcium channel blockers with chronic constipation	12
B5	TCA's with an opiate or calcium channel blocker	9
E4	Long-term use of NSAID (>3 months) for relief of mild joint pain in osteoarthritis	9
B4	TCA's with constipation	7
C1	Diphenoxylate, loperamide or codeine phosphate for treatment of diarrhoea of unknown cause	7
B7	Long-term (i.e. > 1 month) long-acting benzodiazepines	6
F1	Bladder antimuscarinic drugs with dementia	5
H4	Vasodilator drugs known to cause hypotension in those with persistent postural hypotension	5
D2	Systemic corticosteroids instead of inhaled corticosteroids for maintenance therapy in moderate-severe COPD	4
G2	Beta-blockers in those with diabetes mellitus and frequent hypoglycaemic episodes	4
A1	Digoxin at a long-term dose > 125µg/day with impaired renal function	2
B11	Anticholinergics to treat extra-pyramidal side-effects of neuroleptic medications	2
E3	NSAID with heart failure	2
F3	Bladder antimuscarinic drugs with chronic constipation	2
I2	Regular opiates for more than 2 weeks in those with chronic constipation without concurrent use of laxatives	2

Table 46 - START indications identified in cohort

START Code	Indication for drug commencement	N
A4	Antihypertensive therapy where systolic blood pressure consistently >160 mmHg.	41
A8	Beta-blocker with chronic stable angina.	28
E3	Calcium and Vitamin D supplement in patients with known osteoporosis	28
A3	Aspirin or clopidogrel with a documented history of atherosclerotic coronary, cerebral or peripheral vascular	27
A1	Warfarin in the presence of chronic atrial fibrillation.	23
F4	Statin therapy in diabetes mellitus if one or more co-existing major cardiovascular risk factor present	17
B1	Regular inhaled beta 2 agonist or anticholinergic agent for mild to moderate asthma or COPD.	16
A6	Angiotensin Converting Enzyme (ACE) inhibitor with chronic heart failure.	14
F3	Antiplatelet therapy in diabetes mellitus if one or more co-existing major cardiovascular risk factor present	14
F1	Metformin with type 2 diabetes +/- metabolic syndrome (in the absence of renal failure)	13
A7	ACE inhibitor following acute myocardial infarction.	7
D2	Fibre supplement for chronic, symptomatic diverticular disease with constipation	7
E1	Disease-modifying anti-rheumatic drug (DMARD) with active moderate-severe rheumatoid disease lasting > 12 weeks	6
F2	ACE inhibitor or Angiotensin Receptor Blocker in diabetes with nephropathy	5
E2	Bisphosphonates in patients taking maintenance oral corticosteroid therapy.	4
C1	L-DOPA in idiopathic Parkinson’s disease with definite functional impairment and resultant disability	2

3.6.8. Death

Of the 37 participants who died during the follow-up period, 16 deaths occurred in residential and 21 in nursing homes. This difference was not statistically different. However, death rates varied significantly between individual homes, ranging from 0-32% of respondents ($p<0.05$; Chi-squared). These results are illustrated in Figure 11.

A Kaplan-Meier plot curtailed to the planned follow-up of 180 days, by censoring results from those completing follow-up after this time, is shown in Figure 12. This shows early and persistent separation of the curves for residential and nursing homes. The decision was made to curtail the curve because this removes the misleading apparent sharp drop-off in survival caused by the censoring of data from patients who had completed follow-up by the time the last outlier had their data collected at 292 days.

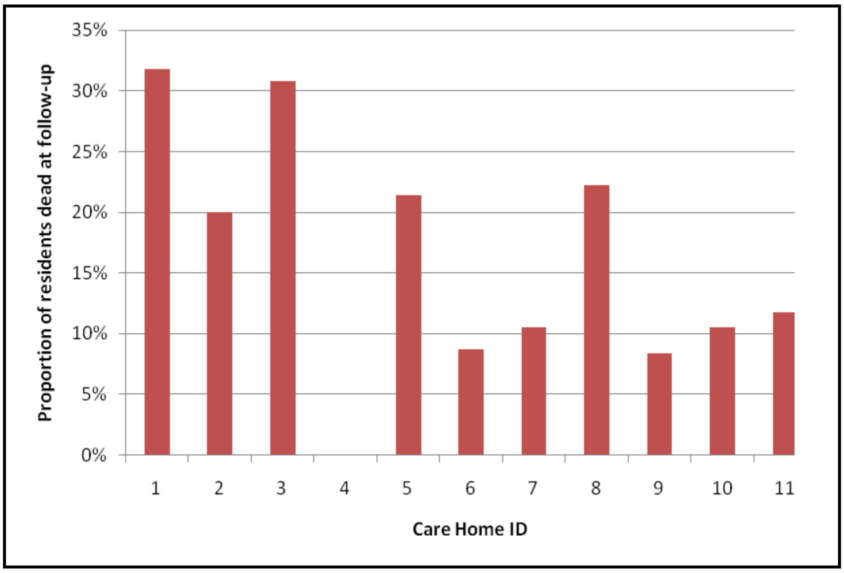


Figure 11 - Death rate by care home

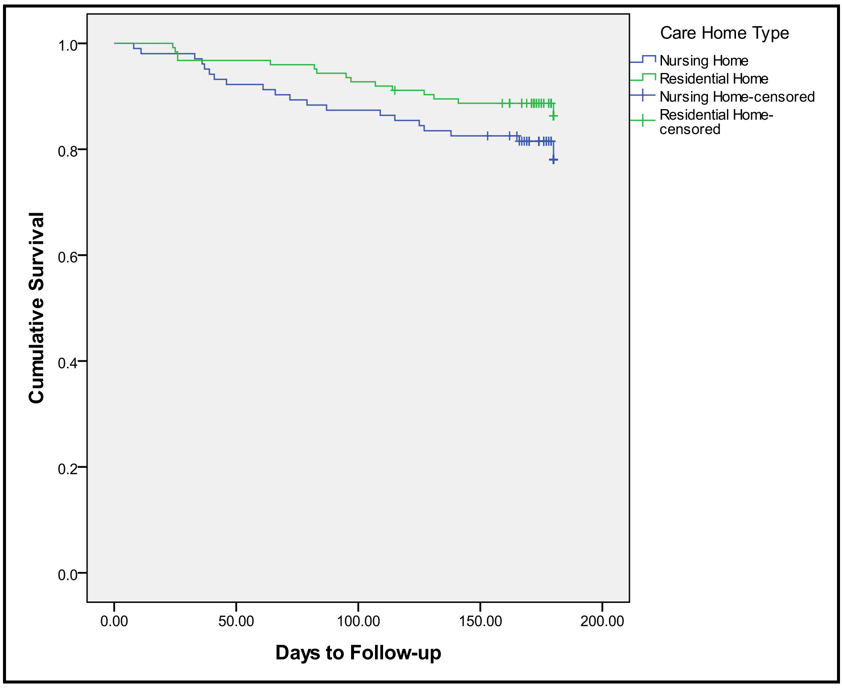


Figure 12 - Kaplan-Meier Curve curtailed to 180 days to remove effect of outliers with longer than anticipated duration of follow-up

Detailed regression analysis was not undertaken because of the statistical limitations imposed by the small number of deaths.

3.6.9. Acute NHS resource use

52 admissions were recorded from 42 participants, with 1-3 admissions per admitted resident. The cohort accumulated a total of 601 NHS inpatient bed days, with a median (IQR) length of stay of 7 (2-12) days amongst those admitted. 1010 investigations were requested for 150 residents, with a range of 1-54 and a median (IQR) of 3 (1-6) investigations amongst those with tests requested – some of these tests were requested as inpatient and some as outpatient investigations. 68 residents attended 142 outpatient appointments, with a range of 1-6 and a median (IQR) of 2 (1.5-2.5) appointments per resident attending. There were 30 emergency department admissions recorded from 27 residents, with a maximum number of attendances per admission of 2 per resident.

Statistically significant differences were identified between the number of investigations and outpatient attendances for participants from residential and nursing homes ($p<0.05$; Mann-Whitney U), with higher resource use recorded by participants from residential homes in both instances.

Episode statistics rates were calculated for each home by using the following formula:

Episode rate per resident per year = (Total number of episodes for home/number of residents enrolled in study) x (365/mean length of follow-up for residents enrolled in study)

This provided a number of episodes/resident/year for each home. These statistics do not include those residents living in the homes who were unable to be enrolled in the study. They are presented in Table 47. These demonstrate wide variation between homes for number of days as inpatient and number of investigations conducted, with less significant variation for number of admissions and A+E contacts. Home 4 was an obvious outlier. This home was within the catchment area of a district general allied to the main teaching hospital which acted as the focus for the rest of the data collection – possibly reflecting differing admission policies in that hospital

Table 47 - NHS resource use expressed as episodes/resident/year by care home ID

Care Home ID	Admissions per resident per year	Days as IP per resident per year	Number of investigations per resident per year	Number of OP contacts per resident per year	Number of A+E attendances per resident per year
1	0.75	7.03	12.67	1.38	0.43
2	0.8	20.75	21.62	2.04	0.51
3	0.08	0.34	0.51	1.02	0
4	0.82	6.99	12.42	2.83	0.22
5	0.15	0.15	5.21	2.45	0.15
6	0.63	3.4	5.99	1.43	0.45
7	0.11	1.26	4.81	0.46	0
8	0.23	1.84	4.61	0.46	0.12
9	0.52	6.22	19.87	0.86	0.17
10	0.34	1.36	3.16	0	0.34
11	0.9	4.89	12.24	0.77	0.64
Mean	0.48	4.93	9.37	1.25	0.28

3.6.10. BI, NPI, ∆ BI and ∆ NPI at outcome

Data for the BI at baseline, follow-up and the change in BI between measurements are summarized in Table 48. There was a trend towards deterioration in BI for the cohort as a whole and a significant deterioration amongst nursing home residents, with the difference between residential and nursing home median BI's persisting to follow-up.

Table 48 – Barthel index at baseline and follow-up by care home type

	N	Median Baseline BI (IQR)	Median Follow-up BI (IQR)	Mean Change in BI (SD)	*p* for difference over time (Wilcoxon Signed Ranks)
Whole Cohort	227	9 (3.5-14.5)	8 (2.5-13.5)	-0.52 (5.22)	0.053
Residential Homes	124	11 (7-15)	10 (6.5-13.5)	-0.23 (6.10)	0.189
Nursing Homes	103	5 (1.5-8.5)	3 (0-7)	-0.74 (4.46)	<0.01
p for difference between types of home		<0.01[τ]	<0.01[τ]	0.510[ττ]	

[τ] Mann Whitney U; [ττ] Student T-test

Similar data is shown for NPI in Table 49, with a statistically significant increase in NPI – indicating a worsening of BPSD across the cohort, both as a whole and for both categories of residential status. The mean increase in NPI was greater in residential homes, however the nursing home cohort continued to have a higher median NPI at follow-up despite this. The large standard deviations for Δ NPI are explained by the fact that most residents demonstrated no change between baseline and follow-up, with a small proportion of residents experiencing improvement or deterioration (see Figure 13).

Table 49 - NPI at baseline and follow-up by care home type

	N	Median Baseline NPI (IQR)	Median Follow-up NPI (IQR)	Mean Change in NPI (SD)	*p* for difference over time (Wilcoxon Signed Ranks)
Whole Cohort	227	3 (0-10.5)	5 (0-13)	2.28 (16.28)	<0.01
Residential Homes	124	2 (0-6.5)	4 (0-10)	3.85 (14.68)	<0.01
Nursing Homes	103	6 (0-19.5)	8 (1.5-14.5)	0.22 (18.05)	<0.01
p for difference between types of home		<0.01[τ]	0.01[τ]	0.128[ττ]	

[τ] Mann Whitney U; [ττ] Student T-test

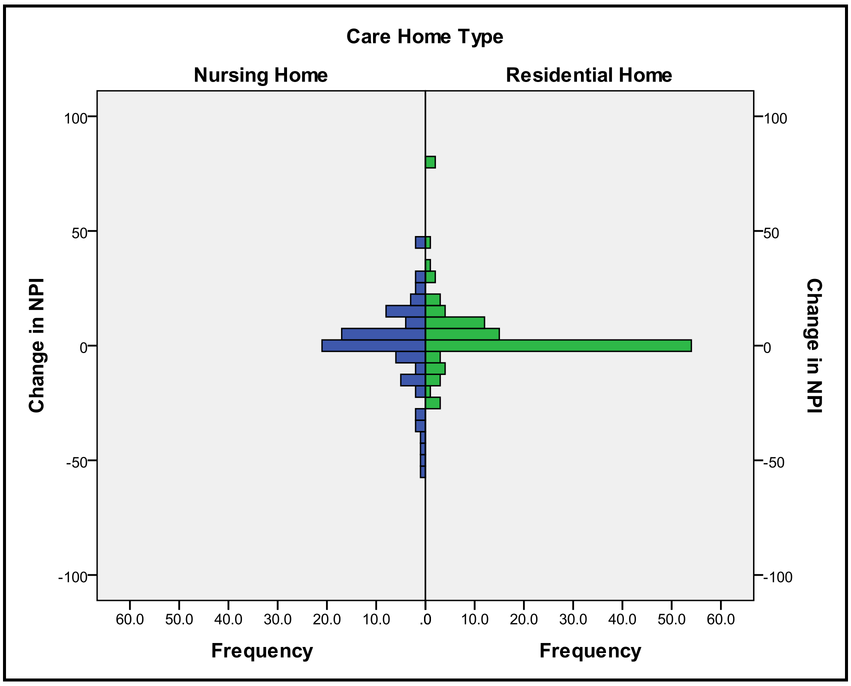


Figure 13 - Change in NPI score between baseline and follow-up in the residential and nursing home populations

3.4.11. Clustering of outcome measures

Intraclass correlation co-efficients for scale outcome variables are shown in Table 50, with the negative ICC for ΔBI indicating the absence of clustering for this variable.

Table 50 - Intraclass correlation co-efficients, standard errors and design effect for scale outcome measures, listed in order of descending magnitude of correlation

	ICC	SE
NPI	.245	.09
BI	.172	.08
Number of investigations per home	.111	.06
ΔNPI	.079	.05
Number of outpatient attendances	.078	.05
Number of days as inpatient	.047	.04
Number of admissions	.024	.03
Number of emergency department attendances	.020	.03
ΔBI	-.013	.02

3.7. Discussion

The cohort was physically dependent, demonstrated prevalent behavioural and psychiatric symptoms, was at high risk of malnutrition, demonstrated multimorbidity defined by chronic conditions and was prescribed complex drug regimens. These findings suggest a need for physiotherapy, occupational therapy, specialist nursing, old age psychiatry, dietetic and pharmacy input to the management of residents. Management of the type of chronic conditions seen could be within the competency of many GPs, but the high prevalence of multimorbidity and conditions routinely cared for by geriatricians raises the possibility that they might also play a role. The wide-variability in measurements seen both for individual participants and homes suggests that individualised assessment of residents could be useful in helping to target expertise to residents with corresponding needs - highlighting a possible role for CGA.

3.7.1. Physical Dependency

The cohort demonstrated a high prevalence of functional dependency as evidenced by the median BI scores of 9, 11 and 5 for all, residential and nursing home residents respectively at baseline, coupled to the significant decline in nursing home residents – and trend towards decline in other groups – at 6 months. Table 36 demonstrates that, even in the residential sector, over three quarters of residents required help with bathing and dressing, around half with toileting and grooming and over a quarter with eating and walking indoors. 28% were incontinent of faeces and 43% of urine. These figures were significantly worse in the nursing sector for all BI domains except stairs and bathing, where functional status was so universally poor as to defy separation by home type.

Functional status as measured using BI has been shown to map to nursing dependencies[512 513]. Comparison can be drawn with the census conducted by Hubbard *et al*[514] of 889 inpatients in Cardiff and Vale NHS Trust in 2003, where the median BI scores were 9 and 3 in rehabilitation and continuing care settings respectively. In that cohort, the NHS continuing care patients – with similar BI scores to the nursing home residents in CHOS – received 20 mins 15 secs of physiotherapy, 44 mins 24 secs of occupational therapy and 1 hour 30 mins of dietetics input per patient per day. The CHOS cohort did not receive such input.

Aside from their implications for nursing, the BI dependencies illustrated in Table 36 suggest possible targets for therapeutic intervention. At the very least, the high incidence of incontinence and immobility mean that specific services for continence, pressure care and input from physio- and occupational therapists for management and prevention of flexion contractures would be required. The prevalent immobility might have been a consequence of a significant number of the cohort having failed to progress with rehabilitation prior to transfer to their care home, especially given the high prevalence of stroke, and might also have encompassed patients with moderate to advanced dementia who would be unlikely to engage with, or respond to, rehabilitation. However, there might also have been a sub-cohort of residents who were legitimate targets for more aggressive multidisciplinary rehabilitation. Only a multidisciplinary team, encompassing physio- and occupational therapists, would be adequately placed to assess who could benefit from such intervention.

3.7.2. Behavioural and psychiatric symptoms of dementia

Given the high prevalence of cognitive impairment, an important consideration was the prevalence of BPSD, as illustrated in Table 37. Two thirds of residents manifested BPSD. The most common symptoms - agitation, nervousness and irritability – were reported in around a third of residents, with the majority of these manifesting symptoms which were frequent but non-severe. The prevalence of BPSD was significantly lower than that reported in several large European cohort studies (n=836 when pooled) of community dwelling dementia-sufferers, where up to 92.5% of participants with an MMSE of 11-20 had detectable BPSD[515], or in studies of US and Norwegian nursing home residents with dementia, where the prevalence of BPSD was 75-79%[516 517].

The reason for the low prevalence in the CHOS cohort was not clear. It was not that the cohort were over-medicated by comparison with other studies, Margallo-Lana *et al* reported prescribing rates of 58% for antipsychotics in their cohort of 231 US nursing home residents with dementia[516], whilst only 12% of CHOS participants were receiving antipsychotics and 13% hypnotics. Based upon observations during data collection, physical restraint was not widely used in the CHOS cohort.

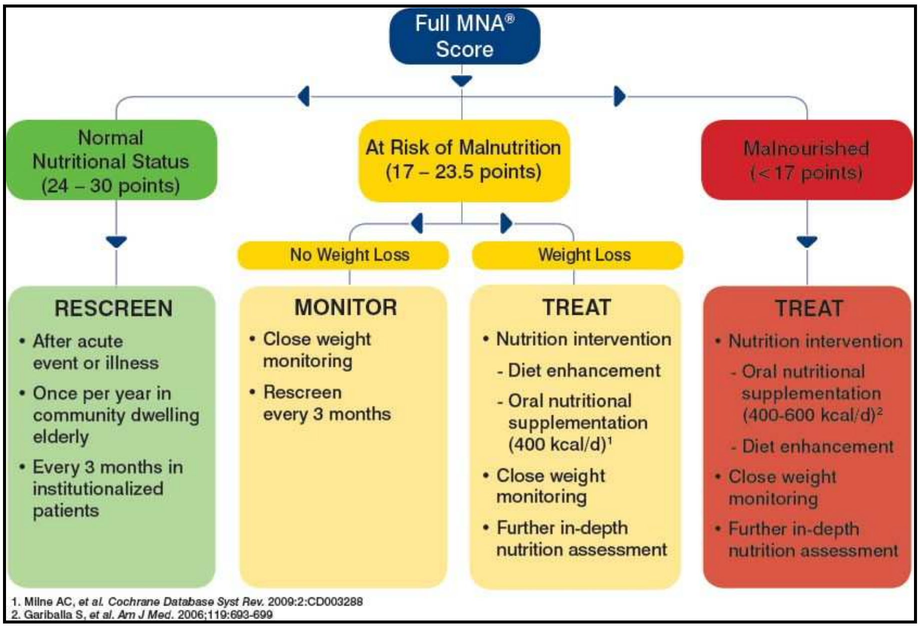
Two of the homes in the sample specialised in the management of patients with behavioural disorders and, anecdotally, researchers on the project witnessed occasional examples of profound behavioural disturbance – with a participant throwing furniture in the direction of a researcher on one occasion. The variability seen between care homes for NPI-totals (Table 39) and the wide range of NPI scores (Table 35) suggest that there were both homes and individuals where NPI was significantly higher than the median.

There might have been reporting bias due to difficulty in establishing responses to the NPI from a composite of care home records and the responses of minimally qualified care staff. Strikingly, the prevalence of apathy, one of the most common manifestations of late dementia in the other studies mentioned[515-517], was relatively low in the CHOS cohort. This could have been due to a failure to recognise apathy on the part of the staff respondents, or a desensitisation towards it.

That BPSD was present suggests a need for psychogeriatric support to care homes. That it was non-severe and moderately frequent, suggests that the prevalent mode of intervention would be non-pharmacological, particularly given concerns about the adverse effects of anti-psychotic medications in this cohort and national guidelines which stipulate a primarily non-pharmacological response to BPSD in all but the most extreme cases[518]. Chapter 2 reported that the evidence-base for non-pharmacological interventions in care homes was uncertain and, whilst interventions such as group-therapy, music-therapy, aromatherapy and snoozelin-based relaxation are suggested in national guidelines, there is an acknowledged need for such therapy to be instituted and monitored based around a process of comprehensive psychogeriatric assessment in partnership with a psychogeriatric multidisciplinary team. That is to say, specialist input would be required if such therapies were to be routinely instituted.

3.7.3. Nutritional measures in the cohort

As illustrated by Table 40 and Table 41, 86% of participants were malnourished or at risk of malnutrition, whilst 28% were underweight. Table 42 showed that 34% of participants would have triggered criteria for “further in-depth nutritional assessment” according to the MNA management algorithm (Figure 14). This suggests a need for regular dietetic input in the cohort – further building the case for multidisciplinary input in the care home setting.



1. Milne AC, *et al. Cochrane Database Syst Rev.* 2009:2:CD003288
2. Gariballa S, *et al. Am J Med.* 2006;119:693-699

Figure 14 - The MNA management algorithm

It was unsurprising, given the comprehensive nature of the MNA, that it detected higher rates of malnutrition than the BMI alone. The MNA gets around the issue of missing weight data in part by allowing substitution of arm and/or leg circumference for BMI but still relies upon data on weight loss – i.e. longitudinal weight records – to build a full score. Most alternative nutritional screening tools – such as the malnutrition universal screening tool (MUST), Nutritional Risk Screening 2002 (NRS-2002), Malnutrition Screening Tool (MST) and Subjective Global Assessment (SGA) – also rely upon weight, either requiring single snapshot or longitudinal weight data, or substituted anthropometric measurements[519].

Based upon the data recorded, weights were clearly difficult to measure in dependent care home residents, whilst anthropometric measurements are time consuming and require specific training[520]. It would clearly be preferable for care home staff to be able to identify malnutrition without using either. The Simplified Nutrition Appetite Questionnaire (SNAQ) is a four-point screening test, which focuses around four questions on appetite and intake (Box 4), rather than anthropometric measurements, to establish nutritional risk[521]. Rolland *et al*[520] compared SNAQ to the MNA demonstrating a positive correlation between the two but found that SNAQ was relatively poorly predictive of malnutrition by comparison with the MNA, misclassifying 28% of the population even after optimizing its cut-off score using threshold analysis. Most of these misclassifications had an abnormal SNAQ with a normal MNA, that is to say that SNAQ tended to over-diagnose malnutrition. Used as a screening test which might trigger more detailed assessment SNAQ might go some way to reducing the need to regularly weigh patients.

1 My appetite is:
   A. very poor
   B. poor
   C. average
   D. good
   E. very good

2 When I eat:
   A. I feel full after eating only a few mouthfuls
   B. I feel full after eating about a third of a meal
   C. I feel full after eating over half of meal
   D. I feel full after eating most of the meal
   E. I hardly ever feel full

3 Food tastes:
   A. Very bad
   B. Bad
   C. Average
   D. Good
   E. Very good

4 Normally I eat:
   A. Less than one meal a day
   B. One meal a day
   C. Two meals a day
   D. Three meals a day
   E. More than 3 meals a day

Box 4 – The Simplified Nutrition Appetite Questionnaire (SNAQ)

3.7.4. Diagnoses

The diagnoses most prevalent in the cohort (Table 43) were chronic diseases. With a few exceptions, such as stroke, ischaemic heart disease and diabetes, these were not diagnoses where hospital physicians particularly hold competencies or specific training. A comparison between Table 43 and the 20 common presentations which comprised the focus of symptom-based competencies in the 2010 curriculum for UK core medical training (Box 5) [522], demonstrates little overlap.

Abdominal pain
Acute back pain
Blackout/collapse
Breathlessness
Chest pain
Confusion, acute/Delirium
Cough
Diarrhoea
Falls
Fever
Fits/seizure
Haematemesis and melaena
Headache
Jaundice
Limb pain and swelling
Palpitations
Poisoning
Rash
Vomiting and nausea
Weakness and paralysis

Box 5 - Top 20 common presentations used as the basis of UK basic medical training [522]

The types of chronic conditions which were seen in the cohort sit much more comfortably within the remit of general practitioners. Chronic disease management is, of course, also central to geriatric medicine and the UK curriculum for specialty trainees in geriatrics[523] contains a curriculum grid on diagnosis and management of chronic disease and disability which maps closely to the diagnoses seen in the CHOS cohort (Box 6).

Ischaemic heart disease, heart failure, atrial fibrillation, hypertension
Chronic lung disease including cancer
Chronic liver disease, malnutrition, chronic bowel disorders including constipation and incontinence
Chronic kidney disease, prostate disease, incontinence
Sensory impairment, movement disorders, stroke
Arthritis, polymyalgia rheumatica, osteoporosis
Falls, dizziness, syncope
Dementia, depression, anxiety
Diabetes, thyroid disease
Skin ulceration and chronic oedema
Anaemia
Weight loss, including sarcopenia
Incurable cancer

Box 6 - Curriculum grid no. 29 from the UK specialty training curriculum for geriatric medicine[523]

The data therefore suggest a possible role for both geriatricians and GPs in caring for care home residents. It is not clear, however, whether both are required, or whether GPs could manage the medical problems of the cohort without specialist geriatrician input. One aspect of the cohort that might suggest a role for geriatricians was the high prevalence of multimorbidity. The mean number of diagnoses per resident was 6.2, considerably higher than the prevalence of multimorbidity seen in the community when Kadam and Croft conducted a cohort study of 9439 over-50 year olds across 3 UK general practices. They reported 23% of participants to have 6 or more morbidities (regarded as high multimorbidity for the purposes of that study)[524]. When compared with results from a representative national sample of all over-65s reported in the 2005 National Health Survey of England (Table 51), CHOS participants showed a higher prevalence of stroke, dementia, psychiatric diagnoses, Parkinson's disease and osteoporosis. Multimorbidity has been suggested as challenge in the management in frail older patients because aggregated pathologies in frail older patients present a challenge to medical decision-making as traditionally taught to doctors[525]. It has also been identified as an area where geriatricians have particular expertise and skills to offer[526].

Table 51 - Comparison of prevalence of common diagnoses in CHOS and as reported in the National Health Survey, 2005

Condition	National Health Survey, 2005		CHOS	
	♀	♂	♀	♂
Hypertension	62%	64%	46%	11%
IHD	16%	23%	23%	21%
Stroke	7%	9%	32%	31%
Diabetes	10%	13%	15%	19%
Arthritis	47%	32%	41%	27%
Osteoporosis	12%	2%	35%	15%
Dementia			66%	54%
Emotional, nervous or psychiatric problems (excluding dementia)	7%	4%	21%	17%
Parkinson's disease	1%	1%	6%	6%

A further piece of evidence supporting a possible role for geriatricians comes from the discrepancy between proportion of the cohort with a formal diagnosis of dementia (64%) and the proportion found to have an MMSE ≤ 26 (92%). This suggests that existing care providers – including GPs – have some difficulty with case-finding and diagnosis in dementia. The diagnosis and management of dementia, although often led by GPs, is increasingly specialised. The most recent NHS National Institute for Health and Clinical Excellence Guidelines on Dementia[518] includes a recommendation for specialist involvement in psychological testing, the selection and interpretation of appropriate cerebral imaging and trial and maintenance of treatments, such that dementia management could not be conducted by a GP in isolation. The most appropriate support would come from an old age psychiatrist or geriatrician, supported by a multi-disciplinary team and leading a process of CGA.

