Dementia Care Mapping™ to reduce agitation in care home residents with dementia: The DCM™ EPIC cluster randomised controlled trial

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Conflict of interest

Surr was previously employed by the University of Bradford, who own the IP to the DCM™ intervention tested in this trial. In this role she held responsibility for DCM training and method development. She was a technical author on the British Standards Institute PAS 800 guide on implementing DCM™ in health and social care provider organizations. She declares personal fees from Hawker publications outside the submitted work.

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Downs works at the University of Bradford which holds the IP for DCM™ and runs courses for practitioners and professionals who wish to learn how to use the method.

Meads was a member of the EESC methods panel

L Robinson was a member of the NIHR Primary Care Themed Call Board

All other authors have no conflicts to declare.

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Abstract

Background: Quality of care for people with dementia in care homes is of concern. Interventions that can improve care outcomes are required.

Objective: To investigate the clinical and cost-effectiveness of Dementia Care Mapping™ (DCM™) for reducing agitation, and improving care outcomes for people living with dementia in care homes, versus usual care.

Design: A pragmatic, cluster randomised controlled trial with open-cohort design, follow-up at 6- and 16-months, integrated cost-effectiveness analysis and process evaluation. Clusters were not blinded to allocation. Primary endpoint was completed by staff-proxy and independent assessors.

Setting: Stratified randomisation of 50 care homes to intervention/control on a 3:2 ratio by type, size, staff exposure to dementia training and recruiting hub.

Participants: Fifty care homes were randomised (31 intervention, 19 control), with 726 residents recruited at baseline and a further 261 at 16-months. Care homes were eligible if they recruited a minimum of 10 residents, were not subject to improvement notices, had not used DCM™ in the previous 18-months and were not participating in conflicting research. Residents were eligible if they lived there permanently, had a formal diagnosis of dementia/score of 4+ on the Functional Assessment Staging of Alzheimer's Disease, were proficient in English, not at end-of-life/permanently cared for in bed. All homes were audited on delivery of dementia and person-centred care awareness training. Those not reaching a minimum standard were provided training ahead of randomisation. Eighteen homes took part in the process evaluation.

Intervention: Two staff from each intervention home were trained to use DCM™ and requested to carry out three DCM™ cycles; the first supported by an external expert.

Main outcome measures: The primary outcome was agitation (Cohen-Mansfield Agitation Inventory) at 16-months. Secondary outcomes included resident behaviours and quality of life.

Results: There were 675 residents in the final analysis (287 control, 388 intervention). There was no evidence of difference in agitation levels between arms. The adjusted mean difference in CMAI score was -2.11 points, lower in the intervention group than control (95% CI -4.66 to 0.44, p=0.104, adjusted ICC control=0, intervention 0.001). The sensitivity analyses results supported the primary analysis. No differences were detected in any of the secondary outcomes. The health economic analyses indicated DCM™ was not cost-

effective. Intervention adherence was problematic; only 26% of homes completed more than their first DCM™ cycle. Impacts of and barriers and facilitators to DCM™ implementation were identified.

Limitations: Primary completion of resident outcomes was by staff proxy due to self-report difficulties for residents with advanced dementia. Clusters were not blinded to allocation although supportive analyses suggested any reporting bias was not clinically important.

Conclusions: There was no benefit of DCM™ over control on any outcomes. Implementation of DCM™ by care home staff was sub-optimal compared to protocol in the majority of homes.

Future work: Alternative models of DCM™ implementation should be considered, which do not rely solely on leadership by care home staff.

Trial registration: Current Controlled Trials ISRCTN82288852

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Glossary

Agency staff: Temporary staff who are provided by an external organisation (Agency) to cover staff shortages/absences when these cannot be met by the care home's own staff pool.

Bank staff: A pool of staff employed by the care home on non- substantive contracts and who are drawn on when the care home is unable to cover absences or shortages with staff who have contracted hours.

DCM™ intervention lead: Member of the trial team who is responsible for oversight and leadership of DCM™ implementation across the intervention care homes and co-ordination of the DCM™ expert mappers.

DCM™ expert mapper: Experienced User of DCM™ appointed by the trial to support trial mappers in completing cycle 1 of DCM™ in each intervention home.