Although not specifically mandated by NICE, specialist support might also be required for the management of a number of other conditions listed in Table 43. For some of these, for example specialist orthogeriatric assessment and support for patients with osteoporosis, geriatricians could provide all required expertise. For others, such as access to diagnostic endoscopy for patients with anaemia and referral of appropriate patients for cataract surgery, geriatricians might provide guidance on prognosis and outcome, in order to guide management plans and referral to appropriate single organ specialists.

Clearly, the requirement for input by a geriatrician for any given care home resident would depend upon both the resident and their GP. GPs present a varying degree of confidence in competence in managing both multimorbidity and the specialist problems of frail older patients – evidence to this effect is presented in chapter 4. The transection of multimorbidity and the type of diagnoses seen are, however, such that geriatricians might have much to offer.

3.7.5. Prescribing

The median number of medications per resident recorded in this study was eight, which is broadly comparable with the Care Home Use of Medication Survey (CHUMS)[13], which reviewed prescribing in 256 residents across 55 homes in 2006-7, revealing a mean number of prescriptions of 7.6 per person. The STOPP-START analysis for CHOS suggested that there were indications for cessation or commencement of a drug – i.e. possible prescribing errors – in 68% of participants, again broadly comparable with the 70% prescription error rate seen in CHUMS.

The most commonly prescribed medications were stimulant laxatives, followed by paracetamol and aspirin. The former two medications are relatively innocuous and neither triggered high numbers of STOPP indications. 29 out of 108 (27%) patients prescribed aspirin triggered a STOPP, on the basis that there was no documented rationale within the medical records for an anti-platelet agent. Whether this represents a deficiency in documentation or in medication review is unclear. The benefit of aspirin in patients without documented cardiovascular disease, or a high cardiovascular risk profile, is unclear and the risk of gastrointestinal bleeding is likely to outweigh any prognostic benefit[527]. The possibility that up to a quarter of patients in the cohort might have been receiving it without a clear indication is therefore cause for concern.

Proton pump inhibitors (PPIs) were prescribed in 85 patients, 37 (44%) of whom triggered a STOPP indication for persistent prescribing at the higher dose over the long term. Although commonly seen as quite innocuous, PPIs are associated with small but significant increases in the incidence of diarrhoea, nausea and vomiting, abdominal pain and headache, with these effects most marked in the elderly[528]. They are an important cause of drug-drug interactions[529] and the British National Formulary was modified in 2011 to recommend that they be prescribed for as short a duration as possible, at the lowest effective dose[509].

The rate of neuroleptic (antipsychotic) prescribing in care homes has previously been reported to be in the region of 24-28%[15] and up to 58% in one US study where those suffering dementia were considered in isolation[516]. In this cohort, there were only 27 prescriptions for anti-psychotics (12% of patients). However, as previously discussed, despite the high prevalence of moderate-severe dementia, the mean NPI was very low and this may go some way to explaining the low rate of prescriptions. It is equally possible that controversies surrounding the prescribing of anti-psychotic medications as a form of chemical restraint in care homes, coupled to the previously discussed MHRA warnings, influenced the low prescribing rate. Antidepressants were commonly prescribed and tricyclic antidepressants and mirtazepine – both suggested as possible alternatives to traditional antipsychotic medications for the management of BPSD[530 531] – were prescribed in 35 (15%) and 5 (2%) of patients respectively.

Given the high prevalence of dementia, with 42% of patients meeting NICE criteria for treatment with acetylcholinesterase inhibitors and 39% for treatment with memantine[532], it was surprising to see drugs for dementia prescribed in only 15 (7%) of cases. These drugs might have been trialled and subsequently discontinued in the majority, however it is more likely that their omission represented a failure of practice to keep up with national guidelines.

Another area in which practice seems to have lagged behind evidence and consensus-based practice was the treatment of hypertension. The HYpertension in the Very Elderly Trial (HYVET), published in 2008, was a landmark study and demonstrating significant morbidity and mortality gains in older patients treated for hypertension[533]. Recommendations for the treatment of hypertension have been modified based upon these findings to stipulate more aggressive management of hypertension in older patients using calcium channel antagonists and thiazide diuretics as first line therapy[534]. 102 (45%) of patients were documented to have hypertension and yet only 46 (20%) were prescribed a calcium channel antagonist or related drug and only 16 (7%) a thiazide diuretic. Some of this might have been explained by co-existent diagnoses of non-insulin dependent diabetes and congestive heart failure, present in 34 (15%) and 12 (5%) of patients, which would mandate use of angiotensin converting inhibitors, prescribed in 36 (16%) of residents, and/or loop diuretics, prescribed in 46 (20%) of cases. It should be noted, however, that 24 patients prescribed loop diuretics appeared to be taking this only for ankle oedema, which triggered a STOPP indication, whilst 41 (18%) of patients triggered a START indication for untreated hypertension.

These discussions serve to underline the complexity of prescribing in multimorbidity whilst adhering to current evidence and consensus-based medical guidelines. To deliver consistent high-quality prescribing in this context would mandate regular medication review, almost certainly in conjunction with an expert pharmacist – which chapter 2 suggested was an evidence-based intervention – and regular updates on best-evidenced prescribing for frail older patients. This builds the case for multidisciplinary involvement in care homes further.

3.7.6. End-of-life care

16% of the cohort died during the 6 month follow-up period, suggesting that around a third would die in one year, assuming a linear progression of the mortality plots (Figure 12). The NHS National End-of-Life Care Programme uses the term “End-of-Life Care” to include the year leading up to death and suggests that those residents approaching the end of their lives be engaged in a process of advanced care planning[535].

Given that up to a third of residents at any given point in time might be at the end of their lives, addressing end-of-life care issues would be expected to be central to much of the work undertaken in care homes. Prognostication in frail older patients, particularly those with dementia, can be challenging and a tension between appropriate palliation and inappropriate nihilism has been identified[536] – identifying which residents in whom to target end-of-life issues might prove difficult for GPs and care home staff. The Gold Standards Framework (GSF) has been recommended as a means by which to facilitate and trigger appropriate end-of-life care for care home residents[537] and both GPs and care home staff have reported it to be useful tool in framing end-of-life decisions[538]. However implementing and maintaining GSF in the care home setting requires specialist palliative care support[539], indicating an ongoing role for a palliative care nurse specialist, at the very least.

3.7.7. Variability between individuals and homes

Taking the previous points in summation, data from the cohort suggest possible roles for physiotherapists, occupational therapists, specialist nurses, dieticians, old age psychiatrists, pharmacists, palliative care nurses, GPs and/or geriatricians in providing care. This describes most, if not all, the members of a CGA multidisciplinary team. It might be argued that, given the comprehensive evidence for CGA in caring for frail older patients in other settings, that it would be the most intuitive and logical way to bring these disciplines together around a common goal. Further evidence that co-ordinated care would be best placed to meet the needs of the cohort, comes from the variability seen between individual participants and homes.

Variability between individuals was broad, as indicated by the large IQRs for BI, MMSE and NPI seen in Table 35. Residents ranged from fully dependent to fully independent in basic ADLs, profoundly cognitively impaired to fully cognitively intact and behaviourally normal to throwing furniture at members of the research team. Variability between homes, shown in Table 39, was also significant and was demonstrated for functional dependency (BI), cognition (MMSE), nutritional status (MNA), grip strength, number of diagnoses, number of medications and behaviour (NPI). Where a positive ICC was reported it implies that the variability between homes was greater than that between individuals within homes – indicating a cluster effect for all of these variables. The ICC of 0.343 for NPI, for example, means that two residents within a home were 34.3% more likely to have identical scores than if they were chosen at random.

The variability between individuals and homes has ramifications at a clinical level, challenging systematised responses to delivery of healthcare in care homes. A "one-size-fits-all" approach to care home healthcare could not take account of the significant variability seen in terms of dependency, behaviour, number of diagnoses and medications. In a home where behavioural problems were severe or frequent, for example, then the desired clinical team would incorporate input from specialists in old age psychiatry, whether community psychiatric nurses or old age psychiatrists. A setting where such behaviour was infrequent, meanwhile, might require such specialists rarely and their regular attendance would be both surplus to requirement and contrary to the goal of cost-effective care. One logical solution to this problem would be comprehensive, individualised assessment of residents to identify which of the array of specialised services already described as being potentially relevant might be required. This adds further weight to the case for CGA.

3.7.8. Strengths and weaknesses of the study

The study successfully addressed a number of the shortcomings identified in the existing literature base. It recorded more detailed data on diagnoses, health status, prescribing and NHS resource use than Bebbington[439], Netten[440] and Bowman[2] were able to. The use of NHS GP records as the definitive source of diagnosis addressed the issue of response bias identified in those accounts. By providing up-to-date data, it overcame the issue of contemporaneity affecting the 1988 OPCS survey.

The cohort recruited was, in most ways, representative of the broader UK care home population. The average age and proportion of female residents were similar to those reported elsewhere[7]. As illustrated in Table 30, the proportions of residents in nursing and residential homes and those with and without specialist dementia registration mapped closely to the percentages for care homes around

Nottinghamshire. The number of GPs per care home, at 5±2.3 was not far from the 7 (range 1-50) GPs per care home identified in a survey of 765 care homes in 2002[540]. Although the number of admissions per home was, at 0.5 per care home per month, considerably below the 2 admissions per home per month cited in the NHS data used for the sample size calculation, a subsequently conducted and more detailed piece of work from NHS Nottinghamshire County PCT[541] suggested the average non-elective admission rate in care homes in the region to be around 600 per 1000 residents per year, which is not far off the 480 per 1000 residents per year recorded here. Thus it is more likely that the initial informally reported statistics used in the sample calculation were an overestimate of admission rates, than there being any systematic error in the cohort data.

One possible explanation for the slightly lower than anticipated admission rate was the nature of recruitment, with homes selected from volunteers who knew at the point of recruitment that the study would focus around medical admissions. Homes which were low admitters might have self-selected for the study on the basis that they regarded avoiding acute hospital admission to be an important marker of quality, or on the basis that they were proud of their record in this regard and had "nothing to hide". An alternative explanation would be that those residents missed from recruitment (n=96), were those most likely to be frequent attenders at hospital and, as a consequence, the number of admissions was undersampled despite a representative sample of homes. One reason that this might be the case is the most common reason for non-recruitment – 61 residents (64% of non-participants) lacked mental capacity without a consultee, or no response was received from their consultee – which may have resulted in a failure to recruit the most vulnerable residents, i.e those with advanced cognitive impairment and limited or no social support.

The failure to recruit these residents was based upon the insistence of the NHS Local Research Ethics Committee (LREC) that residents without mental capacity who were unable to provide consent and who had no available consultee should not participate. It was asserted that care home managers or staff should not be allowed to act as consultees for such participants on the basis of the clause in the Mental Capacity Act which states that consultees must be someone who “otherwise than in a professional capacity or for remuneration, is engaged in caring for or is interested in the welfare” of the participant[506]. The potential harm from involvement in a longitudinal cohort study is very limited indeed and arguably more was lost by excluding these residents than would have been the case had they been included – a case might therefore be made for more flexible interpretation of the Act. Indeed, over the course of conducting the research, it became clear through contact with other care home researchers, that the Act had not been applied so rigidly by other LRECs.

Even though the sample was broadly representative, the in-depth focus on a small group of residents represents a key shortcoming when compared with earlier work. By focussing on a small number of residents in a single geographical region the data are potentially less generalisable than those from the earlier studies, which were more superficial in their data collection but included more residents with coverage across multiple regions or, in the case of Bowman and OPCS, the nation as a whole. Given that such studies had already been conducted, however, the accurate and detailed statistics on dependency, cognition, nutrition, medical diagnoses, prescribing and sample variability, which contributed to an understanding of the role of CGA, were arguably more relevant to the national debate than further broadly-representative surveys.

3.7.9. Lessons from data-collection – what the missing data tells us

A brief digression from the case for CGA will be taken to consider some research lessons from CHOS – particularly what can be learned from the missing data. These inform the discussion on how CGA might be evaluated in the care home setting going forward, a topic which will be revisited in chapter 5.

The fact that only one patient was lost to follow-up over the 6 month period speaks to a very stable, non-migrant population which, once recruited, is liable to remain in situ for follow-up. Longitudinal methodologies are therefore appropriate in this setting.

The poor performance of the question around pension credits suggests that care home residents are poor witnesses with regard to their own financial arrangements. Although non-response to this question was more likely amongst residents with low MMSE, the fact that many of those providing a response did so in very vague terms underlines that financial data needs to be collected, or at least verified, by other means. To collect such data centrally, for example from pension or social care databases, would require ethical and information governance permission, with consequences for how research protocols, ethics and information governance submissions are drafted.

The missing data for weight indicate the technical difficulty of gathering even simple baseline data in dependent older patients – the significant difference in Barthel Index between those with and without weights recorded and the fact that no home established a complete dataset for weights suggests that, in many instances, non-completion was due to the physical difficulty of weighing the participant. The significant variability in the completeness of weight recording between homes, meanwhile, underlines the potential pitfall of depending on “routinely collected” care home data in quantitative research methodology.

The difficulty in using GHQ-12 in advanced cognitive impairment, although not widely discussed in the literature, has been identified before[407]. It is, however, writ large in this cohort, with the complex cognitive constructs presented by this measure proving particularly difficult for residents with advanced cognitive impairment and dependency. Quite how to measure psychiatric morbidity in this setting is unclear. Dementia specific measures of psychological wellbeing in dementia, such as the Psychological Well-being in Cognitively Impaired Persons (PWB-CIP) battery, are usually validated in only mild-moderate disease despite being developed as dementia-specific measures[542]. Colleagues working on the Medical Crises in Older People-Trial of an Elderly Acute care Medical and mental health unit (MCOP-TEAM)[543] study got at the issue of psychological wellbeing through using a combination of dementia-specific health-related quality of life indices and dementia care mapping. However, as discussed below, both of these bring conceptual and practical difficulties of their own[544] and, even in combination, they remain an imperfect response to the difficult issue of measuring quality of life in this cohort.

Considering HRQoL, possibly the most troubling aspect of missing data – given its primacy to health economic evaluation within the UK healthcare sector – is the failure of the EQ-5D to perform adequately. A quarter of respondents had incomplete datasets, with a significant association between cognitive and physical impairment and non-completion – with the implication that HRQoL is impossible to measure using this tool for those with the greatest morbidity. The reason the anxiety variable was so significantly affected is that this is the variable for which proxy respondents most frequently failed to respond. The proportion of EQ-5D responses where proxies were used was not routinely recorded, which is a significant oversight in terms of study design. Anecdotally, however, the majority of residents relied on proxy response for at least one domain. Considering the broader literature around this, the levels of agreement between patient and proxy responses for EQ-5D have been poor to moderate across multiple studies (Table 52), raising further questions about its usefulness as a HRQoL measure in this setting. These issues reflect the problems with proxy measures in care homes in general, as summarised in chapter 2.

Table 52 - Agreement measured using kappa for proxy/patient recorded EQ-5D across multiple studies, as summarised by Selai *et al*[545]

Authors; proxy types; condition	Mobility	Self-care	Usual activities	Pain/ Discomfort	Anxiety/ Depression
Coucill *et al*[546]; patient-carer; dementia	Fair	Fair	Poor	Fair	Fair
Selai *et al*[547]; patient-carer; dementia	Fair	Good	Poor	Good	Moderate
Pickard *et al*; patient-informal caregiver; 6 months post-stroke	Moderate	Moderate	Moderate	Moderate	Fair
Pickard *et al*; patient-informal caregiver; 6 months post-stroke: depression symptom +/-	Fair/Fair	Moderate/Poor	Good/Poor	Moderate/Poor	Fair/Poor
Dorman *et al*[548]; patient-informal caregiver; stroke	Moderate	Good	Moderate	Moderate	Fair

A number of dementia specific HRQoL indices have been developed, of which the DemQOL tool is the most comprehensively validated. DemQOL includes a proxy version which has shown good acceptability and internal consistency and moderate evidence of validity in people with severe dementia[549]. It has not, however, been evaluated in long-term care settings and, as such, it is unclear whether the issues of unreliable proxies in care homes, which confound the EQ-5D, also confound DemQOL. Further research is required.

Pending this, the question remains as to how, if at all, quality of life can be measured in this setting. One legitimate response to the difficulty of measuring quality of life, might be to measure quality of care, either using qualitative indices such as Dementia Care Mapping[550], or more straightforward quantitative check-lists of healthcare quality, such as the International Prevalence Measurement of Care Problems[551]. The former focuses on detailed longitudinal measurements of subjects' behaviour with interpretations of their behaviour as either positive or negative to establish a well or ill-being value (WIB) and to identify care interventions which have either a negative (personal detractors) or positive (positive events) effect. The criticism of this model is that, although it is a considered and highly developed attempt to see the world from the resident's perspective, it remains largely subjective and therefore subject to the vagaries of any proxy measure. The latter meanwhile collects detailed quality measures around pressure ulcers, incontinence, malnutrition, falls, physical restraints and intertrigo and as such can be criticised in taking a healthcare-centric world-view which is quite divorced from the conceptual framework underpinning HRQoL measures. A pragmatic response is that either is better than nothing and potentially more defensible than a non-validated, proxy-dependent HRQoL measure. A third legitimate response might be to consider serum, or salivary biomarkers of stress as more reliable measure of the experience as lived by the patient, as opposed to perceived by the carer. Collection of salivary specimens appears to be feasible in patients with dementia – however, salivary cortisol maps closely to behavioural disturbance in dementia[552], so whether the procedure conveys much advantage over straightforward dementia care mapping is unclear.

Whatever the solution, or compromise position adopted, it is clear that there is much to be done to establish an effective conceptual framework and practical response to measuring HRQoL in this setting.

3.8. Conclusions

The cohort studied was representative of the broader care home population in terms of demographics, distribution of residents by care home type and arrangements for primary care support. It was a slightly low admitting cohort, either as a consequence of the voluntary nature of initial recruitment, or as a consequence of the failure to recruit participants without capacity and an available consultee.

The study added to the existing literature by collecting data on functional dependency, cognition, behaviour, nutrition, diagnoses and medications at a level of detail not previously recorded. It addressed some of the issues around response bias in earlier studies both by collecting data directly from residents and using a combination of care home and healthcare records to maximise accuracy. It provided contemporaneous data, addressing the major shortcoming of the OPCS dataset.

The cohort was dependent, with a distribution of dependency which would suggest a role for input from specialist nurses, physio- and occupational therapists. There was a high prevalence of cognitive impairment and BPSD was relatively frequent, suggesting a role for psychogeriatricians and specialist mental health nurses. Malnutrition was evident and MNA scores suggested that a significant proportion of participants required dietetic input. Diagnoses were dominated by chronic conditions

– the preserve of GPs, geriatricians or both. Whilst geriatricians might not be absolutely essential in providing healthcare to care homes based upon these data, the high levels of multimorbidity seen and the types of diagnosis which were prevalent, including dementia, stroke, continence, arthritis and osteoporosis, suggested that they would have much to offer. Many residents were close to the end of their life, suggesting that GPs and care home staff should have specialist training in end-of-life care and a role for palliative care nurses in facilitating and maintaining this.

Indications for involvement by all members of the CGA MDT were therefore present. Co-ordinating their efforts through CGA would seem logical – given the evidence-base for CGA from other settings. Further weight to the case for CGA came from the wide variability seen for almost all measures both between individual participants and individual homes. A “one-size-fits-all” approach would not efficiently meet the needs of either individuals or homes. Detailed, individualised assessment to identify which members of the MDT were required in each case – i.e. CGA – would seem logical in this context.

Chapter 4 – Staff Interviews in Care Homes (STICH)

4.1. Introduction

The literature review in Chapter 2 demonstrated that there was a body of evidence which could be used by healthcare professionals to drive gold-standard care for care homes, either by providing care home-specific evidence where available, or by allowing careful extrapolation of research-based recommendations from other settings – with awareness of caveats – where it was not.

The cohort study presented in Chapter 3 found that care home residents demonstrated a complex mix of functional impairment, cognitive impairment, malnutrition, multimorbidity and polypharmacy and had health status driven predominantly by chronic conditions. On the basis of these findings it was clear that models of care for residents needed to be comprehensive and multidisciplinary, bringing together expertise in chronic disease management with specialist knowledge in the management of specific conditions including dementia, stroke, continence, arthritis and osteoporosis. Variability between individual residents and individual homes was such that detailed assessment would be required to ensure optimal delivery of care. CGA – and the multidisciplinary teams who characteristically deliver it – would be well placed to meet these needs.

Having reached this conclusion, it became necessary to consider the detail of healthcare as currently delivered to care home residents. Given the flexible nature of the GMS contract and the recent focus on providing innovative models of healthcare to care home residents – through, for example, NHS Quality, Innovation, Productivity and Prevention (QIPP) initiatives explicitly targeting care homes[553] – it was possible that many of the components of CGA were already in place. Geriatrician-supported care home initiatives, whilst evident in geographical pockets around the UK, were not the norm[554-556]. However, whilst many of the descriptions of CGA in the literature focused on the pivotal role of the geriatrician[24 27 28], there were examples from other settings – for example nurse-led community-based intermediate care[557 558] – where the process was conducted without involvement of the specialty. It was therefore conceivable that the needs of care home residents might have been satisfactorily met through the combined efforts of care home staff, general practitioners, community-based nurses and allied health professionals working to the best-available evidence under the GMS contract – a sort of intuitive CGA, without having explicitly attached this label.

If CGA was already being delivered – albeit with no, or cursory, involvement from geriatricians – the central question of this thesis regarding the role of CGA in care homes might have been answered by provision of concrete example. Equally, if it was not being delivered, then assertions that it should be tested in care homes could be made more robustly. Finally, if the conclusion of the thesis was to be that CGA had a role in the care home setting, then some understanding of the day-to-day reality of existing models of care would be essential to define the extent to which implementation of CGA would represent a change from, or an augmentation of, these.

The cohort study did not record day-to-day use of primary care resources by care home residents, nor was it able to take account of resident, resident family, care home and health service staff satisfaction with existing arrangements. It was therefore unable to address the question of whether CGA was already being provided, either in part or in full, as a consequence of measures delivered intuitively under GMS. To address this question, and to provide an overview of the context in which any initiative involving CGA might be launched and tested, the Staff Interviews in Care Homes (STICH) project was undertaken.

4.2. Aim

To describe how care home staff and the healthcare professionals who work with them identify and respond to changes in residents' health.

4.3. Methodology

4.3.1. Choosing a qualitative paradigm and a broad focus of study

It was obvious that quantitative data, even when gathered in precise detail taking account of all available NHS resource use databases, could deliver only a partial overview of how the Health Service connected with care homes to deliver healthcare for care home residents. By the time of commencing STICH, research conducted at the University of Hertfordshire as part of the Analysis and Perspectives of integrated working in Primary Care Organisations and Care Homes (APPROACH) study, had already started to identify that day-to-day healthcare delivered to care homes differed significantly from that specified in commissioning documents, largely as a consequence of negotiated arrangements between individual homes and the healthcare teams that supported them[1]. One could not, therefore, simply read a service specification from an NHS commissioning body and take it for granted that the service delivered to patients would meet that specification. Heroic assumptions would be required to connect outcomes collected as part of a detailed cohort study, with the service as specified in commissioning contracts, without a detailed description of the day-to-day experience that connected them. Qualitative data would be required to better understand the way in which resources were used and

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[1] Personal communication, Professor Claire Goodman, University of Hertfordshire

the rationale underpinning the resources employed.

These insights were not going to come from interviewing residents and their families. Whilst both groups would clearly have a very important perspective on the lived experience of healthcare, they would provide a limited insight on the actual day-to-day delivery of healthcare, and the mechanisms that governed such delivery. Issues around cognition (residents) and amount of time present in a home (relatives) aside, they would rarely be present during interactions between healthcare professionals and care home staff and so would be unlikely to provide the insights required to address the research question specifically raised here.

It was decided, therefore, that the research should focus on care home and NHS staff because they could provide a first-hand account of the systematic and organisational issues affecting healthcare delivery. In doing so, it was recognised that a number of professionally diverse groups – care home staff, nurses, doctors and allied health professionals – each with potentially quite different perspectives on healthcare, would require to be involved.

4.3.2. Data collection

An observational study, focus groups and interview studies were considered.

An observational study, where the researcher spends time watching care home staff at work, or working with them[559], would have had obvious advantages in this context. It would, for example, have allowed interactions between residents, their families, care home staff and health professionals to be observed and recorded in detail. It would have allowed a more detailed understanding of the culture within care homes and, in addition, would have allowed some degree of objectivity to be established – since direct observation crosses the divide between what people say they do (as is recorded in an interview or focus group study) and what they actually do[559 560]. In conducting observational studies, varying degrees of involvement in the culture to be studied have been described, ranging from total abstraction, where observation is formal and overt, to complete immersion, where the subject is not aware they are being observed[561].

A particular concern with these types of study is that the act of observation changes the behaviour being studied – this is sometimes referred to as the Hawthorne effect after an industrial study in which the influence of observation was first noted[562]. This is possibly a particular concern in interactions between care home staff – who, in the case of care assistants, are frequently on low pay and have had no contact with higher education[563] – and university researchers. Although a study using overt participatory observations of low-paid staff in care settings has shown that such work can be undertaken without excessive difficulty[564], other researchers have argued that covert observation is the only robust way to conduct such research[565] and covert research is frequently subject to challenge at ethical review[566]. Another important disadvantage of observational studies is the amount of researcher time required which – in the case of STICH and the time-constraints imposed by a mixed-methods PhD programme – meant that alternative methods had to be used.

At the opposite end of the spectrum, focus groups are very resource efficient by virtue of bringing multiple stakeholders together at the same time to record their views[560]. They have the additional advantage of allowing the researcher to observe the interplay of, and power relationships between, stakeholders[567]. A focus group might allow the opportunity to explore the opinions and experiences of both healthcare staff – including doctors, nurses and allied health professionals – and staff working in care homes. However, whilst focus groups have been used successfully to explore inter-professional boundaries[568], it has been noted that excessive heterogeneity in their composition can be counter-productive and an inhibitor to conversation[567]. Potentially useful accounts of healthcare delivery would have been missed if care home staff had stayed quiet in the presence of NHS colleagues – or vice versa. Given the anticipated variability between individual homes – truly balanced insights would have been unlikely unless NHS and care home staff who regularly collaborated were brought together, which would have increased the likelihood that one or more participant might choose silence over a potentially offensive forthright account of their day-to-day experience. Focus groups were therefore abandoned in favour of an interview study.

Qualitative interviews record a detailed one-to-one conversation between participant and researcher and therefore avoid some of the issues of intimidation which may be problematic in focus groups. There is, however, a persistent issue of the power relationship between the researcher and interviewee[569]. The more structured the interview, the more likely that the conversation will focus on the researchers' intended topic area but the more likely that, potentially relevant, ancillary data will not be mentioned and therefore included in the research data[570]. The possibilities in structuring an interview range from working to a rigid questionnaire (not commonly used in qualitative studies), through semi-structured interviews, to unstructured interviews. For STICH, a semi-structured format was chosen as it was anticipated that this would allow broad accounts of healthcare delivery to be recorded, whilst ensuring that respondents from a variety of professional backgrounds remained focussed around the relatively narrow issue of health and healthcare delivery in order to address the research question.

Mason[571] described a useful stepwise approach to deriving a schedule for a semi-structured qualitative interview from a research question. Starting with the research question, mini-questions are derived, followed by a consideration of how such questions might be worked into an interview scenario, before consideration of a loose structure of how an interview might fit together. Finally, if it is essential that any particular questions are asked to any participant, then these are singled out.

Using this framework it became clear that questions of how health and social care staff interact to provide healthcare would touch on professional background and training, day-to-day role, communication with residents and other professionals, and understanding of health. A vignette was chosen to bring interviewees from diverse backgrounds together around the research question. Vignettes have been shown to be useful as a way of getting interviewees to tackle difficult issues – in this case of role and relationships with residents and other professionals – by using an abstract example to get them talking[572 573].

4.3.3. Data analysis

The most commonly cited mode of qualitative analysis in healthcare studies is grounded theory – indeed it is so commonly cited that Murphy *et al*[560] caution around its use as a "bumper sticker" to garner approval. However, given that its primary aim is to build a theoretical explanation of a social phenomenon under study[574], and that little is currently known about how care home staff interact with health service staff to meet residents' healthcare needs – there were, for example, no significant foreshadowing papers in this arena to inform our interview protocol – it seemed an intuitive choice for STICH.

Grounded theory was first described by Glaser and Strauss in 1967[575] and built upon by Strauss and Corbin in subsequent writings[576]. It takes the stance that the researcher should start *tabula rasa* (as a blank slate) and inductively generate theory through thorough systematic analysis of data. It is therefore frequently cited as a hypothesis-building model of qualitative research. Grounded theory relies upon two central methodological concepts: constant comparison and theoretical sampling.

Constant comparison describes the methodical, iterative, analysis of data as it is being collected[575]. Data is initially coded in as many categories as possible, with an initial theory developed based upon these. Subsequent delimitation of both theories and coding categories allows description of phenomena under a smaller number of higher-level concepts. This process is continued throughout data collection and iteratively thereafter until no further refinement can be achieved – a point which Glaser and Strauss called theoretical saturation.

Theoretical sampling describes using concepts which have emerged from the constant comparative approach in order to guide what data is collected next – perhaps by modifying the individuals or setting studied or the questions asked at interview[560]. This allows for theories to be tested and delimited as research progresses and can be used as a means of ensuring that sufficient data will be accumulated to facilitate theoretical saturation.

Critiques of grounded theory focus predominantly on epistemological concerns revolving around the clash of pragmatist and contructivist ideologies (can one be truly *tabula rasa* if reality is an internal construct?) and fears about its allegiance to naive inductivism (with emphasis on the power of reason, rather than the centrality of empirical evidence)[560 577].

Murphy *et al*[560] and Mays and Pope[578] take a pragmatic step away from such abstract philosophical debate by pointing out that much of the research labelled as "grounded theory" is, in fact, "grounded theory style", and there is much to be gained, by way of rigorous objectivity, from careful application of these principles: particularly simultaneous data analysis and collection; analytical processes aimed at hypothesis generation rather than testing existing theories; and careful methodical application of coding categories with increasing levels of abstraction at each iteration.

The framework approach, a deductive mode of qualitative analysis, has been suggested as an alternative to grounded theory research[559]. It has been highlighted as particularly applicable in health research where the lead-times for analysis and publications of findings are characteristically short, precluding the more lengthy analyses demanded by true grounded theory-style analysis. The key distinction between this approach and grounded theory is that a theoretical framework is established early, with data analysis then conducted to determine the extent to which qualitative transcripts adhere to the framework. In some instances, the theoretical framework is based on *a priori* assumptions and, as such, data-analysis becomes almost entirely deductive[579]. In others, the framework approach can run quite close to grounded theory-style research, where a long period of data immersion is required to establish a theoretical framework[580], almost to the point that the framework itself is an inductively generated piece of grounded theory. Thus, like many putatively distinct research paradigms, there is a continuum between completely grounded research, iterative and inductive to the end, and a truly deductive framework approach based upon *a priori* assumptions – indeed some researchers refer to the framework approach as being an application of grounded theory rather than an alternative approach[559 579].

A priori assumptions were felt to be potentially quite harmful to the establishment of a robust theoretical framework in STICH for two reasons. Firstly, reflection on the experience of running the CHOS study within care homes suggested that the process of getting to know care homes had been one of continual revelation, where the assumptions held by health service-based researchers about day-to-day life in care homes were continually and repeatedly challenged by the experience of the lived reality. Secondly, the assertion from detailed research programmes held elsewhere (APPROACH) that the degree of variation in negotiated arrangements between health and social care providers was very broad meant that a reliable framework would be unlikely to be established through a small number of observations early in the research process. The framework approach was therefore avoided.

4.3.4. Defining a sample

Although qualitative methods make no claims to representativeness, it seemed reasonable – in order to describe the delivery of healthcare with some generalisability – to incorporate a range of homes in an attempt to take account of some of the variability between and within homes.

It was decided that staff would be recruited from homes which had been enrolled in the CHOS study on the basis that a relationship of trust had been built with the owners, managers and staff that would allow a frank exploration of issues around residents' healthcare. In selecting which homes to approach, the outputs from CHOS were considered. Given the identified differences between the cohorts housed in residential and nursing homes respectively, it seemed reasonable to start with these categories as a driver to the sampling framework. Dementia registration – with the implication that the types of care provided and the expectations of staff might significantly differ as a result – was identified as an additional important factor.

Based upon these, a purposive sampling framework was set out which aimed to sample residential and nursing homes, and those with and without dementia specialist registration. CQC ratings were abandoned as a guide to sampling from the outset, largely because of their lability over time as identified in CHOS.

In deciding which staff to recruit, it was necessary to consider both care home and NHS staff. Staffing structures in care homes were fairly standard, with a single manager, with or without a deputy, overseeing care assistants and, in the case of nursing homes, professional nurses. Representatives from each of these groups should be recruited. Given the central role of GPs in co-ordinating healthcare, it was essential to recruit several. Given that much practical day-to-day care was also provided by district nursing staff and allied health professionals, it would also be important to recruit from these groups. Theoretical sampling – with movement backward and forward between theory and data – played an important role in determining the extent to which each of these groups was sampled. It became clear, through early interviews, that the relationship between GPs and care home managers was particularly important in determining how healthcare was delivered to residents. As a consequence, the sample was subsequently around GP/manager dyads – and the care home and NHS staff with which they worked – in order to better understand this interaction.

4.4. The research team

The study was conducted by a team of researchers – Adam Gordon (AG) an academic geriatrician; Isabella Robbins (IR) a post-doctoral sociologist; Jane Dyas (JD) an experienced qualitative health-services researcher; John Gladman (JG) a professorial-level academic geriatrician and PhD supervisor for AG; and Pip Logan (PL) an academic occupational therapist and second PhD supervisor for AG.

AG and IR led the process throughout. As AG was a novice qualitative researcher at the outset, IR performed a mentorship role in addition to acting as co-researcher. All researchers were involved in study design. Interviews were conducted by AG (n=11) and IR (n=21); constant comparative data analysis was conducted by AG and IR – with initial separate coding of all transcripts followed by a process of integration that allowed detailed review and refinement of emerging theoretical constructs; the final synthesis was led by AG and IR – with input from JD, JG and PL. The intellectual ownership of the findings as presented here is shared by all authors with IR and AG acting as guarantors. IR has acted as lead author on a scholarly paper based around the findings which was in preparation for submission to peer-review at the time of writing. Although the results section of that paper shares a common structure with the results section as presented here, the findings are presented here in greater detail and with more comprehensive discussion.

4.5. Methods

Using the steps outlined by Mason[571], an interview schedule was developed as a loose framework for semi-structured interviews. A case vignette was written around a patient with a urinary tract infection, which was chosen as a common problem which would frequently trigger referral to NHS services. Both the vignette (Box 7) and interview schedule were piloted using mock interviews with clinically trained research staff.

“Imagine a resident who is short and stooped with a curved spine. She suffers from stiff, painful joints. She is thin. She becomes muddled and disorientated from time to time. She usually needs some help with personal care and wears a small pad for urinary incontinence – a little leakage.

She keeps getting urinary tract infections. She has long spells when she is well, but when she gets an infections, staff notice changes in her. She starts to become more confused, so that she needs more help with her personal care than usual. She becomes a bit more unsteady on her feet. The last time that this happened, she had a brief emergency visit to hospital and it took a week or two for her to get back to normal.

Can you think about your own experience and recount a similar case?”

Box 7 - Case vignette used in STICH interviews

Staff from the following professional groups were targeted for recruitment: care home managers, registered nurses, care assistants, community nurses, general practitioners and community allied health professionals. Working on the principle of manager-GP dyads as the focus for recruitment, GPs were approached after recruitment of the care home. We were able to enlist one GP attached to each home and sought, within each practice, to speak to the GP who most routinely provided care to the home in question. Nurses and allied health professionals were recruited either opportunistically, from contacts made during conduct of research in GP practices and care homes, or sought-out by a combination of telephone and letter where their opinions were suggested by existing respondents to be particularly important to emerging theoretical frameworks. There were no exclusion criteria.

Care home managers were sent posters and information sheets for dissemination amongst their staff. Staff were subsequently briefed by a researcher on the purpose and content of the research and invited to contact the research team directly to become involved. To minimise the likelihood of actual or perceived coercion by managers encouraging or discouraging staff from participation, or from saying certain things at interview which might in turn bias their account, participants were given the choice of being interviewed at their place of work, at home or in the University. To further protect staff, researchers did not tell managers which staff had agreed to participate in the study.

Interviews were recorded on a digital voice recorder. All of the interviews lasted between 40 and 90 minutes. At the outset of the study, interviews followed a standard format. Following a brief introductory conversation, subjects were given the case vignette and asked to consider how it reflected their own experiences. They were then asked to talk about a similar anecdote based upon these. Spontaneous, unprompted, discourse was encouraged. As the study progressed it became clear that the vignette, whilst very useful in some instances was, in others, interrupting the flow of the interview and taking up time that might be better spent pursuing clarifications of comments already made during the introductory discourse. A decision was therefore made to allow the interviewer discretion as to when, and whether, the vignette was employed. Written field notes were kept in addition to the voice recording.

Interview recordings and field notes were transcribed and anonymised before transfer to an electronic database. Following a constant comparative approach, data was analysed at the time of database entry whilst the study was proceeding. Emerging themes were used to guide theoretical sampling.

Analysis was an iterative process running in parallel with data collection. AG and IR met after each interview, discussing interview content. Memos were written after interviews recording ideas and initial analysis. These were checked against existing data and the emerging theoretical framework, sampling strategy and the interview schedule adapted accordingly (as in the decisions to focus on manager-GP dyads and to use the vignette more flexibly, outlined above). Transcripts were searched for contradicting evidence to our emerging themes. Final analysis was performed using NVivo 8[580] as a method for organising the interview data and memos. Coding of all the data was carried out by the two interviewers (AG and IR), independently initially with subsequent integration of subthemes. The final overarching thesis was triangulated by exposing the emergent theoretical framework to the broader research team.

4.6. Results

All respondents, along with the homes and areas in which they received care are identified in the text below by pseudonyms.

Thirty-two interviews took place with care providers focused around 6 homes. The care homes are described in Table 53. Two homes had close-to-monopoly provider arrangements with a single GP practice, with whom nearly all residents were registered. In one instance this was a consequence of rural locality, with a limited choice of GPs available. In the other home, whilst rural locality also played a part, it was a formal arrangement with a salaried GP maintaining a 1:1 relationship with the care home as part of her job description. The remainder of homes had relationships with multiple practices, residents either retaining their longstanding GP if geographically appropriate or allocated to nearby practices on the basis of preference. None of the homes had private contractual arrangements with GP outside of the GMS contract.

Table 53 - Profile of Recruited Care Homes

CHOS ID	**Type of care home**	**Type of ownership**	**Number of residents**	**Location**	**Pseudonym**
1	Non-dementia dual registered home	Private; small chain of 15 homes	55	Suburban	Mansfield Lodge
2*	Dementia registered residential home	Private; small chain of 3 homes	46	Suburban	Chadwyck Manor RH
10*	Dementia registered nursing home		30		Chadwyck Manor NH
3	Dementia registered nursing home	Owner/manager	41	Rural	Kimpton Lodge
4	Dementia registered residential home	Charity	38	Urban	Brookside Care Home
7	Dementia registered nursing home	Owner/manager	24	Rural	Edenbridge Care Home
8	Dementia registered residential home	Owner/manager	25	Suburban	Dynasty Care Home

*IDs 2 and 10 were treated as separate homes for analysis in CHOS; as, although part of the same home, they were housed in separate buildings, with separate managers, resident cohorts and staff.

We interviewed 7 care home managers, including the managers of CHOS IDs 2 and 10, which were separate residential and nursing buildings within the same institution, 2 care home staff nurses and 9 care assistants. 6 GPs were interviewed, one for each home. We also interviewed 3 members of dementia outreach teams – specialist nurses who provide advice on dementia on an *ad hoc* basis to care homes – 2 district nurses, 2 advanced nurse practitioners – specialist nurses employed by the local primary care trust to provide supplementary advice to care homes – and 1 occupational therapist.

Health and healthcare were identified as being an important aspect of residents' lives throughout their time in care homes from the time of admission, through adjustment and adaptation to the new environment, maintenance, deterioration and death.

There was much to suggest – in keeping with the findings from CHOS – that CGA had a role in care homes. Despite this, there was very little evidence that CGA – whether explicit or implicit – comprised a routine part of healthcare for residents.

The key issues emerging from the data analysis are considered below under the headings of **Context** and **Practice**. **Context** describes the setting in which healthcare practice was presented as taking place and describes: care home residents and their healthcare needs; the organization of relationships between GPs and care homes; and the health and social care staff who provide healthcare to residents. **Practice** focuses on four areas of healthcare delivery where opportunities for CGA were identified: assessment of residents at admission; transfers of care; access to primary care; and anticipatory care.

4.6.1. Context

4.6.1.1. Care home residents and their healthcare needs

Care home residents were described as requiring health and social care as a consequence of functional dependency, multi-morbidity, cognitive impairment and behavioural disturbance. Their admission to a care home was often determined by a new medical pathology, or a deterioration in one or more chronic conditions.

> *"We've got a lady about to be admitted to us, she's obese, lymphoedema, chronic obstructive airways disease, continuous oxygen, they've put in a caecostomy tube, she's catheterised, she's in bed, she's feeling nauseous all the time, she's hasn't been out of bed for 5 months, as far as I'm aware she hasn't got any pressure sores but she does tell me that her bottom's very sore".*
>
> *Camilla, Manager, Kimpton Lodge*

> *"the ambulance man brought her in a chair and next thing the ambulance woman come in, and she said to me, 'look at her legs,' and there was a towel wrapped over her legs, and the blisters, it was weeping, and her legs were weeping with fluid….."*
>
> *Stephanie, Manager, Chadwyck Manor RH*

Most of the respondents reported that the cohort of residents being admitted to residential and nursing care had increased in dependency and morbidity over recent years. This was related to the fact that admission to care, previously a consequence of resident choice or preference, was now a consequence of crisis or necessity. This had the effect – as already described above – that admission, already difficult for staff by virtue of having to come to terms with a new care recipient, was rendered further fraught by the uncertainty that invariably surrounds patients when they are medically unwell and/or unstable. Another consequence was that there had been a gradual increase in the resources required to adequately look after residents.

> *"when Kimpton Lodge opened most people could walk independently, some would use zimmer frames. We didn't have anybody initially that needed hoisting. We bought our first hoist in '91 and that sufficed for about 10 years I think it was. And now we've got hoists coming out of everywhere. I mean we just haven't got the space to store them basically"*
>
> *Camilla, Care Home Manager, Kimpton Lodge*

> *"their mobility is very poor now, where it used to be very good at one time, where you just have ladies who just come in and just, who needed security really. Who did everything for themselves, they didn't need any help at all."*
>
> *Jane, Care Assistant, Brookside Care Home*

Another consequence of marked frailty at the point of admission, was that most residents were at the end of their lives by the time they arrived at care homes. All respondents spoke about death and dying. This is, perhaps, surprising given that the interview schedule did not specifically seek to solicit commentary on end-of-life care and the vignette was focused on relatively routine day-to-day fluctuation. It does, however, underline the importance attached by health and social care professionals to end-of-life care in this setting. Occasionally, residents were described as dying suddenly without warning.

> *"she seemed alright, and all of a sudden she had a funny turn during tea, and so we put her in a wheelchair as quick as we could to get her out of sight from the others you know, because they can't understand what's happening and it upsets some people, and we put her in her bedroom, and we had to dial 999 and the lady actually died before she got to hospital."*
>
> *Agnes, Care Assistant, Dynasty Care Home*

Much more commonly, however, a period of physical and mental decline was described leading up to death. This could either be a non-specific withdrawal from life and living, or a significant illness which clearly moved the resident into a pre-terminal phase.

> *"Biggest health problem would be … deterioration…gradually, yeah, going downhill each day. If I was on holiday and came back and saw, like, a resident, 'Oh, she's changed, she's lost some weight, what's wrong with her?' 'Oh, she hasn't been eating. Why?'….If they just want to be left alone, obviously, there's not a lot you can do, apart from encourage them, prompting. If it's their choice not to eat, then you can only prompt them. You can't force them. It's not our policy to force them."*
>
> *Jane, Care Assistant, Brookside Care Home*

> *"it's a cancer patient who went into hospital last week, who's got renal cancer, is known anaemic and it [blood count] was eight when she came and it was seven point something but she's been tired and the oncology team, there's nothing they can do, she, there's nothing, she's purely palliative, said that she might need a transfusion for symptomatic, just for symptoms."*
>
> *Dr Sandhu, GP serving Edenbridge Care Home*

Residents' time in care homes was described as involving frequent fluctuation in health and functional status. Although deviation from normality was often quite easily recognised, both health and social care professionals spoke of the difficulty in separating day-to-day fluctuation, from deterioration marking an acute medical pathology which might require treatment and from deterioration which marked progression to a pre-terminal phase. This had implications for how and when help was enlisted from outside agencies including from primary care services, the ambulance service and acute secondary care hospitals. In the example below, an experienced GP described a patient, who fluctuated regularly, often as a marker of deteriorating mental or physical health requiring either acute medical or psychiatric input but even he, as an experienced GP, struggled to tell the difference.

> *"you're never quite sure whether she's becoming physically unwell or becoming more mentally unwell….. I'm not sure the staff can but I think I can tell the difference now…..When she gets a urinary tract infection, her diabetes insipidus seems to get worse and she has, now, I can never remember which way round her sodium level goes, it either goes dead high or dead low"*
>
> *Dr Cook, GP serving Brookside Care Home*

Care homes were described as the last refuge for frail older patients. Several respondents reported that care homes – by virtue of having very flexible admission requirements coupled to an unrestricted length of stay – often ended up accepting those whose needs could, or would, not be met in other care settings. This was the case even if the care home was not ideally placed to meet the very high care needs of a particular patient.

> *"I think that, you know, practically, there's nowhere else for them to go, you know, they've tried a more sort of standardised nursing home. Their, either their behaviour or their needs, is too difficult to manage and they've ended up in a place like this, that still struggles to look after them but, you know, there's nowhere really else to go".*
>
> *Dr Cook, GP serving Brookside Care Home*

> *"I don't know what the budgetary implications are between NHS and social care anymore, it's sort of lost, I'm lost in the system there…but……there's nowhere else for them to go so there they go. They're not safe to be at home, what can you do?"*
>
> *Dr Preston, GP serving Mansfield Lodge*

4.6.1.2. Organisation of relationships between GPs and care homes

GPs described care home residents taking up a substantial amount of their workload, with the majority of work involving visits by the GP to the home, rather than by residents to the surgery.

> *“10% of our elderly patients are in care homes, and 10% of our population are over 75... we have at least two to three out of the average of 10 visits a day are to care homes”*
>
> *Dr Mater, GP serving Dynasty Care Home*

Geography played an important role in how healthcare was structured for residents. Many residents changed GP at the time of admission to a home, meaning that the GP had to come to terms with a new patient often at the time of, or immediately following, a medical or social crisis.

> *“although we’ve got a few that we’ve sort of seen through, from.....living in a normal house, and maybe ending up in warden-aided, residential to nursing, the vast majority of the people in nursing homes we look after are strangers to us when they first register.”*
>
> *Dr Preston, GP serving Mansfield Lodge*

The flip-side to this was that patients left the register of their long-term GP when they moved to a care home in a different area. Two of the GPs spoke of attempts to keep providing medical care for such patients, despite them living in care homes that were outside of their practice catchment. In attempting to do this, there was a recognised trade-off between continuity of care and the challenge of providing healthcare to a functionally dependent and medically complex patient at arms length, with consequences for how able or ready the GP was to respond to requests for help.

> *“It is pointless going and travelling out to a nursing home when you've only got one patient there.”*
>
> *Dr Preston, GP serving Mansfield Lodge*

The two rural care homes in our sample – Edenbridge and Kimpton Lodge - described 1:1 relationships with a single GP practice. This arrangement, derived in part out of geographical necessity, was praised by all respondents related to Edenbridge but roundly criticised by those from Kimpton Lodge. At Edenbridge, a constructive working relationship was described, defined by frank and open discussion of differences around patient care and a history of joint initiatives between GP and care home to improve healthcare for residents – including a recent effort to launch and embed in practice the Gold Standards' Framework (GSF) for End-of-Life Care[578].

> *"because we do it that way, we do get to know the patients.....one GP practice covering the whole nursing home, I think also works because the nurses know what to expect when they call the doctors. I mean, they know us and we know them."*
>
> *Dr Sandhu, GP covering Edenbridge Care Home*

> *"looking at the GSF it seemed like it was a fantastic opportunity to try and bring out, get some resolutions to some of these problems, so we were looking at things like inappropriate admissions to hospital, and looking at the things that as a team we feel really sensitive about dealing with...."*
>
> *Sarah, Manager, Edenbridge Care Home*

The relationship at Kimpton Lodge was, by contrast, defined by mistrust, conflict and reluctance on behalf of both care home staff and GP to engage with each other. The sense was that – were it not for a geographical necessity – a 1:1 relationship would not have been chosen. Kimpton Lodge did have a small number of residents from neighbouring villages who had stayed with their previous GP and always described these relationships in preference to those with their majority provider.

> *"Yes they [Kimpton Lodge] are hard work....all the other GP's have said, 'No,' so we are lumbered with it. What we did propose was that we have half the patients in Kimpton [village] and let's have half the nursing home people, but no, all the practices have turned round and said, 'No, it's not in our area'. Of course it's in their area....."*
>
> *Dr Smith, GP serving Kimpton Lodge*

> *"if we make a suggestion then it's like 'well what do you know, you're a nurse' so it's like, we have to not make suggestions so that they'll get treated because if we say 'I think they could benefit from x,' they'll not get it because we've suggested it."*
>
> *Camilla, Manager, Kimpton Lodge*

> *"one of the GP practices locally, if we'll say to them, 'Can we set up a sub-cut infusion', 'Yeah no problem I think that's the right thing to do,' he's dead proactive. The others, anything like that, 'Well what's the point?' 'Well have you ever died, you know, of dehydration? It's not very pleasant, so let's not put them in that situation shall we?"*
>
> *Camilla, Manager, Kimpton Lodge*

Suburban and urban care homes, by contrast, described a default situation where numerous GP practices would cover a single home (n>1:1 relationships). Contrary to the 1:1 relationship, this was discussed in universally negative terms, making it difficult both to establish close working relationships and a consistent approach to healthcare delivery across the home. This was compounded by the fact that GPs were highly variable in their practice.

> *"We have seven GP surgeries looking after our residents.....well sometimes I'll pick up the phone and I'll speak to a GP, 'I don't recognise your name doctor, are you new there?'"*
>
> *Gabrielle, Manager, Mansfield Lodge*

> *"another GP that I escorted out the building, not that many weeks ago because they were trying to do, they were doing an examination and they were trying to do it in the lounge mid-morning in front of everybody. So I walked in the lounge and took them, and told them to leave….we've got some amazing GPs as well, the flipside to that, some really, really good GPs that are really supportive of what we do, that are really caring, anything will... we need a referral for this, they're great...you know, if you want a referral, can you refer me to the dementia outreach team? Yeah. Can you put a referral in to whatever, diet, community dieticians or NHS chiropody or the hospital or for whatever, brilliant..."*
>
> *Helen, Manager, Brookside Care Home*

Urban and suburban GPs could see some intuitive advantages to organising a 1:1 relationship in terms of facilitating a relationship with care home staff and getting to know their patients better. They also perceived barriers to this approach in the form of patient choice and organisational issues with neighbouring practices – particularly the equitable distribution of workload when not all care homes required the same level of support from their GPs.

> *"patient choice scuppers this slightly but you, you should have one practice linked with one care home whereas the current situation is that we all have a few in all of them, probably. And it means that the relationships that you forge, or that you could forge, often you don't forge, with the care home staff, and with the patients to a degree, because you're not in as much when there's only two or three as you would be if they were all yours."*
>
> *Dr Preston, GP serving Mansfield Lodge*

> *"it's a relatively new home that….started about three or four years ago in the area, and what we're doing with them is we've actually said to them, we're prepared to take on ten of your patients but after that, it becomes too much of a sort of, too much of a burden really, because it's a, it's a specialist dementia home and they're very difficult management-wise"*
>
> *Dr Cook, GP serving Brookside Care Home*

A related but separate issue to the number of practices per home was whether GPs organised regular, scheduled visits to homes. This was the arrangement for both Edenbridge and Kimpton Lodge and was seen as going hand-in-hand with the 1:1 relationship. The Edenbridge team described this as being central to effective anticipatory care – with the certainty of once weekly visits acting to limit calls from the home between times.

> *"I would say doing the weekly visit or the weekly contact because it's not always result[ing] in a visit, works really well. Because it is very infrequently that they would call on the other days. Generally everything waits for the Tuesday, and because we do it that way, we do get to know the patients."*
>
> *Dr Sandhu, GP covering Edenbridge Care Home*

> *"if we feel that it's not urgent enough to either call the on-call out of hours, in an evening, or we've started on a Monday and we usually get a regular check on a Tuesday, we'll leave it till Tuesday….as a routine they'll ring up on a Tuesday and see if there's anything for them to do…. I can't think when the last time was that we had to ring [out of hours]"*
>
> *Bella, Trained Nurse, Edenbridge Care Home*

The remainder of the homes studied did not have regular scheduled visits from their

GPs. Two of the city GPs described that they had previously attempted to establish these types of arrangements with homes in their catchment area but had abandoned the practice, concluding that it had no effect on calls from the home between scheduled visits.

> *"we tried to be more proactive and make contact more regularly with the home, but it didn't seem to stop the interim visits at all. So in the end, we've gone back to a sort of reactive service, if they, if they call us, if, then, we'll go on that day, and whoever's in, we'll share it out amongst us sort of thing."*
>
> *Dr Preston, GP serving Mansfield Lodge*

> *"in the past, we used to try and do anticipatory things like a little ward round once a week. And I think we just found that it wasn't making a lot of difference to just letting the staff call us when they needed help. So we were putting more hours in without seeing very much for it."*
>
> *Dr Cook, GP serving Brookside Care Home*

Some of the care home managers treated the concept of weekly visits with suspicion, believing that GPs would use this as justification for not attending between times even if it was necessary to do so, stating a preference for rapidly responsive care whatever the day of the week.

> *"two weeks ago one of the doctors sent a letter…saying that the doctor gets called out on numerous days for minor issues, and they want to come just once a week, so I phoned up the practice manager and said, 'I cannot tell you when a resident is going to be ill, that's fine, I'll call an after hours' doctor out, you'll get charged.' So they know they have to visit, when I want a doctor, a doctor comes."*
>
> *Stephanie, Care Home Manager, Chadwyck Manor RH*

4.6.1.3. The health and social care staff who provide care to residents

A widely recognised boundary was drawn between staff employed by care homes and those employed by the NHS. This was variably labelled as being between health and social care staff, or state and private-sector employees. The distinction served as a focus for conflict and disagreement. Interestingly, however, most perceived differences actually revealed similarities in the stressors and concerns perceived by staff, regardless of sector. Thus both NHS staff and care home staff complained that each other were undertrained and ill-equipped to deal with frail older patients, whilst also recognising the same shortcomings in themselves and colleagues from their own sector.