Independent researcher: A member of the research team who is independent of the care home by virtue of not having previously collected any outcomes data there.

Mapper: Member of care home staff trained to use DCM™.

List of abbreviations

BSC: Behaviours staff may find challenging to support

CACE: Complier-Average Causal Effect

CCA: Complete Case Analysis

CDR: Clinical Dementia Rating Scale

CEAC: Cost Effectiveness Acceptability Curve

CI: Confidence Interval

CMAI: Cohen Mansfield Agitation Inventory

CMAI-O: Cohen-Mansfield Agitation Inventory - Observational

CQC: Care Quality Commission

CRF: Case Report Form

CTRU: Clinical Trials Research Unit

DAT: Dementia Awareness Training

DCM™: Dementia Care Mapping™

DEMQOL-proxy: Dementia Quality of Life measure – proxy version

DMEC: Data Monitoring and Ethics Committee

EAT: Environmental Audit Tool

EPIC: Enhancing Person-centred care In Care homes

FAST: Functional Assessment Staging of Alzheimer's Disease

GHQ-12: General Health Questionnaire – 12 item

GLHC: Group Living Home Characteristics

ICC: Intracluster Correlation Coefficient

ICER: Incremental cost-effectiveness ratio

LAG: Lay Advisory Group

MAR: Missing at Random

MICE: Multiple Imputations by Chained Equations

MNAR: Missing Not at Random

MMSE: Mini–Mental State Examination

N: Number

NICE: National Institute for Health and Care Excellence

NMB: Net monetary benefit

NPI: Neuropsychiatric Inventory

PAS: Pittsburgh Agitation Scale

PCCT: Person-centred Care Training

PPI: Patient and Public Involvement

QALY: Quality-adjusted life year

QoL: Quality of life

QOL-AD: Quality of Life in Alzheimer's disease measure

QUALID: Quality of Life in Late-Stage Dementia

QUIS: Quality of Interactions Schedule

RCT: Randomised controlled trial

RUSAE: Related Unexpected Serious Adverse Event

SD: Standard Deviation

SAE: Serious Adverse Event

SCIDS: Sense of Competence in Dementia Care Staff Scale

SCIE: Social Care Institute for Excellence

UC: Usual Care

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table

Plain English Summary

Agitation is common in care home residents and may result from care that does not meet individual needs. Dementia Care Mapping (DCM™) is a tool used within care homes to improve the delivery of person-centred care, which may help reduce agitation. This randomised controlled trial aimed to understand whether DCM™ is better than usual care at reducing resident agitation, behaviours staff may find difficult to support, anti-psychotic medicines use and for improving their quality of life and staff communication. It also assessed its value for money.

We recruited 726 residents with dementia from 50 care homes. After initial data collection, care homes were randomly assigned to DCM™ (31/50) or continue with usual care (19/50), and data were collected again after 6- and 16-months. A further 261 residents were recruited at 16-months. We also interviewed staff, relatives and residents about use of DCM™ after final data collection had taken place.

Two staff in each DCM™ home were trained to use DCM™ and were helped by an expert to use it for the first time. They were asked to use it again a further twice without support. Results showed that DCM™ was no better than usual care on any of the outcomes. It was also not shown to be value for money. Only one-quarter of care homes used DCM™ more than once. Care staff interviewed said benefits of using DCM™ included, reduced resident boredom and increased staff confidence. There were also many challenges, including the time needed to complete DCM™, lack of managerial support and problems with staffing levels.

Putting DCM™ into practice in care homes was difficult, even with expert support, and most care homes did not complete 3 DCM™ cycles. Future research should explore models of implementing DCM™ that do not rely on care home staff to lead them.

Scientific Summary

Background

At least 80% of people living in care homes have dementia. Concerns have consistently been raised about care home quality and improvement in this area has been a UK wide government research and practice development priority for over a decade. Poor quality care is associated with poor outcomes for people with dementia including an increase in behaviours staff may find challenging to support (BSC) (with the most common of these being agitation) reduced resident quality of life and increased prescribing and administration of anti-psychotic and other tranquillising medications. Person-centred care is a recommended approach to delivery of good quality care.