> *"Some of our residents do have some really complex healthcare needs and, and obviously, because we're not a registered nursing home and we're not healthcare professionals, we're really dependent on the service we get from GPs"*
>
> *Helen, Manager, Brookside Care Home*

> *"the staff particularly in a residential home, are not trained medically so they, they might see there's a bit of a change in a resident but think, 'Oh well, they're just having a bad day today, we'll wait a little bit longer.' And that, you know, we kind of want them to do….It's difficult to get the balance right….very difficult....for them to try and anticipate when people are becoming ill and call us in to pick things up earlier"*
>
> *Dr Cook, GP serving Brookside Care Home*

> *"[Care home staff have] a fundamental lack of understanding of dementia and how it affects people, failure to recognise signs, non-verbal signs, failure to recognise that they can't communicate, you know, their needs and problems very well."*
>
> *Abigail, Dementia Outreach Nurse*

> *"I don't think I did enough [training in managing older patients]. I didn't do any psychiatry. So all the psychogeri stuff is, was, new to me. And all the drugs were new to me. I mean, the, referring to psycho-geriatrician before this job was, I've not done, was new to me on starting this job."*
>
> *Dr Sandhu, GP serving Edenbridge Care Home*

> *"The average General Practitioner isn't experienced enough.....and you need a, basically another specialism going in and I think that would deliver better care to the patient."*
>
> *Dr Smith, GP serving Kimpton Lodge*

Another area where perceived differences served to underscore the similarity of the challenge faced across sectors was highlighted around finance. NHS staff raised concerns about the fact that care homes were privately owned and the perceived conflict-of-interest between profit motives and duty of care, whilst care home staff spoke of an increasingly financially-driven NHS which attracted staff motivated by job security and high pay, rather than a duty of care.

> *"not privatising healthcare for people, such vulnerable people, it's probably the first step taking it back under, you know, health authority, social service control, needs to be done, I think."*
>
> *Abigail, Dementia Outreach Nurse*

> *"there's always the issue about owners wanting the maximum profit, and therefore the minimum staffing and all the rest of it….putting budgets into the hands of private landlords, I can't see as a brilliantly efficient way of a caring service working. So you'd have to change that, I think. But then again, we know that government services are often terribly inefficient. I don't know how you square that circle."*
>
> *Dr Preston, GP serving Mansfield Lodge*

> *"they are extremely business minded in certain ways in the NHS, so play them at their own game, but they don't like it when you do. So, I mean things have got to change, care of older people has got to get far better, they deserve better facilities, they deserve better care, and they deserve the right care"*
>
> *Camilla, Manager, Kimpton Lodge*

> *"it's the underlying policies behind, that determine who gets what, like, the rationing of healthcare services. So the fact that there's a pecking order…..the older you are, the less you need it because it's going to cost a lot of money and then you're going to die, so it's been waste of resources, quality life adjusted years, I think it used to be called."*
>
> *Helen, Manager, Brookside Care Home*

> *"people work in the NHS because of the benefits, that's why they work in NHS, not because they want [to help]…..so it's my choice."*
>
> *Gabriel, Manager, Mansfield Lodge*

A final issue of division which paradoxically revealed similarities across sectors was fear of litigation. Healthcare staff felt this was a motivating factor in the care agenda for homes, whilst care home staff levied the same accusation at the NHS.

> *"there's litigation isn't there, and what previous doctors have done, you know, Harold Shipman…I mean at the end of the day it is them isn't it, they're the ones*

> *that are prescribing, and it's their backs isn't it. So they've got to look out for themselves…."*
>
> *Bella, Trained Nurse, Edenbridge Care Home*

> *"The legal side of things is very difficult for residential homes because they don't want to be sued by anybody for not providing care for patients so if somebody is not well they tend to call an ambulance and tend to get them into hospital very quickly."*
>
> *James, Care Home Nurse Practitioner*

Further evidence of the arbitrariness of boundaries drawn between health and social care staff came from the detail of the day-to-day care provided by care home staff – with much of what was labelled as social care having a direct bearing upon assessment and maintenance of patients' health. Social care staff spoke of a preparedness to perform healthcare tasks where doing so might improve their residents' experience.

> *"I'm not too keen on the blood sugar thing but it does say in the legislation that we can do it as long as we're trained to do it…..so I'm keeping an open mind and I know it's really easy and it's simple and it's not rocket science, it's not difficult to know if it's high or low or okay or, so, at least it means we can be more proactive"*
>
> *Helen, Manager, Brookside Care Home.*

> *"in terms of being trained to do dressings, skin tears, again, fantastic, because it means we can be proactive. Somebody doesn't have to sit there waiting for the [care home nursing emergency] team or the district nurse or whoever to come out to put a dressing on, because we can clean it up, pop a dressing on and, and, and straightaway, so, no, I embrace it because it means that the needs are met at the click of a finger straightaway there and then"*
>
> *Helen, Manager, Brookside Care Home*

> *"there is a protocol that if a particular pressure ulcer, if it's a grade 3, that we inform them (the tissue viability nurse), but that may be it, that we've just informed them that we've got a pressure ulcer, and then they're alerted to that, but if we say that we've had the training and that we know what we're doing, then they're fine to let us carry on at that, but it's just to let them know."*
>
> *Bella, Trained Nurse, Edenbridge Care Home*

> *"if she has got on-going incontinence.... if she keeps getting urinary tract infections then besides liaising with the GP, I would liaise with the continence advisory people as well, and I would get them to come to assess her, because they would look at whether she's retaining some urine as well and that's why she keeps getting the urine infections. And I'd look at her diet and how much she's drinking"*
>
> *Bella, Trained Nurse, Edenbridge Care Home*

In addition, care home staff described a body of experientially-derived, often tacit and unrecognised, knowledge that allowed day-to-day monitoring and management of aspects of health including nutrition, behavioural disturbance and functional dependency that belied the complaints about their lack of preparedness for their care role.

> *"if I get a new lady I'll watch and I'll ask her, 'do you like gravy, do you like so and so, so and so', now if she said to me, if I said a piece of chicken say, and fish fingers or fish cake, and she says 'I'll have chicken' and I notice that she doesn't eat the chicken for a couple of weeks then I know that no, she doesn't like chicken, so I'll go onto something else then, and see. Because you know that when anybody eats their food that they do like it."*
>
> *Agnes, Care Assistant, Dynasty Care Home*

> *"we tried the hoist and he was okay and then, they had to stand him, and I said, 'Could he stand?' and they said 'Yes.' I said, 'Right, don't use the hoist, get the rotunda out, two of you, and do him on that.' So he's going to gain that little bit of strength, isn't he?"*
>
> *Gillian, Manager, Dynasty Care Home*

> *"...they [hospital staff] said he wasn't eating, but he wasn't eating because they didn't give him the time to eat, because he's very slow eater. About one and a half hours it takes him to eat his meal."*
>
> *Gillian, Manager, Dynasty Care Home*

> *"they were telling me how they got somebody up and the, when they did it this way,...we went in and opened the curtains and left them a bit (...) and then went, you know, come on, well, come back ten minutes later, it's slow process but, you know, the person responds really well and didn't get agitated."*
>
> *Abigail, Dementia Outreach Nurse*

A further body of knowledge held by care home staff, that allowed effective management of residents' health, was a detailed understanding of the day-to-day condition of longer-stay residents. This meant that, when a resident's status changed, appropriate healthcare interventions could be initiated.

> *"her behaviour had started changing a little bit, but she has these sort of lulls of being really depressed and then sort of coming out of it again, and we really thought that behaviour had followed the pattern that she was going into one of her lulls of depression. And then she started demanding drinks and ……it suddenly occurred to me that perhaps we ought to test her urine, which we did, and she'd got quite a lot of glucose in and ketones, and so I did her blood sugar and that was off the scale"*
>
> *Bella, Trained Nurse, Edenbridge Care Home*

> *"if you've got a nice cute little lady who is very pleasant to you every time she sees you, and then one day you came in and she's just so confused and disoriented and crying. Aye aye, something's wrong with her. We'll do a sample."*
>
> *Jane, Care Assistant, Brookside Care Home*

> *"they'll come and say, 'oh such and such a person has been really stroppy with me this morning,' or something, and so whereas normally they're quite pleasant, and so you notice that there is a mood change, and so again it's then it encourages the trained staff to look behind why there's a reason"*
>
> *Bella, Trained Nurse, Edenbridge Care Home*

Despite this body of expertise, there were clearly a number of situations where workers trained predominantly to support residents with day-to-day activities of daily living ("social care"), were ill-equipped to deal with healthcare needs. This was particularly the case with acute deteriorations in health which required ongoing monitoring against deterioration.

> *"Often what happens the GP will go in, see the patient with a chest infection whatever, prescribe antibiotics. They feel that they've done what they've got to do but who's checking that the breathing is not getting worse, progressing to pneumonia..It's a lot of responsibility for untrained staff to care for these people. And that's why you have to keep going back and keep reviewing and checking that you've made the right decisions."*
>
> *James, Care Home Advanced Nurse Practitioner*

Nursing homes, by virtue of a trained nurse working on each shift, were possibly better equipped to deal with such issues.

> *"If we suspect a chest infection.... they tend to become drowsy, they tend to, they're a bit..change their mood and all, we can pick certain things, and then from there we need to observe them regularly and then if they really need a doctor we call the doctor right away."*
>
> *Jean, Trained Nurse, Mansfield Lodge*

However, the presence of trained nurses in nursing and dual-registered homes also presented a challenge in that both care home and NHS staff often struggled to identify the boundary between care which should be provided by care home nurses and that which should be provided by NHS district nursing services.

> *"you see the thing as well we don't want to be later on intervening their care and we will be in trouble. Even just sometimes dressing, I said to my nurses to avoid anything, I know sometimes district nurses are so busy, if they are busy we'll slap a dressing to it, but as far as I know we are trying to avoid putting anything in there, that's for the district nurses."*
>
> *Gabriel, Manager, Mansfield Lodge*

> *"And then you've got the fact that you're actually dealing with the district nurse team, so you don't even know the district nurses, they're not that familiar with you. And then there's the argument about how much does a district nurse do when they are qualified nurses in the home"*
>
> *Dr Cook, GP serving Brookside Care Home*

Respondents from a number of backgrounds spoke of the need for increased involvement by specialist multi-disciplinary teams in the management of care home residents. This was largely a response to the complexity of residents' health problems and overlapping functional dependency alongside the challenge that these presented to the training and accumulated experience of care home staff and GPs.

> *"what our residents deserve is a team, a healthcare team, multidisciplinary team of experts and the only experts that they get are us, you know there isn't, you know, GP's might be very good at what they're doing for the general population but we're talking about older people."*
>
> *Camilla, Manager, Kimpton Lodge*

> *"I personally feel that at times it is, there should be a multidisciplinary team going into a nursing home, multidisciplinary meaning, you know, which there is now but at the moment we have to request it but it should be just rotating around. You know it should be, we're talking there should be a psycho-geriatrician, there should be dieticians, you know, for the people that have had strokes, the feeding, etcetera, they should just be automatically done."*
>
> *Dr Smith, GP serving Kimpton Lodge*

> *"But, health-wise, I think they do need quite a lot of input. Not everybody, but there are some people in some homes that do, and that they would be better served by the kind of model of having more of a team that can give them more intensive care. Whether that's done as an outreach from hospital or a specialist GP team, or somebody like a community residential care matron or something like that."*
>
> *Dr Cook, GP serving Brookside Care Home*

Despite this, teams interposed between GPs and care home managers, such as the dementia outreach team, community allied health professionals, and care home nurse practitioners, described a difficulty in negotiating boundaries to their responsibilities when the relationship in which they were interposed (GP and care home) was already relatively uncertain and fluid. This could render them impotent in their attempts to influence GPs, care home staff, or both.

> *"[GPs feel a] little bit threatened a bit, maybe, we're encroaching on their territory a little bit, you know, treading on their toes as it were. And they seem, we don't have, they don't communicate with us."*
>
> *Abigail, Dementia Outreach Nurse*

> *"But the problem is, you can go in and you can ask them [care home staff] to do things, so, can you document this, can you do this thing, that's not got done, then nothing will have happened, so then, we're criticised for saying…..we're not doing anything, but they're not doing the stuff where we've asked them to."*
>
> *Abigail, Dementia Outreach Nurse*

From the opposite perspective there was a sense, at times, of silo working – where specialist members of the MDT brought recognised expertise but communicated this inadequately to GPs, care home staff, or both.

> *"Most of them have got a CPN but there doesn't seem to be any dialogue between me, the CPN and the staff in the nursing home…….the CPN doesn't seem to be around and available to discuss things. It's always up, you know, up to us to get in contact with them. And, you know, there's often a while before they get back in contact with you"*
>
> *Dr Cook, GP serving Brookside Care Home*

Some care home managers described working in an informal capacity to manage and co-ordinate the MDT, or to arbitrate between members of the MDT and the GP.

> *"I've never spoke to a doctor about a physiotherapist but I've spoke to the district nurse and I've spoke to her about a dietician as well, because we have a lady who doesn't stand or doesn't do anything, we don't know whether it's physical or mental, and we mentioned to her about a physiotherapist for this particular lady, and we've referred and we've spoken to her. And the same with the dietician, we probably would go through the back door to the dietician and have a word with her and then she would tell us what to do and then go to the GP and tell the GP what we want."*
>
> *Gillian, Manager, Dynasty Care Home*

Once these issues around negotiated role and routes of communication had been addressed, services provided by members of specialist MDTs were recognised as having positive effects on the care delivered to residents.

> *"can't fault dementia outreach, absolutely brilliant. Loads of input, really, really, best thing that could have happened and I think everybody in the UK or wherever should have a team like that, because they understand the mental health."*
>
> *Stephanie, Manager, Chadwyck Manor RH*

> *"don't know what we'd do without the dementia outreach team, but there's only so much they can do. They come and assess and they caseload, so they do what the CPNs used to do for dementia clients….they come and do reviews, we have the OT come and, the activities person come and work with my activities coordinator, they deal with the medication, they get the GP to change it and review it as necessary, they give free staff training, that's great."*
>
> *Helen, Manager, Brookside Care Home*

> *"the [care home nursing emergency] team's great, and they'll get scripts sorted, they'll prescribe, they'll phone the GP and say, well, I think you need to change this medication"*
>
> *Helen, Manager, Brookside Care Home*

4.6.2. Practice

4.6.2.1. Assessment of patients at admission

Given the frail, dependent and multimorbid nature of care home residents, alongside the fact that they were likely to live in a home from the time of admission until they died, it might have been expected that they would receive a comprehensive medical assessment at the time of admission. However, although care home managers sometimes assessed residents prior to admission, no respondent spoke of systematic assessment by GPs or other healthcare staff at this point.

> *"we do rely heavily really on Sarah's [manager] pre-admission, what she's been able to find out and then what she's been able to liaise to us."*
>
> *Bella, Trained Nurse, Edenbridge Care Home*

Although systematic assessment might have taken place in hospital prior to admission to the care home, it often did not inform management in the home as a consequence of missing or poor quality discharge correspondence.

> *"even if they have been in a hospital ward for the last five months….when they transfer, the information is...you think, you think they'd been there for five months, you could have some information. I mean, Sarah [manager] goes to the hospital wherever they're coming from and tries to get as much information in advance, and if there's, if there's Do Not Resus already set up, she tries to bring that over with the patient, but all those things aren't always communicated."*
>
> *Dr Sandhu, GP serving Edenbridge Care Home*

Where patients were admitted from the community, as opposed to hospital, it was described that social work staff might try to compensate for this lack of medical assessment by passing on what healthcare information was available to them. Care home managers, quite reasonably, treated second-hand information of this type with a degree of caution, understanding that it was likely to be incomplete.

> *"when they first come to us, we would probably know if they've had any form or cancer or whether they've had a stroke or they've got a history of heart problems or, and this normally comes through, like, the social worker but we don't ever really get any proper, you know, like come from the GP, we don't get anything like that."*
>
> *Gillian, Manager, Dynasty Care Home*

There was a sense, from some GP respondents, that the reason for not assessing patients comprehensively at admission was that to do so would be too difficult and time consuming to contemplate.

> *"Now the other thing, complexities is, these people are coming in with six inches, four inches to six inches of complex notes so just to digest that will take one day."*
>
> *Dr Smith, GP serving Kimpton Lodge*

4.6.2.2. Transfers of information

Information flow was described as being particularly poor after a hospital stay. Respondents described poor quality discharge summaries and inadequate verbal communication, even when hospital staff were asked quite specific questions.

> *"she came on loading doses of amiodarone to be, to be decreased over the next two weeks, but she went in on, she was already on digoxin…..on the green sheet, it said, anaemia which we knew about, and DVT excluded but nothing to justify the new*

> *drugs, ondansetron and amiodarone……there was no reason and we won't get a letter for a few weeks, will we?"*
>
> *Dr Sandhu, GP serving Edenbridge Care Home*

> *"this lady's being sent to us at the moment she's on warfarin and her INR all over the place she's supposedly on warfarin for atrial fibrillation but she's also on enoxaparin for, I presume because she's immobile and in bed, so I said, 'Well what are they expecting in terms of INR?' Just got a shrug, 'Is she going to be on continuous oxygen with us,' I just got a shrug and I'm sure they just think, 'we can discharge this lady and it doesn't really matter what we're discharging her on because actually we're not bothered.'"*
>
> *Camilla, Manager, Kimpton Lodge*

Similar issues were seen, however, when patients were admitted from the community. This was an issue because of delays in transfer of notes when patients registered with a new GP.

> *"when she moved into the home, took us ages to get hold of….her old records. And the staff at the home thought she'd got diabetes. But in fact she had diabetes insipidus which is a completely different thing to diabetes mellitus."*
>
> *Dr Cook, GP serving Brookside Care Home*

> *"she's only been with us about five months and I think, while she was at home, she wasn't having this medication, she was supposed to have it and this was from the incontinence clinic and I don't think she was having it on a regular basis, and so when she came to us, one minute we'd got it and the next minute we hadn't….eventually, we worked it out that she should be having that one and so, since she's been on them regular, she doesn't have the problems with the bowels."*
>
> *Gillian, Manager, Dynasty Care Home*

An assumption was made by hospitals that further management and additional care, such as occupational therapy and physiotherapy, would follow with ease of access for care homes. This was not the case, with the consequence that care home staff often ended up making detailed functional assessments and constructing *ad hoc* rehabilitation plans for themselves.

> *"We'll have him walking again. You know, we won't get any help from anywhere but we'll try, you see, we'll keep trying and we'll just, at first keep getting him to*

> *stand, and get a little bit of strength into his legs and things like that, you see. And then, when we think he's ready, we'll try one or two little steps and we'll do it like that and if we do it like that on a daily basis, then, eventually, you've got to, you've got to do something, haven't you, it's got to work, hasn't it?"*
>
> *Gillian, Manager, Dynasty Care Home*

> *"she was discharged after 10 days…. the hospital said she's rotunda, but we didn't use rotunda because she can walk…We just say she can't walk, let's try her to walk or whatever, she's been for x-ray, probably there's nothing wrong because I've not heard anything, so it's ok now, she walks."*
>
> *Gabrielle, Manager, Mansfield Lodge*

4.6.2.3. Access to primary care

Care home staff frequently stated the importance of ready access to advice and/or visits from GPs. This resource was viewed as important regardless of whether homes received regular weekly visits, as there was always a possibility that residents may deteriorate between times.

> *"we're really dependent on the service we get from GPs, district nurses. And that, I find, that makes me feel quite vulnerable, to be honest, and it's really, you can see that somebody's not well and there's obviously something going on but because you're not a doctor or a nurse…"*
>
> *Helen, Manager, Brookside Care Home*

> *"we look at how our residents are prior to a weekend, but I mean there's always, there are always things like if somebody falls over and you don't think it's a fracture but you know there's something that you might need a doctor for."*
>
> *Bella, Trained Nurse, Edenbridge*

GPs also stated the importance of easy availability, with the possibility that patients could deteriorate if medical advice was not provided in a responsive and timely fashion. A tension was noted, however, between ready availability and the possibility that this might result in calls of increased frequency to the point that they became unmanageable, making it difficult to identify the calls of greatest importance. A number of GP respondents drew a distinction between "good" homes, which made "appropriate" calls, and "bad" homes, which made frequent "inappropriate calls".

> *"perhaps they got a urinary tract infection or something that you could have treated and kept them in the residential or nursing home, but by the time you get there, it's kind of, oh God, they, you know, they've got septicaemia or, you know, they just get, they phone an ambulance at ten o'clock at night because the person suddenly becomes very ill"*
>
> *Dr Cook, GP serving Brookside Care Home*

> *"good calls are appropriate calls, and I suppose, the trouble is it's a bit like the call wolf syndrome isn't it, there might be a perfectly appropriate call from a bad nursing home and the danger is that you start saying, 'Oh god, it's them again,' you know, and you either don't go or you know you risk dealing with it by telephone or whatever."*
>
> *Dr Mater, GP serving Dynasty Care Home*

> *"a bad call for us, is a frequent call for, to the same nursing home by different nurses who have, who hadn't, realised we were there yesterday.....so if we're going to the same home, consecutive days for different patients or with ongoing issues that all could have been dealt with in one visit, that's a bad call"*
>
> *Dr Preston, GP serving Mansfield Lodge*

GP practices responded to this tension with an assortment of measures designed to organise, triage, or restrict the calls for home visits from care homes, with the knock-on effect that care home staff found that gaining access to primary care could be difficult and slow. The mechanisms described were loose and informal. No practice spoke of formal and specified triage criteria for dealing with calls from care homes. GP receptionists were often cited as performing this difficult role.

> *"There is always a time limit, sometimes you have to call before 10, but if something like that after 10 I have to do it myself because I have to use my charm again with the [receptionist] there, so that they can book it immediately. So I just have to say, 'I know I'm a bit late, but you see it's a bit of an emergency here.'"*
>
> *Gabrielle, Care Home Manager, Mansfield Lodge*

Informal triage measures could fail in a number of ways. They could, for example, result in failure to identify medically unwell patients, who subsequently deteriorated, requiring admission.

> *"Somebody was almost moribund when I went to see them, and you know, the visit had been put through to reception as just a routine sort of unwell sort of thing, the receptionist hadn't realised quite how unwell, just put it down for a routine visit."*
>
> *Dr Cook, GP serving Brookside Care Home*

Or they could place unreasonable demands on care home staff, which contrary to the stated aim of informing the GP assessment, simply added delays to care.

> *"You cannot get a [urine sample] from a demented patient so they [GP receptionist] said well you've got to get one or we won't prescribe without it, and they can't get one so they [care home staff] end up with the patient getting more and more confused and more and more ill until they end up having to get the doctor to do a home visit".*
>
> *James, Care Home Nurse Practitioner*

A knock-on effect was that some care homes spoke of being afraid to contact GPs on behalf of their residents. Some managers spoke of a desire to avoid "inappropriate" calls to avoid being identified as a "bad" home, in order to protect an effective working relationship with their GPs.

> *"So if we've got a problem, we can ring the on-call doctor, you know, instead of thinking, 'Oh dear, it's past ten o'clock, I daren't ring up now for a home visit.'"*
>
> *Gabrielle , Care Home Manager, Mansfield Lodge*

> *"They are so worried that they are going to get told off if they phone up and ask for a home visit. This really is a big issue. I'm sad to say that I haven't found any doctors in this area who want to come and do home visits. They will come if they have to but they have to have a lot of persuasion to come."*
>
> *James, Care Home Nurse Practitioner*
>
> *"our experience with GPs, particularly GPs who know us, is always pretty good, because I think they know that we respect them and how busy they are and, and I think they, you know, they understand that, like, if they come into Dynasty House, they come into Dynasty House because there's a problem."*
>
> *Gillian, Manager, Dynasty Care Home*

This meant that some homes installed informal and loose triage measures of their own. The end result being that residents faced not just one, but two, possible delays between becoming ill and seeing a doctor.

> *"I don't think that, because somebody's a little bit off colour today, that you should straightaway get the doctor, it's get the paracetamols and the cough medicine and let's have a go for three days, and if there's no improvement or they seem to be going down a bit, then, we'll have the GP in"*
>
> *Gillian, Manager, Dynasty Care Home*

> *"call in the morning and explain, you know, we have got two people have got a cold or a few people is very confused and we check has got no urine infection or temperature, you know, or and we call doctor and make appointment for few people and doctor come can visit may be 3 or 4 people in one time".*
>
> *Agnes, Care Assistant, Dynasty Care Home*

4.6.2.4. Anticipatory care

As already described, residents were reported to have prevalent chronic illness, manifest frequent fluctuation and/or decline and be in the last months or years of life. Despite this, examples of anticipatory care which attempted to put in place advanced plans against such deterioration were few and far between. This stemmed, in part, from the failure to assess residents at the point of admission to the home, meaning that no structure existed around which to consider the impact of medical morbidity on either quality of life or health service resource use. This led to conflict around the management of progressive conditions that might have been avoided had anticipatory care plans been in place.

> *"we had a gentleman who had got gangrene of the foot, and he was dying, his daughter was here on a regular basis, and all I wanted [was] adequate pain relief for him, we all knew what was going to happen, and it's one of the partners and she was a very newly qualified partner at the time, and she came out, and she said, 'Oh he's got gangrene of the foot,' so I'm like, 'yeah.' [She said,] 'We need to admit him.' I'm like, 'No we don't.' And she said, 'Yes we do', and I'm like, 'No, all I want is some adequate pain relief for him'"*
>
> *Bella, Trained Nurse, Edenbridge Care Home*

> *"we had a lady….who had an advanced dementia and had got, had a succession of chest infections and she was asthmatic, and we had a GP come out to visit us from the practice…..he wanted [her] to be admitted into hospital, this is going back some time now, because she needed IV antibiotics, and I didn't think it was the right...myself and the team, the nurse that was on was really quite upset about it, the primary nurse just didn't think it was in this lady's best interests, and he'd sort of put it to the family the way that I don't think they could really have said no"*
>
> *Sarah, Manager, Edenbridge Care Home*

> *"when these blood tests came through, this lady was desperately in need of blood transfusions and the family had said, 'No.' Well, the doctor had give her some tablets and well, I were fuming, and then I thought, you know, this lady's got a decent quality of life, I mean, that's the one who just come to the door, and I think her blood was down to something like four or something like that, and, and she were bleeding internally, and the family had said, 'No.' Well, I sometimes find it hard to be professional, you see."*
>
> *Gillian, Manager, Dynasty Care Home*

A further consequence was admissions to hospital, or attendances at outpatients, that were either distressing for patients, or did not influence their prognosis and thus might have been regarded as both avoidable and inappropriate.

> *"But this lady did go into hospital, she was treated with IV antibiotics, she came out of hospital, and the GP was quite triumphant because she survived, because she was on IV antibiotics. She died eight days later, and I was not quite so triumphant because I didn't think it was in this lady's best interest to have been placed into hospital"*
>
> *Sarah, Manager, Edenbridge Care Home*

> *"her last appointment, by the time she got in, it took me an hour and a half to two hours of consoling her, reassuring her, she was beside herself, she was shaking, with, A, because she was so cold [and], B, frustration. She's being aggressive, she threw a cup full of water over my senior this morning, she won't take any of her medication, she's not eating properly, she's all over the place and she's a thousand times worse after she's been to hospital. Exhausted."*
>
> *Helen, Manager, Brookside Care Home*

On a day-to-day basis, the failure to anticipate fluctuation or decline – or to institute an advanced care plan which allowed for the possibility of such decline – led to the need to use out-of-hours services. These were generally recognised as providing sub-optimal care due to discontinuity of provision and the inability to access residents' normal healthcare records.

> *"they [out-of-hours doctors] don't know anything about the person, do they? It's got to be, it's got to be a new, like, one-off thing, if somebody, you thought, 'Oh, her breathing's quite bad and she's not right,' but they come with no information about that person, and then....for that doctor, it's difficult as well."*
>
> *Gillian, Manager, Dynasty Care Home*

> *"I don't know why but statistics will show you at Kimpton Lodge that when we do need to put somebody on the [Liverpool Care Pathway] it'll be on a Friday night or a Saturday so you've got no access to a GP you've got no outer access to the drugs. So you end up going to out of hours but then out of hours aren't willing to prescribe because they don't know the patient etc"*
>
> *Camilla, Manager, Kimpton Lodge*

Some of the GPs spoke of feeling disempowered to make decisions for their own patients in conditions which, by consequence of their life-threatening nature, had been identified as the preserve of the emergency services. This was the case for chest pain, where the policy was for GPs to advise homes to call an ambulance rather than to attend and assess the resident, for fear that they might delay timely treatment of a myocardial infarction. One GP spoke of her fear that attempts to develop hyper-acute stroke care within the UK along similar lines might further disempower her. None of the respondents identified advanced care planning as a means whereby control could be asserted over such situations.

> *"if somebody has chest pain then the advice is we don't touch them with a barge pole....we're now being put in this position about strokes, and with all this stupid, in my view, campaign about strokes, you know implying that it's the same as heart attacks, that this is something that affects young people and the quicker we can get the anti-embolism stuff into them then the better....but I think strokes are hugely different from heart attacks because I do think they affect an older population and ....you're not really wanting to get every single one of those into hospital."*
>
> *Dr Mater, GP serving Dynasty Care Home*

Some of the GPs seemed to provide paradoxical accounts of their attitudes towards anticipatory care, providing some evidence of a failure to learn, or reflect upon, this topic in the elderly. This was the case when preventative medicine and anticipatory care were conflated, rather than treated as being separate. Thus Dr Preston, below, described inevitable decline as a rationale for not instituting proactive care plans, using the lack of evidence for preventative medicine in this cohort as his justification.

> *"I'm a bit of a cynic about all this proactive stuff, I suppose in some ways, because the problem is, they are just very old and frail and things are going to go wrong, aren't they? And they will fall, they will become ill. So I think once you've got to sort of in your eighties and nineties, all that sort of preventative idea, might have been okay in your forties, [laughs] but it's a bit late now."*
>
> *Dr Preston, GP serving Mansfield Lodge*

GPs spoke about difficulty in deciding whether generic preventative medicine guidelines applied in care home patients. However, even those who were cynical about preventative medicine in this population could cite examples where it might have relevance – with calcium and vitamin D therapy quoted by several respondents as an example.

> *"I mean, when do you give a statin? Do you give it at eighty-five because you've just found the diabetes and they've got dementia and they've got, maybe two to four years?"*
>
> *Dr Sandhu, GP serving Edenbridge Care Home*

> *"Calcichew is an easy thing we've tried to do in nursing home…… and, and, Fosamax, alendronate acid, you know, things have, preventative strategies that are thought to still be useful in the elderly, we would try and, and use."*
>
> *Dr Preston, GP serving Mansfield Lodge*

All respondents seemed to accept the fact that residents within homes were approaching the end of their life. GPs tended to speak of this in epidemiological terms and with a degree of detachment, whilst care home staff more often became emotional. Importantly, any attempts described to formalise advanced care planning that might encompass end-of-life plans had been led by the care home staff rather than GPs. Some GPs spoke of care home leadership on such issues with a degree of discomfort but also acknowledged that the close relationship built between care home staff, residents and their families, meant that staff in homes were well placed to do this.

> *"we had a relatives meeting the other week and I said to them 'right you've all had these [advanced care planning] forms and a lot of you have sent them back saying when the time comes you'll discuss it.' I said 'I hate to tell you this but when the time comes you're not going to be able to discuss it because the person who's time it is isn't going to be able to join in any conversation so as painful as it may be we need you to have these discussions now'"*
>
> *Camilla, Manager, Kimpton Lodge*

> *"[the care home staff] say, 'Oh, we've spoken to the family and the family say they don't want them to go to hospital,' then we'll have to speak to the family. And the problem is they have that discussion before they speak to us, because they've already spoken to the family and said 'No, no, the doctor won't send them to hospital,' before the doctor's been. [laughs] It's just ironing out creases"*
>
> *Dr Sandhu, GP serving Edenbridge Care Home*

> *"I mean, we talk to [families] towards the end, but usually, the general consensus is, you know, keep, it's the keeping comfortable discussion….sometimes it's just….it's just, there are some medical questions because they, that the nursing home, obviously, couldn't answer……the manager knows all of them. So, most questions are answered, and if they're not sure, then sometimes the staff ask us"*
>
> *Dr Sandhu, GP serving Edenbridge Care Home*

Some of the vulnerability felt by GPs in this context seemed to stem from nervousness around the prescribing of opioids in patients who had non-oncological diagnoses and a feeling that such practice might leave them vulnerable to challenge – particularly in dementia, where prognostication was felt to be difficult. This remained the case even when guidelines such as the GSF, were used.

> *"we've learnt from the GSF is that there is this box of drugs and it's got so many drugs in it, and basically we have those drugs so that we can use them, that are prescribed, we have to have them prescribed specifically for the patient, but with*

> *certain clinical indicators we can use these drugs, and what we're increasingly finding is that the GPs are saying to us, 'Well you can have this drug but she's never had pain before now so I'm not going to give you, I'm not going to give you morphine'"*
>
> *Bella, Trained Nurse, Edenbridge Care Home*

> *"now they're on the GSF it's all more, learning more. But you know, we know we can't, it's hard to give a prognosis for a dementia patient. They don't fit easily into the boxes, do they?"*
>
> *Dr Sandhu, GP serving Edenbridge Care Home*

4.7. Discussion

In the introduction to this thesis, CGA was defined as, "a multi-dimensional interdisciplinary diagnostic process focused on determining a frail elderly person's medical, psychological and functional capability in order to develop a coordinated and integrated plan for treatment and long-term follow-up."[24] Several of the respondents to STICH, whilst stating their discomfort or dissatisfaction with current healthcare arrangements for care home residents, defined an idealised service as one which was multidisciplinary and sufficiently expert and resourced both to assess the current health status of complex frail older people and to plan for future changes in their health. Although not mentioned by name, this seems close to a call for CGA.

It was evident from the transcripts that CGA was not being delivered. Healthcare was described as being, for the most part, defined by discontinuity and lack-of-anticipation. Residents frequently moved to a new GP when they moved to a care home or changed between homes. It was described that appropriate and available care home places were often not geographically close to residents' long term homes. GP interviewees, meanwhile, spoke about the need to visit most care home residents *in situ*, with consequent difficulty in looking after residents who were geographically remote. Taking these points in summation it seems logical, or at least defensible, for a resident to change GP when they are admitted to a care home. This would allow them to have a doctor close enough to visit their home rather than remain under the care of a long-term GP who might struggle to attend.

Discontinuity at the point of admission was made more challenging by residents arriving at a home either following a progression in a chronic condition or whilst recovering from an acute medical crisis. This seems unavoidable given the position that care homes occupy in the modern health and social care continuum, widely acknowledged by interviewees, as the point of final refuge – the place that care recipients go when nowhere else will, or can, provide care.

Accepting that a resident's admission to a home will often be defined by medical instability and change of GP, it would seem intuitive that they undergo comprehensive medical assessment to establish management priorities at this time. Much of this medical assessment might have taken place before the resident arrives at a care home, given that they will previously have been seen by a GP or hospital doctor about the chronic conditions, or the acute medical crisis, which shaped their admission. Interviews suggested, however, that the results of such pre-admission assessments were usually not passed onto the new GP, or to care homes. Discharge communication from hospitals was inadequate, whilst GP records could take months to catch up with the resident. New GPs made no attempt to compensate for this by undertaking comprehensive medical assessment at the point of arrival to the care home. GPs, where they discussed this, seemed to perceive such comprehensive assessment as being too much work. Attempts to establish advanced care plans – predominantly focused around end-of-life care – were occasionally described as being undertaken by care home managers and staff. However, due to the lack of medical assessment already described, these were conducted in partial or complete ignorance of medical problems. They were also, for the most part, conducted with minimal or limited input from primary healthcare teams.

One key component of CGA – multidisciplinarity – was evident in the transcripts. Doctors, nurses, care assistants, physiotherapists, occupational therapists, dieticians, social workers and speech and language therapists were either interviewed, or spoken about as being involved in care delivery by interviewees. However, far from acting as a single coherent multidisciplinary team, they showed evidence of silo communication where each profession would speak only to the care home staff, or only to the GP, or occasionally only to another professional attending the home. This is different from the type of MDT communication which sits at the core of CGA, which is multidirectional and, by virtue of taking place at widely-attended MDT case conferences, allows broad understanding and sharing of ideas (illustrated in Figure 15).

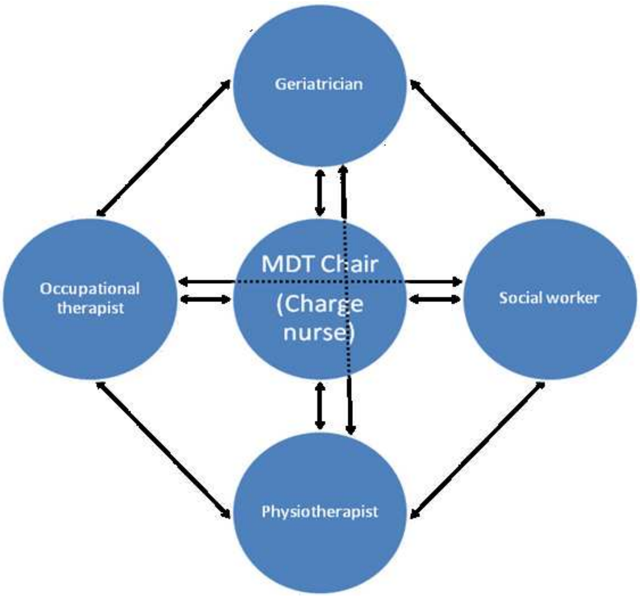

Figure 15 - MDT communication as routinely conducted during CGA

The mode of communication described in interview transcripts was variable. At its best, the care home manager, or occasionally the GP, was used as a *de facto* care coordinator and therefore all communication was channelled through them (see Figure 16). This had the advantage, at least, of ensuring that there was one person with a near complete overview of a resident's healthcare. It had the disadvantage that the person chosen – either care home manager or GP – had to act as an information conduit to other professions and might not understand, for example in discussions with a physiotherapist, which aspects of that discussion would be most relevant to a social worker, or general practitioner. This represents a challenge to effective multi-disciplinary working.

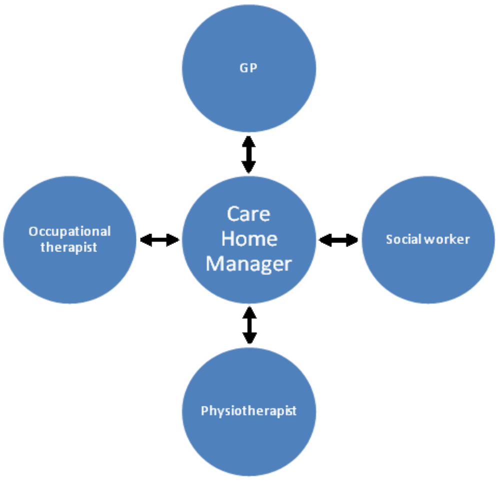

Figure 16 - MDT working in care homes where care home manager acted as *de facto* care co-ordinator

However, in some instances, it was clear that not all communications were channelled through the care home manager or GP, with the result that no single professional was able to co-ordinate care. This was the least functional model of MDT communication described. It had implications for the resident, with poorly coordinated and disjointed care (see Figure 17).

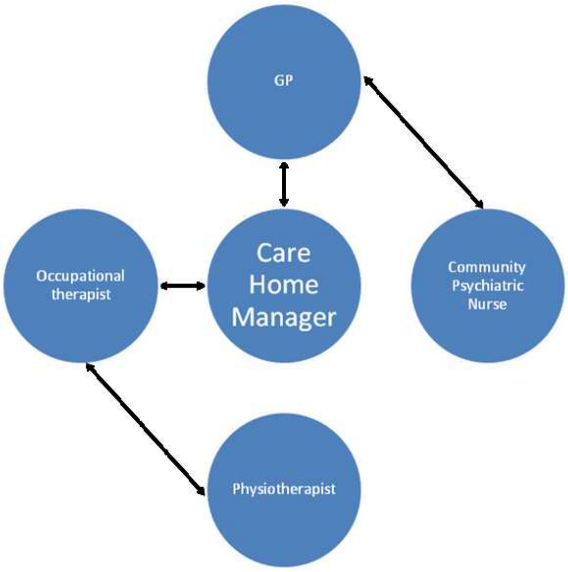

Figure 17 - Dysfunctional MDT communication as seen in some care home settings

Accepting that CGA did not take place for residents, whilst acknowledging that most respondents seemed to call for a process analogous to CGA, the next question is why it did not take place. The transcripts suggest the explanation to encompass: a lack of training and expertise in managing frail older patients, which was evident in all professional groups; the arbitrary boundaries drawn between care homes and the NHS that interfered with effective multidisciplinary care; and a failure to adequately structure GP relationships with care homes.

4.7.1. Inadequate training and expertise in the management of frail older patients

CGA could not take place because those providing care felt insufficiently knowledgeable to conduct detailed assessment of residents and put in place individualized care plans. Staff from all sectors reported struggling with complexity, multi-morbidity, cognitive impairment, functional dependency and, perhaps most tellingly, the ethical dilemmas and communication challenges that surrounded end-of-life care. GPs spoke of difficulties in applying their generic skills, for example the preventative medicine that they practice so competently for other population groups, in this cohort. They identified challenges in weighing the benefits and risks of treatments, including when to admit residents to hospital following acute deterioration. They found management of cognitive impairment, behavioural problems and prognostication in patients with dementia particularly challenging.

The minimal training required to work as a member of care home staff was a source of concern for respondents working in both the NHS and care home sectors, however it was evident from several of the transcripts that care home staff possess a body of tacit expertise in day-to-day assessment and management of health problems. They described how these skills were brought to bear to support nutrition, mobility, continence and manage cognitive deficit and behavioural disturbance. Care home staff were also clearly experts on their own residents and what represented normality for them. This meant that they were able to identify, often subtle, deviations from the norm which might herald a medical problem. Failure by NHS staff to recognize and capitalize on these bodies of expertise was arguably to the detriment of residents.

Specialist expertise was available in the community in the shape of dementia outreach nurses, district nurses, care home nurse practitioners and routine provision from community SALT, OTs, physiotherapists and dieticians. This expertise might have gone some way to addressing the identified knowledge deficiencies amongst both GPs and care home staff. These specialists, however, found it difficult to integrate themselves into existing relationships between GPs and care homes. At its worst, they found themselves unable to influence care homes, GPs or both. Integration might have been less difficult had communication taken place along the more open lines typical of a CGA MDT as described above, however, this group in particular were singled out for failure to include all relevant parties in their correspondence.

4.7.2. Arbitrary boundaries between care homes and the NHS

Both of these failures – to recognize the expertise of care home staff and to effectively capitalize on the specialist knowledge of community-based specialists – were a symptom of the larger issue of the arbitrary but widely acknowledged boundaries drawn between care homes and the NHS.

It was clear from the transcripts that care homes were a venue for care in all its forms. Care and caring, in their lay sense, were evident in the strong sense of responsibility and advocacy which care home staff spoke of feeling – and, by anecdote, of delivering – for their residents. Social care, when defined as support with activities of daily living and functional impairment, comprised a significant amount of the routine work described by staff. Healthcare – as evidenced by the detailed attention to nutrition, mobility, continence, behaviour and cognition, alongside daily vigilance for evidence of medical deterioration – was also an important part of their role. Many of the routines described in homes were focused around these health domains. Thus, for care home staff, the boundaries between caring, social care and healthcare were blurred. Healthcare staff, meanwhile, seemed more able to identify a clear boundary around their professional obligations to residents. This is perhaps unsurprising given that their contact with residents was usually indication-specific and time-limited.

Despite the fact that care home staff were an integral part of healthcare delivery, most respondents showed a readiness to draw clear distinctions between health and social (or private- and state-employed) care which at times amounted to battle-lines.

These comments generally served, however, to reveal a marked similarity in the challenges faced by staff across care sectors. All recognized that training in their sector was inadequate. All recognized significant stresses in delivering care which is of high quality, whilst also responding to cost pressures – albeit that in care homes these were around maintaining a working profit, whilst in the NHS they were around cost-reduction. All recognized the growing threat of litigation, perhaps using this as an expression of the increasing role of regulation, accountability and governance in all aspects of care.

As discussed above, failure to establish effective lines of communication between health and social care staff frustrated attempts at multidisciplinary working and contributed to failure to recognize or capitalize upon expertise already present. There is a significant body of health and social policy literature suggesting that the boundaries between health and social care, as drawn within the UK, are in many ways arbitrary[582-584]. From a political standpoint, attempts to integrate or harmonise social care, which is means-tested and locally coordinated, with healthcare, which is free at the point of delivery and nationally coordinated, have long been seen as contentious and difficult to deliver without wide-sweeping and potentially unpopular reforms to the finance of health and social care[585-587]. A detailed interrogation of these issues is beyond this thesis. It is perhaps sufficient to note that, within STICH, care was reported as being at its' most effective where NHS and care home staff had established clear lines of responsibility and communication, which allowed frank discussion of the difficult issues faced in supporting residents' health. This was the case in Edenbridge care home. To deliver this, front-line staff had to recognize the arbitrariness of the boundaries drawn between health and social care and work to mitigate them. Broader systematic reform might act a facilitator to this type of integrated working but dedication to teamwork amongst front-line staff is the necessary pre-requisite, regardless of the policy context.

4.7.3. Failure to adequately structure GP relationships with care homes

Care homes which had to engage with multiple GPs from different practices – n>1:1 relationships – found it difficult to accommodate their differing approaches to healthcare and acute medical crises. This was contrasted by the consistency of relationships described by homes with 1:1 relationships with GPs. These relationships were not always described as satisfactory. Both the staff of Kimpton Lodge and the GP who served the home described a relationship which, although consistent, was consistently dysfunctional and defined by conflict and mistrust. City-based GPs, whilst acknowledging some benefits to 1:1 working, described the significant challenges in establishing such relationships, including work and contractual arrangements with neighbouring practices and the need to account for patient choice.

Similar difficulties were identified around the issue of scheduled weekly contact. Staff at Edenbridge described this as central to effective anticipatory care and the multidisciplinary work across health and social care boundaries which defined their approach. GPs in other settings acknowledged theoretical benefits to regular visiting, particularly building closer relationships with care home staff and establishing a closer understanding of how residents' health changed week-to-week. They conducted pilots of regular visiting but reported abandoning these, not because of failure to realize the hoped-for gains in communication, teamwork and continuity, but because they failed to reduce the number of calls for GP attendances between programmed visits. This is, perhaps, typical of local initiatives in the NHS, where failure to establish sufficiently robust outcome measures at the commencement of a service result in its abandonment for reasons unrelated to the specified service objectives.

Why some GP:care home dyads were able to realize the benefits of structured relationships invoking 1:1 relationships and regular visiting, whilst others were not, is unclear. It is, however, likely that the satisfactory results seen by Edenbridge were a factor not only of their structured relationship with a GP but also broader aspects of their practice, such as their work to overcome and dispense with the arbitrary boundaries between health and social care already described above. This allowed them to make the most of their structured relationship. A structured GP-care home relationship is perhaps, therefore, necessary but not sufficient to ensure delivery of integrated, organized care.

4.7.4. Towards a synthesis….and towards CGA in care homes

Bringing these threads together, STICH suggests that in order for CGA to work in care homes the following criteria would require to be met:

- It would have take place in the care home because residents find it difficult to travel to healthcare due to their significant functional dependency and cognitive impairment.
- Staff from all disciplines necessary to conduct a comprehensive assessment of residents' health and functional status would have to work in the community and be able to travel to care homes. For the most part these team members were described as already being in place.

- Staff from all disciplines would have to be appropriately trained in the assessment and management of frail older patients in order to participate. For specialists based in the community – such as care home nurse practitioners, dementia outreach teams, dieticians, physiotherapists and occupational therapists – this expertise was reported already to be in place. For care home staff and general practitioners, deficiencies were reported. The possible responses to this are manifold. Taking the issue of GPs, for example, additional training in the management of older patients could be provided. Alternatively specialist geriatricians could replace GPs in some or all aspects of care home support. A third possibility would be more robust provision of specialist advice from geriatricians and old age psychiatrists for GPs.

- Staff from all disciplines would have to function like a geriatric medicine MDT, with open and transparent communication to which all team members were party. Within this context, a nominated care coordinator or key worker, whether doctor, nurse or member of care home staff, would have to be recognized.

- To facilitate the above, clear roles and lines of responsibility within the MDT would require to be identified. These would have to be aligned with patient care requirements rather than arbitrary distinctions between health and social care which, although widely recognized, seem to have little resonance with the needs of residents.

- If such a team were to function effectively and if GPs were to remain central to management of care home residents, then structured relationships between GPs and care homes would be required. 1:1 relationships and regular visiting seem logical and were reported to provide consistency of care where they were part of a broader programme of multidisciplinary working. Whilst such arrangements were not always reported as meeting with success, a positive impact would seem more likely if the other measures outlined above were in place.

4.8. Conclusion

Numerous frustrations with the existing model of healthcare delivery for care homes were identified. Some of these are unlikely to change. Residents will inevitably be frail, dependent and approaching the end of their life. They will continue to have to change GP at the time of admission to care home. They will frequently arrive at care homes following a deterioration in chronic conditions or an acute medical crisis.

CGA seems a reasonable response to these challenges and maps closely to the sort of multidisciplinary care models, driven by assessment and appropriate expertise, highlighted by many respondents as a solution to the daily challenges of delivering care in care homes.

CGA is not currently being delivered. The staff required to deliver it are, for the most part, already in place but they are prevented from acting to deliver coordinated multidisciplinary care by a combination of: lack of training and expertise; arbitrary boundaries drawn between health and social care, which hamper communication and have little relevance to the lived reality of residents; and inadequate organizational structures around which MDTs can coalesce.

Chapter 5 – Conclusion

In conclusion, there *is* a role for Comprehensive Geriatric Assessment in UK care homes.

Chapter 1 presented care homes as integral to long-term care of older people in the UK. It suggested that care homes would be part of the care landscape for the foreseeable future. Demographics are such that the sector is likely, in fact, to grow. It highlighted that care homes have evolved significantly over the last 25 years, with a trend towards increasing dependency amongst residents (an assertion which was subsequently borne out by the findings of CHOS and STICH in chapters 3 and 4). Healthcare support to care homes has been slower to evolve. The default model of healthcare delivery – the GMS contract – is the same for care home residents as it is for community dwelling patients. This has been shown to result in failures of quality and safety in healthcare, and inequalities in healthcare access to the disadvantage of residents. Quality Outcomes Framework targets, meanwhile, have been shown to be either not achieved, or not achievable.

CGA is a model of healthcare delivery which involves comprehensive and detailed assessment of all aspects of a frail older patient's health and subsequent implementation of an individualised management plan, with regular review and follow-up. It is defined by multidisciplinarity and regular meetings of the MDT, where each part of the team is kept abridged as to what is happening elsewhere in the patient's care. It has a strong evidence-base in a number of settings, including acute hospital inpatients, day hospital and early supportive discharge in a community hospital setting.

It was suggested, based upon the available evidence, that the cohort in care homes had much in common with the cohorts from other settings where CGA had been shown to improve care, in so much as they were old and frail. There was reason to believe, therefore, that CGA might have a role in improving care for residents. Indeed CGA had been shown to work in the long-term care sector in other countries but the significant international differences in how long-term care was provided were such that these interventions could not be assumed to have a role within the UK.

Three discrete but overlapping pieces of research were proposed to address the question of whether CGA had a role in the UK care home sector:

- The Care Home Literature review (CHoLiR) would describe the research conducted using RCTs in care homes to establish whether an evidence base for CGA – or component interventions which might comprise part of CGA – had already been built.
- The Care Home Outcome Study (CHOS) would comprehensively describe the health and functional status of care home residents, and how they use NHS resources.
- The Staff Interviews in Care Homes (STICH) would describe how care home staff and the healthcare professionals who work with them identify and respond to changes in residents' health.

CHoLiR was presented in Chapter 2. It started from the premise that, in order to review the evidence-base for CGA in care homes, it would be necessary not only to search for studies focussing on CGA, but also studies of sub-components of CGA which, when combined, might build some of the case for the intervention. It focussed on RCTs on the basis that these are perceived as the gold-standard evaluative methodology in medical research. CHoLiR demonstrated that much research work had been undertaken in care homes, that most of it had taken place outside of the UK but that a significant proportion of the findings were applicable here. It showed an acceleration of the rate of care home publications over the last 10 years. It found 10 studies which evaluated CGA or case management as a whole intervention, however these were either too narrow in their remit – focussing on predominantly psychogeriatric interventions – to shed light on the broader question of whether CGA had a role, or had significant methodological shortcomings, a recurrent theme being the failure to account for clustering in the population. There was, however, evidence for a number of component interventions which might comprise a part of CGA: advanced care planning; pharmacy interventions to reduce prescribing; staff education around prescribing, dementia and end-of-life care; calcium and vitamin D in preventing fractures; alendronate in preventing osteoporosis; influenza vaccination; oseltamivir or zanamivir for influenza prophylaxis; functional incidental training and bladder training for incontinence; and risperidone and olanzapine for agitated behaviours in carefully selected patients under expert guidance. Only hip protectors had been conclusively shown not to work. For all other interventions, the literature was inconclusive. The breadth of interventions evaluated and the relatively broad spectrum of targets suggested a need for broad-ranging expertise transecting a number of disciplines, making a case for multidisciplinarity in the healthcare response to care homes.

One of the outstanding questions at the end of Chapter 2, was the extent to which the gaps identified in the care home literature could be filled by evidence from other settings. Considering the data from CHOS, it is clear that there are many similarities between the frail older patients seen in care homes and those seen elsewhere. This was seen, for example, in comparison with the historical cohort studied by Hubbard *et al*[514] from NHS long-term care. Clearly, if RCT-evaluations previously conducted in these long-term care patients had shown positive outcomes, there would be a case for considering them in care homes. This line of argument is much more logical for interventions at the individual resident level, such as drug-based and some rehabilitative interventions, than it would be for home-level interventions, such as changes to institutional routines to, for example, promote feeding or reduce restraint. The answer seems to be that, if there were demonstrable similarities between the sample in an individually-randomized RCT and the cohort described in CHOS, then there might be a case for extrapolating findings to care home residents. Deciding which research findings to extrapolate, and in which patients, would be likely to require skill and knowledge both of the care home cohort in general and the home and patient under consideration in particular.