Dementia Care Mapping™ (DCM™) is a whole home, practice development intervention, that has been widely used in health and social care settings nationally and internationally, to support the embedding of person-centred care in practice. There is good evidence of its use in practice settings as a quality audit and improvement tool. This trial was designed to provide robust evidence on the clinical and cost effectiveness of DCM™ as an intervention to support care homes to sustainably transfer learning from person-centred care training (PCCT) into care practice. The trial aimed to determine whether DCM™ could provide a solution for achieving widespread implementation of an approach to training and practice development, which is practical for use in routine health and social care and which improves care quality and outcomes for people living with dementia.

Objectives

The primary objective of the DCM™ EPIC (Enhancing Person-centred care In Care homes) trial was to determine whether the intervention is more effective in reducing agitation in residents with dementia as measured by the total Cohen-Mansfield Agitation Inventory (CMAI) score, and more cost-effective than the control (usual care) at 16-months post-randomisation. The secondary objectives were to determine whether the intervention is more effective at reducing behaviours that staff my find challenging to support (BSC), use of antipsychotic and other psychotropic drugs, and improving mood and quality of life of residents with dementia, care home staff well-being and role efficacy, and the quality of staff/resident interactions at 6- and 16-months.

Other questions the trial sought to explore included the safety profile of the intervention, any differential predictors of the effects of the intervention, and the process, challenges, benefits and impact of implementing the intervention.

Methods

Design

The DCM™ EPIC trial was a pragmatic, multicentre, cluster randomised controlled trial utilising an open-cohort design with embedded cost-effectiveness and process evaluation analyses.

Setting

Fifty residential, nursing and dementia care homes across West Yorkshire, Oxfordshire and South London, providing care for people with dementia, were recruited using a random sampling method. Homes were eligible if they could recruit a minimum of 10 residents, had no improvement notices and were not taking part in any conflicting research.

Participants

Residents recruited at baseline were registered after care home recruitment, confirmation of eligibility, informed consent and collection of baseline data, but prior to care home randomisation. At baseline residents were eligible for the trial if they were a permanent resident in the care home, had a formal diagnosis of dementia or a score of 4+ on the Functional Assessment Staging of Alzheimer's Disease (FAST) and had sufficient proficiency in English to understand what the research involved, if able to do so. Residents were not eligible if they were known to be terminally ill, permanently bed-bound/cared for in bed or were taking part in other conflicting research.

Following a design-change to an open-cohort design, due to greater than expected loss to follow up amongst residents, further residents were recruited at 16-months. In addition to the baseline eligibility criteria, residents recruited at 16-months were not eligible if they had declined trial participation at baseline or moved into the home or participating unit less than three-months prior to screening.

Randomisation

Care homes were randomised on a ratio of 3:2 to intervention or control. Treatment arms were balanced for home/unit type (general residential/nursing, specialist dementia care), size (large≥40 beds, medium/small<40 beds), provision of dementia awareness training by research team (yes, no) and recruiting hub (West Yorkshire, London, Oxford).

Intervention

The intervention followed standard procedures as set out in the DCM™ manual and guidance. Two staff members from each intervention care home were trained to use DCM™,

followed by implementation of three standard DCM™ cycles (each comprising of briefing; observation; data analysis, reporting and feedback; and action planning). The first cycle was supported by an external DCM™ expert mapper provided by the research team, who attended the first cycle and provide additional support remotely. This is a higher degree of support that mappers would usually receive post-training, but was required to support standardised intervention implementation across all intervention care homes. To support intervention fidelity and its measurement, care homes were provided with guidelines which included standardised templates for recording attendance at briefing and feedback sessions and for DCM™ reporting and action planning. Additional mechanisms for supporting intervention adherence included sending SMS reminders and hard copies of all paperwork to mappers ahead of each cycle, and provision of telephone support from the DCM™ intervention lead. Intervention homes were asked to complete DCM™ alongside usual care.

Control

Control homes were asked to continue with usual care.