CHOS was presented in Chapter 3. Existing cohort studies and surveys conducted in care homes had described a cohort of patients that was disabled, cognitively impaired and near the end-of-their lives, with prevalent syndromes and diagnoses matching the profile of other cohorts where CGA had been shown to be effective. Residents were thought to access NHS resources differently to patients who lived in their own homes. Detail was lacking, however, and some of the data was out of date. There were issues with the accuracy with which medical diagnoses had been recorded and some issues around response bias in existing studies. By conducting a detailed longitudinal cohort study, which took data from health and social care records, as well as directly from residents and care home staff, CHOS addressed the issues of accuracy, response bias and contemporaneity in the existing literature, as well as providing data on diagnoses, dependency, prescribing and resource use at a level of detail not previously seen for care homes. It described a cohort with significant physical dependency, with care needs driven by immobility, incontinence, cognitive impairment and behavioural disturbance. It demonstrated a high prevalence of malnutrition, or risk of malnutrition. It described residents’ medical problems as being dominated by chronic illnesses and end-of-life considerations. It identified significant issues with polypharmacy and under-diagnosis of dementia which suggested that current care models were not meeting residents’ needs. In presenting these findings it demonstrated a need for input from specialist nurses, mental health services, palliative care services, occupational therapists, physiotherapists, dieticians and general practitioners. The extent to which geriatrician involvement was mandated by the findings was not clear. Obviously, general practitioners are experts in the management of chronic diseases and might not require much support in this respect. However, the high prevalence of multimorbidity and of syndromes in which geriatricians have specialist expertise, the under-diagnosis of dementia and the dominance of end-of-life issues – which are notoriously complex in frail elders – all suggested a possible role for geriatricians.

An additional important finding from CHOS was the significant variability seen between residents within homes, and between homes. Dependency, cognition, behaviour, multimorbidity, prescribing, death rate, proximity to death and NHS resource use all demonstrated both wide variability and significant clustering. In this context, the level of input from each of the specialists already described would be expected to vary significantly from individual to individual and, more importantly, home to home. The only logical response to this – if redundancy of staff and resources was to be avoided – would be to ensure that management planning and allocation of resources was preceded by comprehensive and detailed assessment of individuals and homes.

Given that many of the resources required to fulfil the needs identified in Chapter 3 – specialist nurses, occupational therapists, physiotherapists, dieticians, end-of-life-care teams, mental health teams, and general practitioner – were already in place in the community, it was possible that CGA was already taking place intuitively under the auspices of the GMS contract. STICH, summarised in Chapter 4, set out to explore the existing healthcare arrangements in place for care homes. It did not describe that CGA was already in place. Instead it described a situation defined by discontinuity and lack-of-anticipation. These were driven by failures of communication, inadequate training and expertise in the management of frail older patients, arbitrary boundaries drawn between care homes and the NHS which acted as barriers to care and did not stand up to close scrutiny, and failure to adequately structure GP relationships with care homes. Importantly, it described that much day-to-day healthcare was provided by care home staff and identified a body of tacit expertise amongst the care home workforce which, if harnessed, could help to optimise the management of residents' health. Respondents to STICH defined the idealised model of healthcare as being one which was multidisciplinary, defined by expertise in care of the elderly and sufficiently resourced to assess residents in detail and plan for their future based upon these assessments.

Thus there is evidence that the ideal model of healthcare for care home residents would be one which:

- Takes place in the care home.
- Recognises and keeps up-to-date with the growing body of care home-specific literature.

- Has the skills and knowledge to implement the findings from the emerging care home evidence-base and to interpret when evidence from other settings can be applied in the care home sector.

- Has the specialist expertise required to meet the care needs identified in CHOS and reported by the respondents to STICH. This would mandate input from physiotherapists, occupational therapists, nurses, dieticians, mental health and end-of-life care teams, general practitioners and geriatricians. Although all of these specialties currently work in the community, it was clear from STICH that many felt inadequately trained in management of frail older patients. This was particularly the case for general practitioners.

- Recognises the variability between homes, and between residents. In this context, efficient use of resources would demand that the care plans implemented, and expertise harnessed in order to deliver them, would vary from case to case. The only logical response to this would be to use detailed assessment to shape management plans.

- Draws staff together as an MDT in order to counter the deficiencies in communication seen in STICH. Within this context, a nominated care coordinator or key worker, whether doctor, nurse or member of care home staff, would have to be recognized.

- Dispenses with arbitrary boundaries drawn between health and social care and structures working relationships, instead, around patients’ needs. This would allow for the expertise of care home staff to be recognised and for open MDT communication to be conducted.

- Puts structures in place that reinforce effective working-relationships between GPs, the rest of the primary care team, and the care home. Based upon the findings from CHOS and STICH it seems reasonable to suggest the following structures would be necessary, if not sufficient, to support best care: comprehensive baseline assessment of residents at the point of admission; 1:1 GP:care home relationships; regular contact between GPs and care home staff (and residents); and open channels of communication, with sharing of records between GPs, care homes and acute healthcare providers.

Taken in summation, these points describe a model of individualised, assessment-driven, multi-disciplinary healthcare supported by appropriate expertise – Comprehensive Geriatric Assessment.

Accepting that CGA has a role, the next question becomes how it should be delivered. Healthcare to care homes in the UK underwent further evolution during the writing of this thesis. Whilst GMS-driven healthcare remains the norm, the types and number of innovative interventions developed by the NHS have continued to grow. Because of the regional nature of NHS commissioning and provision – and the paucity of a clear evidence-base to drive healthcare provision in care homes – they have shown significant regional variability. They include but are not limited to: care home nurse practitioners, care home rapid-response teams, care home outreach teams, care home practices, locally enhanced service contracts and partnership-initiatives between health and social care driven through the My Home Life project[554]. Most, if not all, of these have aspects of the ideal service specified above – and therefore features of CGA. Because they all differ significantly in their commissioning, funding and staffing arrangements, not to mention their day-to-day delivery, it is likely that they will have variable effects on measurable clinical outcomes, and differing cost-benefit ratios.

It would be wrong to assert, given the array of models already in place which partially or fully embrace the principles of CGA, that the next step is an RCT of CGA in care homes. It would be impossible to know which of the existing models in place should be trialled, or whether an entirely new model should be developed, without first undertaking further descriptive work to define the strengths and weaknesses of the systems already implemented. The need to understand a complex intervention with absolute clarity before subjecting it to RCT, intrinsic to the MRC framework[62], is particularly acute in care homes, given the assorted challenges of conducting RCTs and of measuring resident and home-level outcomes in this setting discussed in Chapters 2 and 3. Indeed, in reflecting on the MRC framework, Campbell *et al*[46] suggested that phases zero, one and two be considered as a single iterative process (Figure 18). Further iteration is required.

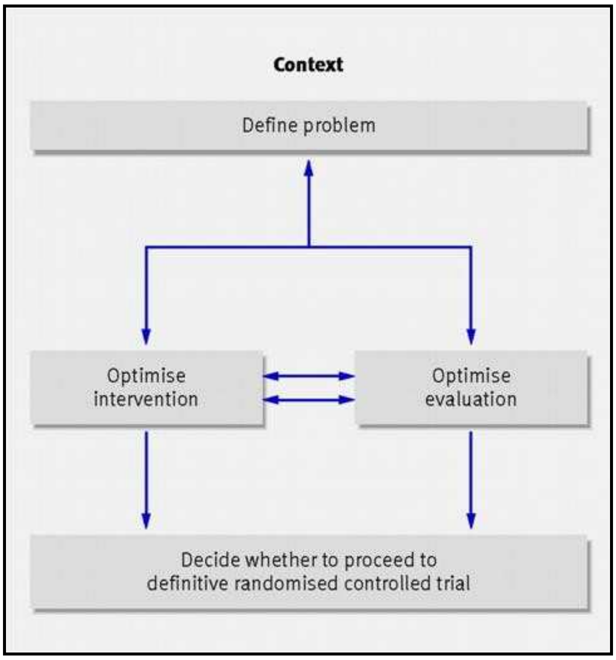

Figure 18 - The early stages of the MRC framework for design and evaluation of complex intervention, from Campbell *et al*[46]

A logical approach would be to consider the service models already in place and the extent to which they reflect the idealised service defined above. It is likely that, by studying them, the specification of an idealised service could be further developed. Such research would be likely to be mixed-methods and would draw heavily on qualitative paradigms. In defining services and how they impact residents, systems-oriented methodologies would be appropriate, an example being the CATWOE framework, derived from the soft-systems approach described by Checkland and Scholes[588]. This would describe, for each model of care: the **C**ustomers (in this case the residents and their families); **A**ctors (health and social care staff); **T**ransformations (perceived changes in health or wellbeing as a consequence of healthcare interventions); **W**orld-view (the prevalent perceptions and philosophies in the health, social care and resident communities regarding healthcare delivery); **O**wners (in this case health and social care commissioners); and **E**nvironment in which the model of healthcare operates. The data collected under each of these headings would be used to generate a root-definition of each of the service-models studied. The next steps would depend upon the observations made. If care home healthcare interventions were to continue to develop at the rate recently witnessed, it might be that care-home specific models would, in a few years, become the norm. If this were the case, then the evidence-based assertion, stated here, that CGA has a role in care homes, coupled with root definitions of the services which most effectively deliver CGA, might be sufficient to ensure that it sits at the core of healthcare to care homes going forward. If specific evaluation of CGA were required to prove its effectiveness, then the dilemma would be between a naturalistic evaluative methodology, such as realistic evaluation – which draws together qualitative and quantitative data to compare interventions accepting that some questions are beyond the reach of probability theory[589] – and randomized controlled trial. The challenge of such an RCT would be to ensure that it was adequately powered, allowing for clustering and accounting for all possible sources of confounding, that it was adequately blinded, that the intervention was delivered with sufficient uniformity and that it used outcome measures unlikely to be confounded by the dependency, cognitive impairment and multimorbidity of the cohort. Such a trial would, if successful, be large, technically demanding and operate at the skill limits of even the most accomplished triallists.

There is a role for CGA in UK care homes. Based upon the available evidence it is not currently being delivered. Or rather, whilst pockets of CGA might exist, its delivery is not the norm. Many of the resources and much of the expertise that would facilitate its delivery are already in place. The ideal service, as specified here, could perhaps be seen as a checklist against which aspiring healthcare providers could evaluate existing, or proposed, models of care. Given the variability of care homes and care home residents, it may be that CGA can be accomplished by a number of different systems. It is likely that some, if not all of the new, innovative models of healthcare developed by the NHS for the care home sector contain components of CGA. Some may contain all of the components of the idealised service. Further research is required to work out which of these best fulfils the goal of optimising outcomes for care home residents and address issues around cost-benefit. Given the challenges to RCT methodology in this setting, it would be wrong to conduct one evaluating CGA In this care homes before further, significant work is undertaken to describe the existing models of care.

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Appendix 1 – Glossary of abbreviations

AARS=Apparent Affect Rating Scale

ABID=Agitated Behaviours in Dementia

ABRS=Agitated behaviour rating Scale

ADAS=Alzheimer's Disease Assessment Scale

ADCS-ADL= Alzheimer’s Disease Cooperative Study Activities of Daily Living Scale

ADCS-ADL-SEV=Alzheimer’s Disease Cooperative Study Activities of Daily Living Scale-Severe

ADL=Activities of Daily Living

AES=Apathy Evaluation Scale

AFBS=Aversive Feeding Behaviour Scale

AGECAT=Automated Geriatric Examination for Computer Assisted Taxonomy

AICT=Advanced Illness Care Teams

AIMS=Abnormal Involuntary Movements Scale

AMED= Allied and Complimentary Medicine Database

AMS=Alzheimer’s Mood Scale

AMT=Abbreviated Mental Test

BAGS=Behavioural Assessment Graphical System

BASDEC=Brief Assessment Schedule Depression Cards

BARS=Brief Agitation Rating Scale

BBS=Berg Balance Scale

BEHAVE-AD=Behavioural Pathology in Alzheimer's Disease Rating Scale

BGS=British Geriatrics Society

BI=Barthel Index

BIP=Behavioural Observation Scale for Intramural Psychogeriatrics

BMD=Bone Mineral Density

BMI=Body Mass Index

BNI=British Nursing Index

BPRS=Brief Psychiatric Rating Scale

BPSD=Behavioural and Psychological Symptoms of Dementia

BRS=Behaviour Rating Scale for Dementia

BSAP=Bone Specific Alkaline Phosphatase

BSI=Behavioural Status Index

BUN=Blood Urea Nitrate

CAM=Confusion Assessment Method

CAMCOG=Cambridge Cognitive Examination

CANE=Camberwell Assessment of Need in the Elderly

CAREBA=Care Recipient Behaviour Assessment

CAS=Clinical Anxiety Scale

CAS-COG=Communication Assessment Scale for the Cognitively Impaired

CDR-SB=Clinical Dementia Rating Scale-Sum of Boxes

CDS=Care Dependency Scale

CFSEI=Culture-free Self-esteem Inventory

CFU=Colony Forming Units

CGA=Comprehensive Geriatric Assessment

CGI=Clinical Global Impression Scale

CGI-2=Clinical Global Impression Scale – item 2

CGI-C=Clinical Global Impression for Change

CGI-S=Clinical Global Impression for Severity

CHoLiR=Care Home Literature Review

CHOS=Care Home Outcome Study

CHS-M=Modified Caregiving Hassles Scale

CHUMS=Care Home Use of Medications Study

CI=Charlson Index

CIRS-G=Cumulative Illness Rating Scale-Geriatrics

CINAHL=Cumulative Index to Nursing and Allied Health Literature

CMAI=Cohen-Mansfield Agitation Inventory

CMS=US Centres for Medicare and Medicaid Services

CONSORT=Consolidated Standard of Supporting Trials

COS=Communication Observation Scale for the Cognitively Impaired

COVS=Clinical Outcomes Variables Scale

CQC=Care Quality Commission

CRBRS=Crichton Royal Behavioural Rating Scale

CRP=C-Reactive Protein

CSDD=Cornell Scale for Depression in Dementia

CST=Cognitive Screening Test

DBS=Disruptive Behaviour Scale

DMAS=Dementia Mood Assessment Scale

DMSS=Dementia Management Strategies Scale

DS-DAT=Discomfort Scale for Dementia of the Alzheimer’s type

DSST=Digit Span Substitution Test

EBAS-DEP=Even Briefer Assessment Scale for Depression

EMG=Electromyography

EPPI= Institute of Education’s Evidence for Policy and Practice Information and Co-ordinating Centre

EQ-5D=EuroQoL 5 Dimension Quality of Life Scale

ESBL=Extended-spectrum beta-lactamase producing bacteria

EXIT=Executive Interview

FAM=Functional Assessment Measures

FES=Falls Efficacy Scale

FICSIT 4= Frailty and Injuries: Cooperative Studies of Intervention Techniques Scale 4

FIM=Functional Independence Measure

GDS=Geriatric Depression Scale

GHQ-12= General Health Questionnaire-12 point version

GHQ-28=General Health Questionnaire-28 point version

GIPB=Geriatric Indices of Positive Behaviour

GMS=General Medical Services Contract

GP=General Practitioner

GPM-M=Modified Geriatric Pain Measure

HADS=Hospital Anxiety and Depression Scale

HAM-D=Hamilton Rating Scale for Depression

HDL=High Density Lipoprotein

HIV=Human Immunodeficiency Virus

HRQoL=Health Related Quality of Life

HUI=Health Utility Index

ICD-10=10th version of the WHO International Classification of Diseases

ICED=Index of Co-existent Disease

ICF=WHO International Classification of Functioning, Disability and Health

IL-6=Interleukin-6

LDL=Low Density Lipoprotein

LEIPAD=Leiden-Padua Quality of Life in the Elderly Questionnaire

LSES=Salamon-Conte Life Satisfaction in the Elderly Scale

LSI=Life Satisfaction Index

LSI-A=Life Satisfaction Index-Form A

LRTI=Lower Respiratory Tract Infection

MADRS= Montgomery-Asperg Dementia Rating Scale

MBI-D=Maslach Burnout Inventory

MDS=Minimum Dataset

MDS-COGS=Minimum Dataset Cognition Scale

MDT=Multidisciplinary Team

MeSH=Medical Subject Headings for Medline

MHAQ=Modified Health Assessment Questionnaire

MHQ=Multidimensional Health Questionnaire

MHRA=UK Medicines and Healthcare Products Regulatory Agency

MOSES=Multidimensional Observation Scale for Elderly Subjects

MNA=Mini-Nutritional Assessment

M-NCAS=Modified Nursing Care Assessment Scale

MPB=Management of Problem Behaviours

MRC=UK Medical Research Council

MRSA=Methicillin-resistant Staphylococcus Aureus

MSQ=Mental Status Questionnaire

MUNAI= Memorial University of Newfoundland Activities Inventory

MUNSH= Memorial University of Newfoundland Scale of Happiness

NHS=National Health Service

NICE=UK National Institute of Health and Clinical Excellence

NHP=Nottingham Health Profile

NOSIE=Nurses' Observation Scale for Inpatient Evaluation

NP=Nurse Practitioner

NPI=Neuropsychiatric inventory

NPI-NH=Neuropsychiatric Inventory-Nursing Home version

NSAID=Non-steroidal Anti-inflammatory Drug

NTX=N-telopeptide

OAS=Observed Affect Scale

ODAS=Observable Displays of Affect Scale

PEFR=Peak Expiratory Flow Rate

PCS=Perceived Competence Scale

PGCARS=Philadelphia Geriatric Centre Affect Rating Scale

PGCMS=Philadelphia Geriatric Centre Morale Scale

PGDRS=Psychogeriatric Dependency Rating Scale

POMS=Profiles of Mood States

POTTI=Performance-based Assessment of Toileting skills

PPT=Physical Performance Test

PRISMA=Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PRN=Pro Re Nata (as required medication)

PSMS=Physical Self-maintenance Scale

PTH=Parathyroid Hormone

QL-I=Quality of Life Index

QoL=Quality of Life

QoL-AD=Quality of Life in Alzheimer’s Disease Scale

QWS=Quality of Wellbeing Scale

QOF=NHS Quality Outcomes Framework for GPs

PAINAD= Pain in Advanced Dementia

PCT=Primary Care Trust

PDI=Physical Disabilities Index

PGC=Philadelphia Geriatric Centre Morale Scale

RAFS-II=Risk Assessment for Falls Scale II

RCT=Randomized Controlled Trial

RMBPC=Revised Memory and Behaviour Problems Checklist

RMDQ=Roland Morris Disability Questionnaire

RTI=Respiratory Tract Infection

SADQ=Stroke Aphasic Depression Questionnaire

SALSA=Search, Appraisal, Synthesis and Analysis Framework

SAPS=Scale for the Assessment of Positive Symptoms

SCAG=Sandoz Clinical Assessment-Geriatric

SCES=Sheltered Care Environment Scale

SF-12=Short Form-12 Question Version

SF-36=Short Form-36 Question Version

SF-MPQ=Short Form-MCGIll Pain Questionnaire

SHBG=Sex-hormone Binding Globulin

SIB=Severe Impairment Battery

SIP=Sickness Impact Profile

SIP-NH=Sickness Impact Profile for Nursing Homes

SIL-2R=Soluble Interleukin-2 Receptor

SIPO=Social Interaction Scale for Psychogeriatric Older People

SKT=Syndrom Kurz Test

SSCQ=Short Sense of Competence Questionnaire Competence Questionnaire

SSRI=Selective Serotonin Reuptake Inhibitor

STI=Serial Test Intervention

STICH=Staff Interviews in Care Homes

TDF=Thiamine Diphosphate

TNFR =Tumour Necrosis Factor Receptor

TUG=Timed Up and Go

UPDRS=Unified Parkinson’s Disease Rating Scale

URTI=Upper Respiratory Tract Infection

UVB=Ultraviolet B spectrum

VF-14=Visual Function Index-14 point version

VRE=Vancomycin Resistant Enterococci

WAIS=Wechsler Adult Intelligence Scale

WHO=World Health Organisation

Appendix 1 – Glossary of Abbreviations

WHO-DAS=World Health Organisation-Disability Assessment Scale

WHOQoL-BREF=World Health Organisation Quality of Life Scale, Brief Version

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Interventions targeting behaviour

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures (for glossary of abbreviations see end of document)	Findings
Pharmacological					
Acetaminophen[160]	25	Placebo	25	Behaviour and emotional well-being recorded using dementia care-mapping; CMAI; psychotropic medication administration	Intervention subjects had better social interaction, media engagement, work-like activity engagement and social interaction but more unattended distress and talked to themselves more.
Alprazolam[102]	48	Low-dose haloperidol	48	Number of behavioural episodes; Blessed dementia scale; Abnormal involuntary movements scale; CGI; SCAG	No effect.
Aripiprazole[109]	131	Placebo	125	NPI-NH; BPRS; CGI; CMAI; CSDD; ADCS-ADL-SEV	Improvements in NPI-NH total, BPRS total; CGI and CSDD total with intervention; no difference in adverse effects between arms.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Carbamazepine[112]	27	Placebo	24	BPRS; CGI; Overt aggression scale; BRS; MMSE; PSMS; comorbidity	Decreased agitation and aggression but no effect on cognitive or functional status.
Divalproex sodium[111]	75	Placebo	78	BPRS; CGI-C; CMAI; safety; tolerability	No effect
Donepezil[154]	103	Placebo	105	NPI-NH; CDR-SB; MMSE; PSMS; adverse effects.	Improvement in CDR-SB and MMSE but no effect on NPI-NH in intervention arm.
Haloperidol[104]	20	Oxazepam/ Diphenhydramine	19/20	BPRS; ADAS; PSMS; NOSIE	Less agitated behaviour and improved functional status in all three arms with no difference between arms; similar levels of adverse events.
Melatonin[131]	24	Placebo	17	Actigraphy; CMAI; ABRS	No effect.
Olanzapine 5mg per day/olanzapine 10mg per day/olanzapine 15mg per day[103]	42/41/38	Placebo	32	NPI-NH; BPRS; MMSE; Extra-pyramidal symptoms; Simpson-Angus Scale; AIMS; Barnes Akathisia Scale	Hallucinations less common with increasing dose, no significant difference between groups for delirium.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Olanzapine 5mg per day/olanzapine 10mg per day/olanzapine 15mg per day[108]	56/50/53	Placebo	149	NPI-NH; BPRS; Occupational Disruptiveness Scale; MMSE; Simpson-Angus Scale; Barnes Akathisia Scale; AIMS	Occupational disruptiveness and NPI-NH significantly lower in olanzapine group. Olanzapine group drowsier.
Propranolol[168]	17	Placebo	14	NPI; CGI-C	Improvement in NPI and CGI-C scores for propranolol arm.
Risperidone[106]	20	Usual care	14	Observed wandering behaviour and sleep pattern; BEHAVE-AD	Less daytime sleep, more night-time sleep and less wandering in the intervention arm.
Risperidone[101]	46	Placebo	45	BEHAVE-AD; CGI-C; CGI-S	Risperidone reduced psychosis and improved global functioning - only significant side-effect was somnolence.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Risperidone[110]	60	Haloperidol	60	BEHAVE-AD; CMAI (Korean Versions)	Risperidone better for wandering, agitation, diurnal rhythm disturbances, anxiety regarding upcoming events, physical sexual advances, intentional falling, hoarding things, performing repetitious mannerisms.
Risperidone[105]	143	Placebo	136	M-NCAS; CMAI	Significant early and sustained reduction in nursing staff burden measured by M-NCAS in risperidone arm.
Risperidone[100]	167	Placebo	170	CMAI; BEHAVE-AD; CGI-S; CGI-C	Significant improvement in CMAI; BEHAVE-AD; CGI but significantly higher serious adverse events, extra-pyramidal symptoms and gait disorder in intervention arm.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Risperidone[107]	235	Placebo	238	BEHAVE-AD; CGI	Somnolence more common with risperidone; significant improvement in CGI-C subscale for patients with severe dementia but not for cohort as a whole; otherwise no change.
Withdrawal of antipsychotic medication[172]	15	Usual care	15	NPI; Actigraphy	Decreased average sleep efficacy; no significant change in NPI with cessation.
Withdrawal of antipsychotic medication[171]	27	Usual care	28	Successful withdrawal of medication; NPI	No change following withdrawal of medication.
Physical therapy					
Group exercise programme[193]	67	Usual care	67	Katz ADL Score; 6 meter walk; TUG; one leg balance; MNA; NPI; MADRS	Improved six-meter walk speed; slower decline in ADLs - otherwise no effect.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Morning bright light/afternoon bright light[221]	29/24	Usual care	17	NPI-NH	Agitation and aggression increased, as did aberrant behaviour for both treatment groups; depression decreased in morning light group and increased in afternoon bright light group.
Morning bright light[225]	15	Morning Dim Red Light	15	Sleep log; BEHAVE-AD; CSDD	Improved sleep at night but no change in agitated behaviours.
Morning bright light[222]	30	Evening Bright Light/Morning Dim Red Light	31/31	CMAI; ABRS	Delayed acrophase of agitation, otherwise no effect.
Occupational therapy, aids and appliances					
Activity programme, guidelines for psychotropic prescribing and educational rounds[262]	42	Usual care	39	Behaviour disorder present/absent; CMAI; PGDRS; antipsychotic and restraint use; MMSE; patient activity level; cost of care	Intervention patients were less likely to be prescribed neuroleptics, demonstrate behavioural disorder, or be restrained during activities and were more likely to participate in activities at follow-up.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

ADL intervention/psychosocial intervention/combination[274]	28/29/22	Placebo visit	29	DBS; MMSE; ODAS; AARS; Positive and Negative visual analogue scales	No effect.
Backward chaining protocol for orientation[387]	17	Usual care	15	Pittsburgh Agitation Scale; Spatial orientation subscale of the abilities assessment instrument.	Improved ability to find room one week after the intervention but no persistent improvement. Agitation got worse in the intervention group.
A canary/a plant[248]	48/43	Usual care	53	MMSE; LEIPAD-short version; BSI	Significant improvement in BSI and LEIPAD-SV in animal group.
Live music/recorded music[264]	32/32	Silent periods	32	Dementia care mapping of muted video recordings by blinded observer	Significant and positive improvement in response to live music, not seen in recorded music or silence arms
Music therapy[260]	20	Usual care	18	BEHAVE-AD	Mild reduction in activity disturbance with effect disappearing at one month.
Music with movement therapy[261]	18	Usual care	18	CMAI	CMAI better in intervention arm.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Staff education					
Education package delivered to staff on goal planning for BPSD[279]	54	Usual care	51	AGECAT; CRBRS; BI	Improved scores for depression and cognitive impairment but not behaviour rating or BI.
Family visit education programme[286]	32	Usual care	34	MOSES; CSDD; CMAI; GIPB; MPB; psychotropic medication and restraint use; DMSS; CHS-M; visit satisfaction questionnaire	Decreased problem behaviours; decreased symptoms of depression and irritability in intervention arm.
Staff training in non-verbal emotion signals in dementia[280]	41	Staff training in the cognitive and behavioural aspects of dementia/no training	23/27	BEHAVE-AD; CMAI; CDS; BSI; facial expressions of emotion during a brief interview	Facial expressions of emotion became more positive in intervention group - otherwise no treatment effect.
Nursing assistant communication skills programme[288]	49	Usual care	56	Knowledge of Alzheimer's test; Penn State MHQ in Nursing Assistants; Prevalence of BPSD; CSDD; CMAI; MOSES; psychotropic medication use in residents	No impact on knowledge of dementia in staff; reduction in behavioural disturbance and aggressive behaviour in intervention residents.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Psychological or Behavioural therapy					
Integrated emotion-oriented care[328]	67	Usual care	79	Assessment scale for elderly patients; CSDD; CMAI; Geriatric Resident Goal Scale; Philadelphia Geriatric Centre Morale Scale	Residents in intervention arm less anxious about maintaining an emotional balance and preserving a positive self image.
Psychomotor activation programme[263]	45	Usual care	47	BI; CST-14; CST-20; BIP; SIPO	Improvement in cognition and better group behaviour.
Sheltered workshop/reality orientation[334]	8/7	Usual care	8	LSI-A; NOSIE; Behaviour Mapping Index	Improvement in LSI-A for sheltered workshop.
Staff training on dementia management[293]	Not clear	Usual care	Not clear	GDS; CAS; RMBPC; ABID; NPI; SSCQ	Improvement in all measures at 8 week follow-up.
Nursing					
Towel bath[386]	25	Person-centred showering/usual care	24/24	CAREBA; Health skin condition data form; CIRS-G; CMAI; MMSE; MDS-COGS	Positive effect on agitation and aggression from intervention.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Case management/CGA					
Comprehensive psychogeriatric assessment[373]	48	Delayed intervention arm	51	CMAI; MMSE; BAGS	Modest but significant decrease in agitation with intervention.
Individual assessment and individualized non-pharmacological behaviour management[330]	89	Education package delivered to staff	78	Agitation behaviour mapping instrument; Lawton's modified behaviour stream	Decrease in agitation and increase in interest and pleasure sub-domains in intervention arm.
Individual case management, with stimulation or retreat determined[329]	49	Usual care	48	BEHAVE-AD; CMAI; MOSES; Mattis Dementia Rating Scale; Global Deterioration Scale	Marginal effect - lesser decline in positive affect and increased external engagement in intervention arm.
Psychogeriatric Case Management[376]	19	Psychogeriatric consultation/ usual care	17/16	EBAS-DEP; HAM-D; CSDD; GDS; NPI; BEHAVE-AD; SAPS; Clinical interview	No difference between groups.
Aromatherapy					
Lavender aromatherapy[388]	70	Sunflower aromatherapy (inactive aroma)	70	CMAI; NPI (Chinese versions)	Improvement in both measures in the intervention arm.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Interventions targeting prescribing

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Benzodiazepines weaned to placebo[174]	20	Usual care	17	Benzodiazepine withdrawal symptom questionnaire; Groningen sleep quality scale; the Geriatrics Behaviour Observation Scale	Some aspects of behaviour observation scale improved with withdrawal. Withdrawal was possible.
Medication review by pharmacist[176]	158	Usual care	172	MMSE; GDS; BASDEC; CRBRS	Pharmacist reduced number of drugs in the intervention arm but there was greater cognitive deterioration and behavioural disturbance in intervention arm.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Medication review by pharmacist[179]	331	Usual care	330	Number of changes in medication per participant; number and cost of repeat medicines per participant; medication review rate; mortality; falls; hospital admissions; GP consultations; BI; MMSE	Significant number of drug changes (3.1 per patient) in intervention group, leading to significant reduction in falls. No significant change in any other outcome measure.
Medication review by pharmacist and cardiologist[178]	43	Usual care	37	Changes of drug therapy; global scores computed from symptom scales (21-item symptom list questionnaire; Health Index questionnaire; ADL questionnaire)	No effect.
Neuroleptic withdrawal[169]	22	Usual care	14	Physical aggressiveness; verbal aggressiveness; wandering	98% of the patients completed withdrawal regimen; physical and verbal aggressiveness the same between groups.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Once daily IM cefipime[122]	32	Once daily IM ceftriaxone	29	Clinical success: cure or improvement; cost; serum levels of antibiotic; adverse events	No difference in effectiveness; Cefepime considerably cheaper.
Pharmacist medication review and nurse education[177]	905	Usual care	2325	Continuous drug use data; cross-sectional drug use data; deaths and morbidity indices (hospitalization rates, adverse events and disability indices)	Decreased medication use in intervention arm with associated cost savings without adverse effect on morbidity or mortality.
Pharmacist outreach visit to prescribing physicians[182]	381	Usual care	334	3 month fall rate; 12 month fall rate; antipsychotic prescription; aspirin and warfarin prescription	No effect

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Pharmacy discharge co-ordinator[184]	56	Usual care	54	Medication Appropriateness Index; emergency department visits; hospital readmissions; adverse drug events; falls; worsening mobility; worsening behaviours; increased confusion and worsening pain	Less worsening of pain, fewer hospital admissions, less deterioration in medications appropriateness index and fewer new drugs commenced in intervention arm.
Protocol for diagnosis and management of UTIs[181]	2156	Usual care	2061	Antimicrobial prescribing for UTI; total antibiotic prescribing; admission to hospital; deaths	Change in antibiotic prescribing for UTIs in favour of the intervention.
Team prescribing meetings[389]	626	Usual care	1228	Number of antipsychotics prescribed; number of medicines prescribed; appropriateness of medications	Levels of antipsychotic, benzodiazepines and antidepressant prescribing decreased in intervention arm.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Withdrawal of antipsychotic medication[170]	35	Usual care	35	BPRS; CMAI	No effect
Withdrawal of dopaminergic therapy in parkinsonian patients[175]	6	Usual care	5	UPDRS; Hoen and Yahr Scale; MMSE; Nursing Assistant Behavioural Detection Form	No effect.
Withdrawal of SSRI[173]	35	Usual care	35	MADRS; Global Assessment for Functioning Health Index; Symptom Assessment Form	No effect.
Staff education					
Education package delivered to MDT at homes[295]	Not clear	Education package delivered to physicians only	Not clear	Oral vs parenteral antibiotic prescribing rates; hospitalisation rates.	No effect.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Education package on geriatric psychopharmacology[183]	349	Usual care	326	MMSE; delayed-recognition-span test of memory; ADL performance; letter-cancellation test; anxiety; depression; behaviour; self-reported sleep problems; distress amongst staff members; prescribing	Less inappropriate prescribing and less antipsychotic prescribing in intervention group.
Education package on management of psychotic behaviours[282]	575	Usual care	577	Change in days of antipsychotic use per 100 days of nursing home residence; withdrawal from antipsychotics; reduction in antipsychotic dose by 50% or more	Significantly lower antipsychotic use in intervention homes at 6 months.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Educational package aimed at pain management and reducing NSAID prescribing[294]	81	Usual care	77	NSAID and Paracetamol prescription rates; analogue pain scale; MHAQ; MMSE; SIP-NH	No difference in pain scores between groups. Significant reduction in NSAID prescribing and uptake of paracetamol prescribing in the intervention group.
Regular MDT discussions about drug therapy[389]	1228	Usual care	626	Change in self-perceived staff-knowledge about drug therapy	Staff felt more knowledgeable in intervention arm.
Staff training on dementia management[292]	181	Usual care	168	Neuroleptic prescription rates; CMAI	Number of neuroleptics prescribed significantly less in intervention homes at 12 months; no change in CMAI.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Interventions targeting malnutrition

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Megestrol acetate[129]	26	Placebo	25	Weight and appetite change; sense of well-being; enjoyment of life; change in depression scale; laboratory nutrition parameters; energy intake counts; body composition; adverse events	Better appetite, enjoyment of life and wellbeing in intervention arm.
Megestrol acetate[130]	36	Placebo	33	Prealbumin; IL-6; TNFR-p 55; sIL-2R; Osoba and Murray enjoyment checklist; appetite grade; assessment of wellbeing	Rise in prealbumin, decrease in IL-6, TNFR-p55 in the intervention arm. These correlated to improvement in appetite and quality of life.
Megestrol acetate[128]	36	Placebo	33	TNFR subunits, TNFR-p55 and TNFR-p75; interleukin 6 (IL-6); and the soluble interleukin-2 receptor (sIL-2R). Weight and mortality	No difference in weight or cytokine levels but correlation between weight and cytokine levels and trend towards lower CK levels and higher weight in intervention arm.
Multivitamin supplement[137]	379	Placebo	384	Total number of clinical infections per subject	Less antibiotic prescribing in intervention arm, although no effect on infection rate.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Nutritional interventions					
Buffet-style dining[318]	20	Tray style dining	20	Weight; haemoglobin; haematocrit; cholesterol; prealbumin; lymphocyte count	No effect.
Family style meals[317]	94	Usual care	84	Energy intake; MNA; Body mass; Body composition	Weight gain recorded in intervention arm and weight loss in controls; better macronutrient intake; improvement in MNA risk-stratification.
Feeding Assistance[315]	63	Usual care	61	BMI; Food and fluid intake	When receiving the intervention participants increased total caloric intake and increased or maintained weight.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Flavour plus monosodium glutamate added to food/monosodium glutamate alone added to food/flavouring alone added to food[322]	22/19/19	Usual care	23	Anthropometry; Dietary intake; MNA; Pleasantness; GDS; Anger, hunger feelings and sensory perception questionnaire	No effect.
Fortification of breakfast and lunch/fortification of lunch only[304]	33/33	Usual care	33	Amount of food consumed	No effect from fortified foods on amount of food consumed.
Fortified diet[305]	22	Usual care	30	BMI; MNA; Bioelectrical impedance; Handgrip; BI; PEFR; SF-36	Improved protein intake and improved PEFR in intervention arm - all other variables unchanged.
Low-lactose powdered-milk[323]	28	Usual care	21	Bowel frequency; anthropometry; grip strength; BI; AMT; nutrient intake	No significant effect.
Medical nutrition therapy protocol[308]	222	Usual care	171	Dietician questionnaire; medical records audit; weight; rate of unintentional weight loss	Intervention arm most likely to identify unintentional weight loss but both arms equally effective at treating it.
Nutritional supplementation[313]	15	Placebo	18	Food consumption; body weight; grip strength; blood pressure; serum thiamine; pyridoxine; pre-albumin; CRP; alpha-glycoprotein; transferrin; vitamin C; homocysteine	Improved thiamine, pyridoxine, body weight and decreased serum homocysteine in intervention arm.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Nutritional supplementation[309]	19	Placebo	16	Dietary and medication intake; BI; anthropometry; plasma homocysteine levels; thiamine; TDF and pyridoxine levels; vitamin D and B12 levels	Improvement was observed for body weight, homocysteine, vitamin B1, TDF, vitamin B6, vitamin B12, folate and vitamin D levels in the intervention arm.
Nutritional supplementation[312]	24	Placebo	26	Food weighing; anthropometry; body composition; gait velocity; habitual spontaneous activity levels; Katz ADL; GDS	Improved BMI; body weight; energy and water intake in intervention arm.
Nutritional supplementation[307]	34	Usual care	34	Food intake; Body Weight; Severe Impairment Battery; Global Deterioration Scale; NPI-NH; London Psychogeriatric Rating Scale	Increased protein energy intake but tendency for those with lower body mass index to compensate by reduction of intake at other meals.
Nutritional supplementation[310]	47	Usual care	41	MNA; Weight; Body Mass Index; grip strength; energy intake; protein intake	MNA improved in those receiving supplements.
Nutritional supplementation following acute illness[311]	18	Usual care	16	Body weight; upper arm circumference; calf circumference; triceps skinfold thickness; dietary intake; need for care.	Significant weight gain in intervention arm and weight loss in control.
Nutritional supplementation plus exercise programme plus routine oral care[186]	62	Usual care	59	Senior fitness test; BBS; MDS; handgrip strength	Improvement in weight, BMI, protein intake, calorie intake, BBS - no effect on handgrip strength.
Nutritional supplementation plus oral functional training[314]	7	Nutritional supplementation	7	Nutritional status: serum total protein; albumin; total cholesterol; HDL; haemoglobin	Significant increase in serum albumin and serum total protein in intervention group, with additional significant weight gain.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Interventions targeting depression

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Low-dose nortriptyline[150]	22	Regular-dose nortriptyline	47	HAM-D; CGI; GDS; plasma nortriptyline levels	Improvement in HAM-D for both groups but no difference between. Normal dose was better in cognitively intact (MMSE>24) sub-group.
Paroxetine[152]	12	Placebo	12	CGI-S; CGI-C; HAM-D; CSDD; GDS; anticholinergic activity	No effect.
Sertraline[151]	17	Placebo	14	CMAI; CSDD; Gestalt scale; AFBS; Facial behaviours	No effect.
Venlafaxine[149]	27	Sertraline	25	HAM-D; time to discontinuation; adverse events; side-effects	Venlafaxine less well tolerated and no more effective than sertraline.
Physical therapy					
10,000 lux light therapy[224]	10	300 lux light therapy/usual care	10/10	GDS scores	Significant improvement in GDS in intervention arm.
Combined exercise and behavioural intervention[336]	13	Usual care	7	Schedule for affective disorders; MMSE; GDS	Improvements in activity and affect in the intervention arm.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Exercise programme/supervised walking[190]	Not clear	Social conversation	Not clear	CSDD; DMAS; AMS; OAS	OAS positive and AMS negative subscale better in treatment group.
Morning bright light[225]	15	Morning dim red light	15	Observed sleep pattern; BEHAVE-AD; CSDD;	Improved sleep at night but no change in agitated behaviour.
Seated exercise, 40-60 mins twice weekly for 5 weeks[214]	28	Usual care	28	Rivermead Mobility Index; HADS; SADQ	No effect.
TENS[235]	17	Placebo	17	General self-efficacy scale (Dutch); Groninger activity scale; Philadelphia geriatric centre morale scale; GDS	Mild improvement in mood and self-efficacy in intervention group but significant deterioration in placebo arm - therefore strongly significant difference.
Wheelchair Bicycling[219]	Not clear	Delayed wheelchair bicycling	Not clear	GDS; CMAI; data on sleep	Improvement in GDS, sleep pattern and activity participation.
Wheelchair Bicycling[218]	19	Usual care	20	Mean GDS Scores	Significant reduction in GDS score for the care group.
Yoga/ayurveda[233]	18/12	Usual care	20	GDS	Significantly lower depression in yoga group.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Occupational therapy, aids and appliances					
Recreation therapy[259]	11	Wait-list for cross-over	11	HAM-D; GDS; Global rating of depression; PCS; SCES; AES; EXIT; CIRS-G; Keitel and Barthel Measures	Participants categorised into responders and non-responders. Responders (n=14) improved significantly during the intervention but improvement was not persistent after the intervention stopped.
Psychological or Behavioural therapy					
Reminiscence therapy[324]	12	Planned activities	12	GDS; Self-transcendence scale	No effect
Self-worth therapy[332]	31	Social visit	32	GDS; MMSE; Barthel	Depressive symptoms reduced in intervention arm.
Case management/CGA					
Psychogeriatric case management[372]	44	Usual care	41	GDS; Mood subset of MDS; MMSE; LSES; functional ability	Reduced depressive symptoms in the intervention group.
Psychogeriatric case management[376]	19	Usual care	16	EBAS-DEP; HAM-D; CSDD; GDS; NPI; ; BEHAVE-AD; NPI; SAPS; Clinical interview	No statistical significance between groups.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Interventions targeting influenza

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Long term amantadine prophylaxis[147]	170	Short term amantadine prophylaxis	244	Laboratory confirmed clinical influenza	No difference.
Oseltamivir[148]	272	Placebo	276	Laboratory-confirmed clinical influenza	Significantly lower rates of influenza in intervention arm.
Rimantadine 100mg/rimantadine 200mg[145]	132/130	Placebo	66	Influenza-like illness; laboratory confirmed clinical influenza; influenza virus infection	No difference.
Zanamavir/rimantadine[144]	238/231	Placebo	13	Laboratory-confirmed clinical influenza	Zanamavir more effective in prophylaxis.
Zanamavir[143]	240	Placebo	249	Laboratory-confirmed clinical influenza	Reduction in laboratory-confirmed influenza with fever in intervention arm.
Zanamavir[146]	100	Rimantadine	40	Laboratory confirmed influenza	No difference between zanamivir and rimantadine.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Vaccine Studies					
60 mcg haemaglutinin influenza vaccine/20 mcg haemaglutinin influenza vaccine[360]	26/28	10 mcg haemaglutinin influenza vaccine	25	IgG, IgA, Haemaglutinin inhibition titres	20 mcg represents optimal dose for elderly (60 mcg produced no additional immunity).
60 mcg haemaglutinin influenza vaccine/20 mcg haemaglutinin influenza vaccine[361]	31/30	10 mcg haemaglutinin influenza vaccine	31	Haemaglutinin inhibition titres	Higher titres in higher doses for some but not all vaccines and/or centres.
Haemagglutinin-diptheria (HA-D) toxoid conjugate vaccine[363]	204	Haemagglutinin subunit vaccine	204	Antibody titres; clinically confirmed influenza	HA-D was more immunogenic and resulted in lower levels of confirmed influenza infection.
Influenza vaccination[359]	Not clear	Placebo	Not clear	Serum antibody response; rates of influenza-like illness	Combination influenza vaccine most-effective.
Influenza vaccination booster programme[366]	73	Usual care	204	Hospitalisation, antibiotic use, death, seroprotection	No benefit from booster programme.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Intranasal bivalent live attenuated vaccine[364]	25	Placebo	25	Nasal wash antibody response	Enhanced local antibody response in intervention group, however clinical relevance uncertain.
Intranasal influenza A vaccination[390]	162	Placebo	169	Laboratory confirmed influenza A; adverse events	Lower rates of laboratory confirmed influenza in the intervention group.
L-cystine and L-threonine co-administration with vaccine[370]	32	Placebo administration with vaccine	33	Serum influenza antibody titres	Improved vaccine response in intervention arm.
New vaccine (influsome)[369]	48	Old vaccine	33	Seroconversion rates; neuraminidase levels	Increased seroconversion rates with increased neuroaminidase-N2 response in new vaccine group.
Staff vaccination against influenza[358]	1270	Usual care	1391	All cause mortality, influenza-like illness and health service use in residents	Lower mortality, health service use and influenza like illness in the intervention group.
SU/MF99 influenza vaccination SU/VIR influenza vaccination [368]	99/93	SPLIT influenza vaccination	93	Protections and seroconversion rates.	SU/MF59 vaccine gave best immune response.
Subunit adjuvated influenza vaccination/virosomal subunit influenza vaccination[367]	41/37	Inactivated whole virus vaccination	33	Influenza-like illness rates; influenza antibody titres	Better influenza titres in two intervention arms.

Virosome vaccine[365]	32	Whole virus vaccine	32	Serological response to vaccine	Better immune response from virosome vaccine.

Interventions targeting quality of life

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Donepezil plus reminiscence therapy and reality orientation[153]	12	Donepezil	12	MMSE; QoL-AD	No difference between groups for MMSE; better QoL indices for the intervention arm.
Physical therapy					
26 weeks of structured tai chi[231]	66	Usual care	73	Chinese versions of State Self-Esteem Scale; SF-12; satisfaction with the nursing home instrument.	Improvement in composite of all three measures in intervention arm.
Back rubs[230]	6	Rest period	6	Heart rate; Respiratory rate; EMG activity of trapezius and masseter; skin temperature; tactual minimizing scale; territorial intrusions and personal space scale	Positive psychological effect from back rub - more so than for rest alone; no difference between groups on physiological parameters.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Functional incidental training[210]	74	Usual care	74	Incidence of Comorbid Conditions - Cost of Care	No difference.
Occupational therapy, aids and appliances					
Immediate spectacle correction of refraction error[253]	78	Delayed spectacle correction of refractive error	64	Nursing Home Vision-Targeted Health-Related Quality-of-Life Questionnaire; VF-14; GDS	Better quality of life and lower depression in the intervention group.
Resident involvement in voluntary activity (mentorship of "teaching English as a foreign language" group)[256]	15	Usual care	13	GDS; LSI-A; self-rated health question	Improvement in self-rated wellbeing in the intervention group.
Robotic dog[247]	12	Living dog/usual care	13/13	UCLA Loneliness Scale	Robot and living dog groups less lonely - no difference between robot and living dog groups.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Staff and family education					
Staff training in end-of-life care[290]	Not clear	Usual care	Not clear	Depression factor of POMS; Srole's alienation scale; Sherwood's Self-Esteem Scale; Rotter's Locus of Control Scale; Rapid Disability Rating Scale; Satisfaction with Care Scale	Less depression and more satisfaction with care in the care homes.
Training in dementia management/ training in relaxation techniques[281]	68/68	No training	74	Assessment of staff knowledge and competencies; MBI-D; level of staff health complaints; use of physical restraints and drugs on residents.	Significant improvement in staff knowledge in intervention group; less use of restraints in the intervention group; relaxation group reported less health complaints following intervention.

Training on conflict resolution for families and relatives[289]	431	Usual care	468	Interpersonal conflict scale; staff provision to relatives scale; staff behaviours scale; staff empathy scale; the nursing home hassles scale; the family involvement scale; Zarit burden interview; studies for epidemiological studies - depression	Less staff burnout; better family communication with staff and less perceived negative behaviour from staff; residents less agitated.
Nutritional interventions					
Family style mealtimes[316]	95	Usual care	83	Dutch Quality of Life of Somatic Nursing Home Residents Questionnaire; physical performance; body weight; energy intake	Overall quality of life, fine motor function and body weight better in intervention group.
Psychological or behavioural interventions					
Counselling intervention to promote self-esteem[333]	9	Usual care	12	CFSEI; Hunter Self-esteem inventory	Significant improvement in self-esteem in the intervention group.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Life review group programme[325]	36	Waiting list	39	LSI-A; Rosenberg self-esteem scale	Improvement in self-esteem and life-satisfaction in intervention arm.
Reminiscence therapy[326]	36/35	Social talking group/usual care	36	Social Engagement Scale; Wellbeing/Ill-being Scale.	No effect.
Reminiscence therapy discussion group[327]	Not clear	Current topics discussion group/usual care	Not clear/not clear	MUNSH; MUNAI; SGRS; MUMS	Significant improvement in MUNSH in both intervention groups with no difference between. Patients who talked the most showed the greatest change.
Nursing					
Comfort touch[384]	Not clear	Verbal interaction only/no interaction	Not clear/not clear	MSQ scores	Improvement in MSQ scores in the intervention arms.
Care home administration					
Resident controlled visitation/pre-scheduled visitation/random visitation[345]	10/10/10	No visitation	12	Wohlford Hope Scale; Subjective ratings of "zest for life" and "Health status"; activity diaries	Improvement in all variables where residents could have control over visitation.

Visitation[344]	12	Usual care	12	Vocabulary subtest of WAIS; Raven's Coloured Progressive Matrices; Strategic-semantic Memory Test; Twenty-Questions Problem-solving Test; LSI-A; PGC and Self-perceived Health Scale; subjective ratings of home activity coordinators re.: alertness/sociability	Significant improvement in self-perceived health and activity directors' ratings of sociability, physical health and alertness.
Case management/CGA					
Psychogeriatric case management[374]	53	Usual care	53	GDS; HoNOS 65+; MMSE; NPI	No effect.

Interventions targeting mobility

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Physical therapy					
Assisted walking/assisted walking with conversation[196]	21/26	Conversation only	24	Modified 6 minute walk; fidelity of treatment	Less decline in walking performance in combined walk and talk group, followed by talk group, followed by walk group.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Exercise classes[187]	34	Usual care	37	Sit-stand test	Significant decrease in sit-stand times in intervention arm.
Exercise programme[195]	42	Social visit	39	Fear of falling; balance; ankle strength; walking speed; MMSE; RAFS II; FES	Smaller decline in semi-tandem stance and improvement in fear of falling in intervention arm.
Functional Fitness for Long-term care programme[197]	36	Seated ROM exercises	32	TUG; BBS; Gait speed; Stair Climbing Power; FIM; flexibility measures; hand; shoulder; hip; and knee strength	Significant improvement in mobility, flexibility, balance, knee and hip strength for intervention arm. Shoulder strength only improved for controls.
Functional Incidental Training[208]	32	Usual care	29	Timed walk; sit-to-stand; upper and lower body strength; continence	Improvement in all variables for intervention group.

Group exercise[192]	17	Self-directed exercise	15	Fear of falling; muscle strength; Timed Up and Go; BBS	Improvement in balance, functional mobility and flexibility in intervention arm.
Mobility exercise, safety practice and rowing exercise[210]	35	Usual care	37	Maximum time walking, wheeling, rowing; number of sit to stands; safety of walking; judgement; transitions.	Improvements in upper body strength and safe mobility.
Seated exercise programme[216]	15	Reminiscence sessions	26	Postural sway; grip strength; knee flexion and extension; spinal flexion; BI; GDS; LSI; MMSE; sit-to-stand time	Grip strength, spinal flexion, sit-to-stand, ADLs all improved in intervention group. Lower self-rated depression in intervention group (although both groups lowered over time).
Strength and Flexibility Programme[217]	11	Recreation therapy with art therapist or social worker	9	TUG; BBS; PPT; MMSE	Decreased TUG, increased PPT, increased BBS and increased MMSE in intervention group.
Seated exercise, 40-60 mins twice week for 5 weeks[214]	28	Usual care	28	Rivermead Mobility Index; HADS; SADQ	No effect.
Vibration therapy plus physiotherapy[234]	22	Physiotherapy	20	Tinnetti Balance Assessment Tool; TUG; SF-36	Improved SF-36 and body balance in intervention arm.
Occupational therapy, aids and appliances					
Goal setting and individual ADL activities[275]	330	Social conversation	352	Late-life Function and Disability Instrument; Timed Up and Go; EQ-5D; Elderly Mobility Score; FICSIT 4 Balance Test	No effect.

Hip protectors; staff education; environmental modification; physical therapy[202]	59	Usual care	42	BBS; Functional ambulation categories	Improvements in independent ambulation in intervention arm.
Visual feedback balance training[200]	28	Usual care	8	Standing body sway; dynamic weight shifting; and BBS performance	Improvement in dynamic balance tests and BBS at follow-up in intervention group.

Interventions targeting oral health

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Subantimicrobial dose doxycycline (SDD)[121]	12	Placebo	12	Dental examination.	Significant improvement in intervention arm.
Dental and oral health interventions					
0.05% phenoxyethanol and 0.05% chlorhexidine mouthwash/ 0.05% phenoxyethanol and 0.025% chlorhexidine mouthwash [355]	10/8	0.12% chlorhexidine mouthwash	9	CFU/ml of salivary mutans streptococci	Control group showed greater reduction in CFU/ml of mutans streptococci.
0.4% stannous fluoride toothpaste[351]	32	0.2% sodium fluoride toothpaste	32	Plaque-index (PI) on four anterior teeth and four molars and gingival index (GI).	Stannous fluoride produced significantly lowered PI but had no effect on GI.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Advanced Restorative Dentistry Techniques (ART)[356]	78	Usual care	84	Restoration survival rate.	No difference.
Chewable toothbrush (patient administered)[251]	14	Conventional toothbrush (staff administered)	14	Plaque index	Effective at plaque removal - better than a control for lingual plaque removal.
Chlorhexidine acetate and xylitol chewing gum/xylitol chewing gum[354]	43/37	Usual care	31	Plaque index (PI) and gingival index (GI); participants attitudes towards gum.	Lower PI and GI for chlorhexidine than for xylitol alone and for chewing vs non-chewing. Improvements in taste and chewing function vs decline in non-chewing group.
Fluoride containing tooth varnish[353]	52	Placebo	50	Size and severity of caries; number of type of salivary micro-organisms	Severity of caries increased in control arm but remained static in intervention arm. No change in salivary micro-organisms.
Microwave dentures[357]	15	Soak dentures	19	Thrush growth on dentures and in mouth.	Microwaves reduced recurrence of thrush on dentures.

Oral healthcare education[301]	144	Usual care	151	Knowledge and attitude test	Improved knowledge and attitude scores in intervention arm
Oral healthcare education[302]	155	Usual care	182	Denture plaque scores; denture induced stomatitis prevalence; dental plaque scores; gingivitis prevalence	Denture plaque and dental plaque scores and prevalence of denture induced stomatitis lower in the intervention group.
Profylin fluoride gel with buffering components[352]	14	Profylin fluoride gel without buffering components; rinsing with water	14	Plaque pH; stimulated salivary secretion rate; buffer capacity; number of colony forming units of various bacteria	No significant difference.
Regular tongue brushing[350]	50	Tongue rinsing only	40	Taste thresholds for sweet, salty, sour and bitter	Fall in salty and sour taste thresholds - no effect for bitter or sweet.
Sonic electric toothbrush[252]	17	Manual Toothbrush	20	Plaque index (PI)	Sonic toothbrushes better.

Interventions targeting falls

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Vitamin D 800 IU/vitamin D 600 IU/vitamin D 400 IU[114]	23/25/25	Placebo	25	Number of falls; compliance; serum vitamin D levels	Reduced incidence rate of falls in highest dosage group but time to first fall remained the same.
Vitamin D supplementation[116]	313	Placebo	312	Rate of falls and fractures; serum vitamin D levels	Reduction in rate of falls in treatment arm.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Physical therapy					
Ankle strengthening exercises and walking[201]	9	Usual care	7	Parallel stance; semi-tandem stance; tandem stance; ankle strength; six meter walking; fear of falling; falls efficacy; number of falls	No effect.
High-intensity functional exercise programme[191]	91	Seated activities	100	Falls rate and number of residents sustaining a fall; MMSE; BBS; BI; GDS	No real effect - some evidence that those who improved balance fell less on subgroup analysis.
Occupational therapy, aids and appliances					
Education, physical exercises, environment, hip protectors[188]	509	Usual care	472	Fall rate; fracture rate	Reduction in falls and fallers, although no reduction in number of fractures, in intervention arm.
Falls prevention programme[215]	77	Reminiscence sessions	56	Number of falls sustained; functional reach; reaction time; TUG; grip strength, spinal flexibility; PGC; MMSE	No change to number of falls sustained or risk of falling but postural hypotension and poor visual acuity reduced in the intervention arm.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Falls prevention programme[267]	102	Usual care	94	Number of falls/recurrent falls per person; number of medications per person; Tinetti gait and balance score.	Modest reduction in falls rate but failed to reach statistical significance.
Falls prevention programme[266]	200	Usual care	269	Number of falls	Significantly lower falls incidence in the intervention group.
Falls prevention programme[269]	239	Usual care	177	Falls; injurious falls; seriously injurious falls	No effect.
Falls prevention programme[268]	261	Usual care	221	Number of recurrent fallers; number of injurious falls	Reduction in the number of recurrent fallers; no change in the number of injurious falls
Staff education					
Education about falls prevention[284]	210	Usual care	169	Falls rate	Intervention reduced rate of falls by 50%.
Care home administration					
Falls menu driven incident reporting system[337]	424	Usual care	428	Falls, documentation of falls	Better documentation of circumstances around falls and near falls in intervention arm

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Interventions targeting quality of care

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Staff education					
Education on person centred care for bathing/education for person centred care for towel bath[297]	Not clear/not clear	Usual care	Not clear	Caregiver Behaviour Bathing Rating Scale; Care Effectiveness Scale; Confidence Scale; Hassles During Bathing Scale; Stevens Caregiving Hassles Scale	Improvements in gentleness; confidence; and ease but not hassles
Education package on communication delivered to families and staff[287]	456	Usual care	227	Interpersonal Conflict Scale; Staff Behaviours Scale; Staff Empathy Scale; Zarit Burden Interview; Family Behaviours Scale; Family Empathy Scale; Maslach Burnout Inventory; intention to quit	Families had more empathy for and less conflict with staff; staff less likely to quit job in next 12 months.
Training about death and dying[290]	296	No training	290	Collett-Lester Death Anxiety Scale; attitudes towards caring measured using Semantic Differential Technique	More fear of own dying, less fear of residents dying. More positive attitude towards care of dying amongst staff in intervention.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Care home administration					
Advanced directive support programme[343]	636	Usual care	656	Resident and family satisfaction with healthcare; health resource use	Fewer hospital admissions and shorter length of stay per resident in intervention arm. No difference in resident satisfaction.
Interview assessing appropriateness for hospice-care, with results revealed to patient and their physician[236]	107	Interview assessing appropriateness for hospice-care, without results revealed	98	Venue of care; hospital admissions; days in hospital; symptom control	More appropriate venue of care in intervention group. Fewer admissions and days in hospital in the intervention group. Better objective quality of end-of-life in the intervention group.
Invitation for family to be involved in care (and involvement in care)[346]	16	Usual care	15	Family perceptions of care tool (FPCT)	No difference.
MDS quality indicator workshop+ quarterly MDS score feedback/ MDS quality indicator workshop + quarterly MDS feedback + clinical consultation (clinical nurse specialist)[342]	Not clear/not clear	Usual care	Not clear	MDS quality indicators.	No significant difference between groups.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Quality assurance package with support from quality assurance nurse consultant[339]	768	Usual care	757	Quality of care determined by note abstraction against predetermined quality markers	Improvement in constipation and mobility care for homes where quality assurance took place.
Quality assurance package with support from quality assurance nurse consultant[341]	345	Usual care	113	Knowledge test on staff; pre-determined palliative care quality indicators.	Improvements in knowledge test scores for care workers. Improvements in number of residents appropriately admitted to hospice, receiving appropriate analgesia, receiving non-pharmacological therapy, with do not resuscitate order, with advanced care plan.
Quality improvement programme[338]	102	Usual care	99	QUALCARE Scale	No change.
Relocation to new home[348]	34	Staying in current home	43	Salivary Cortisol; AARS; MMSE; Blood pressure; Pulse intensity	Early-morning serum cortisol higher one week after move. Afternoon cortisol significantly lower 4 weeks after the move. AARS significantly lower 4 weeks after the move.
Case management/CGA					
CANE followed by case management[375]	92	Usual care	100	CANE; QoL-AD	No change in unmet needs relative to control group.

Interventions targeting urinary incontinence

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Antimicrobial eradication of bacteriuria[125]	71	Usual care	71	Frequency and volume of urinary incontinence	No effect.
Oral oestrogen and progesterone[134]	15	Placebo	17	Measures of incontinence severity; the clinical appearance of the vagina; vaginal and urethral cytology; urine and vaginal cultures	No effect.
Oxybutynin MR[156]	26	Placebo	24	CAM; MMSE; SIB; BARS	No effect.
Oxybutynin plus prompted voiding[157]	63	Placebo plus prompted voiding	63	Amount and frequency of urinary incontinence	No effect.
Physical therapy					
Functional incidental training[212]	94	Usual care	96	Endurance; upper and lower body strength; severity of incontinence	Intervention residents maintained or improved performance whereas the control group's performance declined on 14 of 15 outcome measures.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Occupational therapy, aids and appliances					
Bladder training[270]	65	Usual care	68	Incontinence episodes, time spent by care staff, and supplies used	Reduction in severity of incontinence; cost-effectiveness uncertain
Bladder training and Kegel exercises[272]	25	Usual care	25	Frequency and volume of urinary incontinence	Decrease in urgency, frequency, nocturia and volume of incontinence in intervention group.
Mobility and toileting skills training[273]	29	Usual care	28	Frequency and volume of urinary incontinence; POTTI	Reduction in incontinence in intervention arm by 37.7%
Mobility programme; staff education in continence care[189]	17	Usual care	16	Continence questionnaire; Rivermead Mobility Index	Improved continence questionnaire scores and mobility in the intervention group; intervention feasible and well received; compliance good.

One-step incontinence system[255]	15	Usual care	9	Time to clean and change patient; use of cloth towels; use of disposable wipes; use of disposable gloves; interruptions during cleaning.	Reduced use of cloth towels; increased use of disposable, emollient impregnated, disposable towels; decreased time for continence care.
Patterned-urge response toileting[271]	51	Usual care	37	Amount and frequency of urinary incontinence	Significant reduction in urinary incontinence in intervention arm.
Nursing					
Clean intermittent catheterisation[383]	38	Sterile intermittent catheterisation	42	Clinical urinary tract infection	No difference between arms.

Interventions targeting cognitive performance

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Donepezil[155]	128	Placebo	120	SIB; ADCS-ADL; adverse events	Intervention group showed more in improvement in SIB and less decline in ADCS-ADL.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Donepezil[154]	103	Placebo	105	NPI-NH; CDR-SB; MMSE; PSMS; adverse effects	No effect on NPI-NH, improvement in CDR-SB and MMSE in intervention arm.
Ginkgo biloba[167]	79	Placebo	44	SKT; CGI 2; Nuremberg Gerontopsychological Rating Scale for Activities of Daily Living	No effect.
Physical therapy					
Bright white light +/- melatonin +/- placebo[132]	98	Dim light +/- melatonin +/- placebo	94	MMSE; CSDD; PGCMS; PGCARS; MOSES; CMAI; Actigraphy; NPI-Q; NI-ADL	Melatonin led to low mood but not in combination with light. Light attenuated aggressive behaviour, depressive symptoms and increase in functional impairment.
Exercise programme[203]	24	Social visit/Usual care	21/30	Clock drawing test; REPDS	Better clock drawing test results in intervention group; better scores in self-help and sociability subdomains of REPDS but overall score unaffected.
Exercise Programme[198]	10	Video of Exercise Programme	10	SET test; symbol digit test; word fluency	Improvement in semantic memory immediately post-test for the intervention group.
Planned walking[199]	15	Conversation only	15	COS; CAS-COG	Communication improved significantly in the intervention group.
Occupational therapy, aids and appliances					
Psychomotor activation programme[263]	45	Usual care	47	BI; CST-14; CST-20; BIP; SIPO	Improvement in cognition and better group behaviour in intervention group

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Psychological and behavioural interventions					
Conversational skills training[331]	4	Placebo discussion group/ Usual care	6/6	Objectively rated conversation skills; Zung's Self-rated Depression Scale	Better conversation skills and less depression in intervention arm.
Donepezil plus reminiscence therapy and reality orientation[153]	12	Donepezil	12	MMSE; QoL-AD	No difference between groups for MMSE; better QoL indices for the intervention arm.
Care Home Administration					
Visitation/visitation plus cognitive games[344]	12/15	Usual care	12	Vocabulary subtest of WAIS; Raven's Colored Progressive Matrices; Strategic-Semantic Memory Test; Twenty-Questions Problem-Solving Test; LSI-A; PGC and Self-Perceived Health Scale; subjective ratings of home activity coordinators re.: alertness/sociability	Significant improvement in self-perceived health and activity directors' ratings of sociability, physical health and alertness for both treatment arms, greatest improvement for visitation plus cognitive games.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Interventions targeting sleep

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Temazepam/diphenhydramine[163]	17/17	Placebo	17	Sleep diary; morning drowsiness; sleep latency; DSST; Tapping Board Test; Digit Span Test; Standardised Vocabulary Test; Cancellation Test; Word Lists	Shorter sleep latency and longer sleep with diphenhydramine but otherwise placebo better.
Melatonin[131]	24	Placebo	17	Sleep (actigraphy); CMAI; ABRS	No effect.
Withdrawal of antipsychotic medication[172]	15	Usual care	15	NPI; Actigraphy	Decreased average sleep efficiency; no significant change in NPI with cessation.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Physical therapy					
Controlled sunlight exposure; sleep hygiene; physical activity regimen[204]	62	Usual care	56	Night-time sleep; night time awakenings; duration of night-time awakenings recorded using actigraphy; day-time sleep recorded by observation	Amount of time spent asleep during day reduced by intervention.
Functional incidental training[205]	33	Row-wheel-walk training	32	Mobility endurance; physical activity levels; daytime sleep; night-time sleep	No effect.
Morning bright light/evening bright light[223]	Not clear	Morning dim light/daytime sleep restriction	Not clear.	Night-time sleep; daytime alertness; circadian rhythms - all recorded via actigraphy	No effect.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Morning bright light[220]	24	Usual care	17	Night-time sleep efficiency; sleep time; wake time; numbers of awakenings; daytime activity - all recorded using actigraphy	No effect.
Morning bright light plus evening melatonin[133]	16	Morning bright light plus evening placebo/usual care	17/16	Night-time sleep variables; day sleep time; day activity; day:night sleep ratio; rest–activity parameters – all recorded using actigraphy	Decreased daytime sleep increased daytime activity, improved day to night activity ratios, increased amplitude in sleep wake cycle in treatment arm.
Sleep hygiene; physical activity regimen[206]	15	Sleep hygiene alone	14	Night-time noise; night-time light; night-time sleep; day-time sleep; physical activity monitor recordings	Improved night time sleep and decreased day-time agitation in the intervention arm.

Sleep hygiene; physical activity regimen (FIT) ; increased exposure to daytime bright light[213]	54	Usual care	46	Actigraphy; behavioural observation; bedside light and noise monitoring	Improvement in daytime activity, not much effect on night-time activity.

Interventions targeting fractures

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
"Safehip" hip protectors[242]	109	"Hipsaver" hip protectors	53	Compliance with hip protectors	No difference in hip protector use. Low BI, residence in a dementia specialist home and injurious fall in last 12 months predictive of compliance with treatment.
Hip protectors[240]	1042	Usual care	1042	Hip fracture incidence	No effect.
Hip protectors[246]	86	Usual care	88	Falls; fractures; other injuries; rate of fall injury; mortality; adherence	No effect but poor adherence. Study underpowered.
Hip protectors[244]	276	Usual care	285	Time to first hip fracture; fall and fracture rate	No effect.

Hip protectors[245]	459	Usual care	483	Hip fractures; compliance with intervention; other fractures; falls; hospital admissions; consultations; QoL; costs	No effect.
Hip protectors[241]	459	Usual care	483	Hip fractures; cost; cost-effectiveness	Lower fracture rate but not cost effective - would become cost-effective if cost of hip protectors < $22.
Hip protectors freely available[243]	1366	Usual care	2751	Uptake rate of hip protectors; fracture rate	No effect.
Soft hip protectors[239]	660	Hard Hip Protectors	576	Compliance with hip protectors	No effect.

Interventions targeting immune function

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
17g supplemental arginine per day/8.5g supplemental arginine per day[139]	11/11	0g supplemental arginine/day	10	Immune status; nutritional status; plasma arginine; ornithine levels	No effect.
Ferrous gluconate/chelated iron[142]	4/4	Usual care	6	Serum iron studies; influenza serology	No effect.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

L-arginine[138]	12	Placebo	14	Serum immunoassays; serum arginine, citrulline and ornithine levels; MNA; serum nitric oxide levels	No effect.
Vitamin A supplementation[141]	56	Placebo	53	Clinically diagnosed antibiotic treated infections; vitamin A levels	No effect on infections despite good serum vitamin A levels.
Vitamin supplementation/trace element supplementation/vitamin and trace element supplementation[135]	Not clear/not clear/not clear	Placebo	Not clear	Serum beta carotene; retinol; alpha-tocopherol; selenium; zinc; red blood cell selenium dependent glutathione peroxidase; superoxide dismutase; total glutathione; oxidised glutathione; thiobarbituric acid reactants.	Supplementation with vitamins improved superoxide dismutase activity and levels of alpha tocopherol, beta carotene and vitamin C. Trace element supplementation improved serum zinc and serum selenium. Both improved glutathione peroxidase activity.
Vitamin supplementation/trace element supplementation/vitamin and trace element supplementation[136]	33/34/35	Placebo	32	Vitamin and trace element levels; red blood cell selenium dependent glutathione peroxidase; superoxide dismutase; total glutathione; reduced glutathione; oxidised glutathione; interleukin 2 levels; lymphocytes subsets	Increase in glutathione peroxidase, CD2 and CD19 lymphocyte subset levels in intervention arms.

Physical therapy					
Resistance and endurance exercises[209]	94	Usual care	96	Motion sensor; behavioural observation; heart rate; immune measurements	No effect.
Nutritional					
EXP nutritional formula[306]	81	Standard liquid nutrition	76	Immune response to influenza vaccination; fever; number of prescribed antibiotics	Better immune response in intervention arm.

Interventions targeting decubitus ulcers

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Collagen protein hydrolysate supplement[164]	56	Placebo	33	Pressure Ulcer Scale for Healing (PUSH) scores	Significantly better PUSH scores in intervention arm.
Oxyquinolone containing ointment[123]	Not clear	Standard emollient	Not clear	Rate and extent of ulcer healing	Better and quicker healing with quinolone ointment.
Physical therapy					
Massage with sulmethydioxyl[229]	59	Massage with indifferent cream/Usual care	55/29	Pressure ulcer presence, size and grade.	No effect.

Ultrasound therapy[232]	45	Sham ultrasound	43	Surface reduction; volume reduction; healing velocity; overall impression.	No effect.
Occupational therapy, aids and appliances					
Low air-loss bed[250]	43	Corrugated foam mattress	41	Ulcer healing; wound surface area.	Better ulcer healing in low-air loss beds.
Pressure-relieving cushion[249]	15	Foam cushion	17	Incidence, size and stage of pressure ulcers.	Pressure-reducing cushions better at preventing ischial pressure ulcers. No effect on other pressure ulcers.
Nursing interventions					
Turning with unequal time intervals[382]	122	Turning with equal time intervals	113	Pressure ulcer size and grade.	No effect.

Interventions targeting osteoporosis

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Alendronate[162]	Not clear	Placebo	Not clear	BMD of spine and hip; biochemical markers of bone turnover.	BMD significantly better in intervention arm at 24 months.
Daily vitamin D/weekly vitamin D/monthly vitamin D[115]	55/54/57	Placebo	172	Serum levels of 25-hydroxy vitamin D3; PTH; bone turnover markers.	Daily vitamin D administration had most significant effect on all biomarkers.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Risedronate plus calcium and vitamin D[113]	Not clear	Placebo plus calcium and vitamin D	Not clear	BSAP; NTX; Vitamin D; PTH levels.	No effect.
Vitamin D every three months[118]	1762	Placebo	1955	Non-vertebral fractures; falls; vitamin D; PTH levels.	No effect.
Vitamin D three times a year[120]	1725	Placebo	1715	Incidence of first fracture; incidence of hip fracture; fracture at common osteoporotic sites; mortality; serum vitamin D; PTH.	No effect.
Staff education					
Osteoporosis nurse led education day for care home staff[285]	3315	Usual care	2322	Total fractures; total hip fractures; total falls; number of residents sustaining a fall; number of residents prescribed bisphosphonates; number of residents prescribed calcium and Vitamin D; number of residents wearing hip protectors.	Calcium and vitamin D and bisphosphonate prescribing increased in intervention group. No effect on other outcomes.
Care home administration					
Audit and feedback loops, educational modules, teleconferences, and academic detailing[340]	293	Usual care	313	Adherence to osteoporosis prevention guidelines.	No difference.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Interventions targeting pain

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Regular paracetamol[161]	18	PRN paracetamol	21	DS-DAT	No difference.
Physical therapy					
Functional incidental training[211]	27	Usual care	24	GPM-M; Count of number of verbal and non-verbal expressions of pain.	No effect.
Reflexology[391]	21	Social visit	21	Salivary alpha-amylase; Apparent Affect Rating Scale; checklist of nonverbal pain indicators; blood pressure; pulse; MMSE	Significant reduction in observed pain and salivary alpha amylase.
Staff training					
Education package about the Back Book (activity therapy for back pain)[296]	233	Education package about the Back Manual (postural therapy for back pain)/education package about optimizing cardiovascular health	199/241	Visual Analogue Scale for Pain; RMDQ; Fear Avoidance Beliefs Questionnaire; SF-12	The Back Book showed improvement measured against the RMDQ in subjects with and without back pain.

Behavioural and psychological interventions					
Cognitive behavioural therapy[335]	11	Attention-support therapy	10	SF-MPQ; RMDQ; GDS; Pain medication use	Less pain and pain related disability in intervention arm; no effect on depression or physician prescribing.
Case management/CGA					
Case management[378]	57	Usual care	57	BEHAVE-AD; DS-DAT	Reduction in discomfort in intervention arm.
Medication review; pain control; activity review; psychological review; behavioural review[379]	57	Usual care	61	CMAI; Faces Leg Activity Cry Consolability Scale; CSDD; PAINAD	Significant reduction in physically non-aggressive behaviour on CMAI - otherwise no effect.

Interventions targeting physical function

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Donepezil[155]	128	Placebo	120	SIB; ADCS-ADL; adverse events	Intervention group improved more in SIB and declined less in ADCS-ADL.
Physical therapy					
Physiotherapy programme[228]	97	Social visit	97	PDI; Katz ADL scale; SIP; MMSE; GDS; Upper and lower limb muscle strength	Improvement in mobility subscale of PDI - less likely to use aids for locomotion in the intervention group.
Exercise programme[203]	24	Usual care	30	Clock drawing test; revised elderly physical	Better clock drawing test results in intervention

				disability scale (REPDS)	group; better scores in self-help and sociability subdomains of REPDS but overall score unaffected.
Occupational therapy, aids and appliances					
Help with jigsaw (verbal)[257]/Encouragement with jigsaw	Not clear/not clear	Usual care	Not clear	Performance in completing jigsaw.	Performance of encouragement group improved and of help group deteriorated.
1 PT and 1 OT per 50 residents[227]	58	1 PT and 1 OT per 200 residents	57	FIM; FAM; COVS	Improvement in all measures with higher intensity rehabilitation. Higher intensity rehabilitation more cost efficient, saving $283 per patient per year.

Functional training[276]	Not clear	General stimulation/Usual care	Not clear/not clear	Physical Self Maintenance Scale; Performance Test of Activities of Daily Living; goal attainment	Functional training best for physical self maintenance scale and goal attainment tests, followed by stimulation, followed by control; no significant differences for performance test of activities of daily living.
Occupational therapy[278]	63	Usual care	55	BI; "poor outcome"; Rivermead Mobility Index	Less deterioration in BI; less likelihood of "poor outcome" in intervention arm.
Care home administration					
Negotiated family involvement in care[347]	93	Usual care	71	Global Deterioration Scale; Functional Assessment Checklist	No difference.

Interventions targeting constipation

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Resistance training/functional independence training[194]	40/41	Education	31	Accelerometer recordings; bowel frequency chart	No effect.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Nutritional interventions					
Bran mixture[319]	12	Usual care	12	Bowel frequency; laxative prescribing	Reduction in medication use and improved bowel frequency in intervention arm.
Fermented oat drink with bifidobacteria longum/ Fermented oat drink with bifidobacteria lactis[321]	56/86	Placebo	67	Regularity and consistency of bowel movements; MNA; Cognitive Performance Scale; Hierarchical ADL Scale; Depression Rating Scale; laxative use	Bowel movements normalised in both intervention arms - no difference between intervention arms.
Oat bran in diet[320]	15	Usual care	15	Body weight; bowel habit; laxative use	Laxative use decreased significantly in intervention arm.
Smooth Move herbal tea[158]	42	Placebo	44	Bowel movements; no of treatments dispensed; cost	Significantly increased no of bowel movements in intervention arm. No difference in cost.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Interventions targeting respiratory infections

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Intramuscular cefoperazone[126]	50	Intramuscular ceftriaxone	54	Days of therapy; final maximum temperature; clinical and bacteriological response; adverse effects	No difference between groups.
OM-85 BV bacterial extract[127]	147	Placebo	143	Incidence of respiratory infections; serum immunoglobulin levels; adverse events	Reduced incidence of bronchitis in treatment group.
Pneumococcal vaccination[371]	59	Tetanus vaccination	59	Seroconversion rate	Higher seroconversion rates in intervention arm.
Vitamin E[140]	231	Placebo	220	Incidence of RTI; no of people and no of days with RTI; no of new antibiotic prescriptions for RTI	Lower incidence of URTI and cold in intervention arm; no effect on LRTI.
Care home administration					
Protocol for management of pneumonia in situ[181]	314	Usual care	347	Hospital admission rates and length of stay	Fewer admissions and shorter length of stay and cheaper care in intervention arm.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Interventions targeting physical restraint use

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Educational package[299]	55	Usual care	96	Restraints per patient in nursing home and BARS.	Significant reduction in the use of restraints in intervention group - but follow-up immediately after intervention.
Educational package[300]	86	Usual care	58	Percentage of residents with restraint use; type of restraints in use.	No effect.
Restraint education/restraint education with consultation[298]	152/127	Usual care	184	Restraint use	Education resulted in larger reductions in restraint use (however intervention home was a lower restraining home to start with).

Interventions targeting skin health

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Physical therapy					
Continence care and mobility intervention; FIT[207]	70	Usual care	74	Skin Health; skin hydration.	Overall improvement in skin health.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Nursing					
No-rinse cleanser during bathing[385]	24	Detergent cleanser during bathing	24	Skin condition; skin-related prescriptions; odour control; cleansing efficacy; patient comfort; bathing time; cost.	No difference in clinical measures. No rinse detergent cost more.
Whirlpool bath/ultrasound bath[254]	29/29	Usual care	29	Skin condition; skin cultures; microbial content of water; staff satisfaction.	No effect. Nursing assistants preferred whirlpool or ultrasound baths as easier to clean residents and had a better sound.

Interventions targeting vitamin D deficiency

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Vitamin D[117]	Not clear	Placebo	Not clear	Vitamin D metabolites, PTH, bone GLA hormones	Serum 25 OH Vitamin D increased with treatment.
Vitamin D 800 IU per day/vitamin D 400 IU per day[119]	Not clear/not clear	Usual care	Not clear	25 OH-D; PTH; calcium; phosphate creatinine; alkaline phosphatase; gamma-GT; albumin; LDL; HDL; urinary hydroxyproline; osteocalcin.	400 IU resulted in sufficient improvements of Vitamin D levels, with some PTH and bone turnover suppression.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Physical therapy					
UVB therapy/oral vitamin D[226]	15/15	Usual care	15	Serum Vitamin D; Serum PTH; Serum SHBG; Serum calcium	Higher serum Vitamin D, higher serum calcium, lower serum PTH in both treatment groups. No difference between treatment groups.

Interventions targeting general health

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Care home administration					
NHS Nursing Home[349]	236	NHS Continuing Care	228	Survival; Satisfaction at interview	No difference.
Case management/CGA					
Physician-led CGA[380]	33	Usual care	36	Prescription medication use; Health service utilization	Greater health service utilization and fewer medications prescribed at 6 months in CGA group. No difference in hospital admissions or longevity.

Interventions targeting swallowing

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Pharmacological					
Oral theophylline[166]	32	Placebo	31	Latent-time swallowing reflex	Significant improvement in the theophylline group.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Physical therapy					
Cervical mobilization therapy[237]	15	Social visit by physiotherapist	15	Feasibility; dysphagia limit	Improvement in the dysphagia limit in the intervention group.

Interventions targeting other domains

Intervention	Subjects in intervention arm	Control	Subjects in control arm	Outcome measures	Findings
Target: Compliance with OT					
Added purpose exercise[258]	15	Rote exercise	15	Frequency of stirring some cookie mix.	Much more compliant (higher frequency of stirring) in the added purpose group.
Target: COPD					
Protocol on COPD management for community nurses to follow[377]	48	Usual care	41	Barthel Index; GHQ-28; respiratory function; satisfaction	Significantly higher satisfaction; significantly higher lower scores for psychological distress and anxiety and insomnia subset of the GHQ-28.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Target: Cough Reflex Sensitivity					
Oral care by caregivers after every meal for 1/12[303]	30	Usual care	29	Cough reflex sensitivity to citric acid; serum substance P concentration; cognitive function; ADL performance	Improved cough reflex sensitivity in intervention arm. All other outcome measures the same.
Target: Dehydration					
Prompting and preferred beverage programme (3 phase) to promote fluid intake[277]	48	Usual care	15	Fluid consumption between and during meals; serum osmolality; BUN; creatinine	Significant increase in fluid intake and drop in BUN in intervention group.
Target: Dementia					
Training in identification and management of dementia[283]	198	Usual care	228	GDS; Staff recognition of dementia; treatment of dementia	Detection rates increased and a non-significant increase in treatment rates in intervention arm.

Appendix 2 – Table of Care Home Interventions Studied at RCT by Target

Target: Hypertension					
Music therapy[265]	15	Usual care	15	Twice weekly blood pressure recordings	Substantial reduction in systolic blood pressure with music therapy.
Target: Interpersonal skills					
Interpersonal skills training[392]	9	Discussion control/Usual care	9/9	Interpersonal Situation Inventory; Behaviour Roleplay Test; Behaviour Roleplay Test Satisfaction Rating; Simulated Real-life Test	Interpersonal skills training best for situations which training covered – skills did not transfer well to other situations.
Target: Microbial colonization					
Routine glove use[381]	136	Contact isolation precautions	147	MRSA; ESBL; VRE swabs	No difference between routine glove use and contact isolation precautions in preventing infection. Contact isolation precautions (i.e. Routine care) more expensive.
Target: UTI					
Antibiotics for all bacteriuria[124]	24	Antibiotics for symptomatic bacteriuria only	26	Bacteriuria; re-infection rates; signs and symptoms of UTI	No difference between arms.