Outcome measures

The primary outcome was agitation at 16-months measured by the Cohen-Mansfield Agitation Inventory. Other resident outcomes included: BSC and mood measured by the Neuropsychiatric Inventory (NPI); quality of life measured by the QUALID, QoL-AD, DEMQOL, DEMQOL-proxy, the ED-5D-5L and ED-5D-5L-proxy; prescribed and administered medications and safety data (e.g. hospitalisations, deaths). Staff outcomes were sense of competence in caring for people with dementia using the Sense of Competence in Dementia Care Staff (SCIDS) Scale. Care home outcomes were the quality of staff interactions with residents measured using the Quality of Interactions Schedule (QUIS).

Sample size

The sample size was calculated to detect a moderate standardised effect size of 0.4 on the primary outcome: the between-arm difference in mean CMAI scores at 16-months. Fifty care homes, each recruiting 15 participants provided 90% power at a 5% significance level to detect a clinically important difference of 3-points (standard deviation (SD) 7.5 points), assuming 25% loss to follow-up and an inflation factor of 2.0 (i.e. cluster size of 11 participants available for analysis after loss to follow-up) and an intracluster correlation coefficient (ICC) no greater than 0.1. As the ICC was anticipated to be higher in the intervention arm, an allocation ratio of 3:2 was used, giving 30 (450) and 20 (300) care

homes (residents) in the intervention and control arms respectively, equating to 50 care homes (750) overall.

During the trial loss to follow-up was higher than the anticipated maximum of 25%, mainly due to death rates. In order to preserve statistical power close to 90%, and our ability to detect a moderate standardised effect size of 0.4, maintain validity and increase the generalisability of the trial, we recruited additional, newly-eligible, consenting residents from the randomised care homes at 16-months post randomisation and performed a cross-sectional analysis of the data.

Results

Out of 335 screened care homes, 241 randomly sampled care homes were approached, 94 formally expressed interest and were assessed for eligibility. Of the 63 eligible care homes, 50 consented to take part, were able to recruit a minimum of ten resident participants and were randomised into the trial; 19 to control and 31 to intervention.

At baseline, a total of 1564 residents were screened for eligibility, 1069 were eligible, 781 consented, 743 registered and 726 residents were registered at the point of care home randomisation. Following the approved design change, a further 1444 residents were screened from 48 care homes at 16-months post-randomisation. Of those, 421 were eligible, 266 consented and 261 residents were subsequently registered (99 residents in control homes and 162 in intervention homes).

Overall at 16-months, a total of 675 residents were included in the cross-sectional sample: 414 residents from the original cohort who reached 16-months and 261 additionally-recruited residents.

Primary analysis was conducted on the cross-sectional sample. All 675 residents in the cross-sectional sample at 16-months were included in the primary analysis, 666 of which had complete data. No evidence of a clinical or statistical difference was found between treatment arms in the primary outcome of agitation at 16-months. The mean adjusted difference in total CMAI score was -2.11 points lower in the intervention arm, than in the control (adjusted means 45.47 points in control; 43.35 points in intervention, 95% confidence interval (CI) -4.66 to 0.44, p=0.104). The adjusted ICC was zero in the control and 0.001 in the intervention arm.

A complier average causal effect (CACE) analysis of the cross-sectional sample, comparing care homes in the intervention arm that completed at least one cycle to an acceptable level, with care homes that would have completed at least one cycle to an acceptable level had the

intervention been offered to them, gave a mean difference in CMAI score at 16-months of -2.5 points (95% CI -5.4 to 0.4, p=0.089) lower in 'compliers' compared to 'non-compliers'.

The sensitivity analyses and the CACE analysis supported the results found in the primary analysis that the intervention is not superior to the control.

Analyses of BSC, mood, quality of life, PRN prescription medications and quality of staff interactions were conducted on closed-cohort at 6-months and on the cross-sectional sample (primary) and the closed-cohort (supportive) at 16-months. No statistically significant differences were found in the closed-cohort between arms on any resident-level or care-home level secondary outcome at 6-months. Although no statistically significant differences were found between arms in the primary cross-sectional sample at 16-months, trends in favour of the intervention in behaviours staff find challenging and mood were found in the closed-cohort at 16-months.

There were no reported unexpected serious adverse events (RUSAE).

In the health economic base case cost-utility analysis, the intervention was more costly (by £1,479) and more effective (.024 QALYs) than control. This yielded an ICER of £60,627; well above the £20,000 NICE threshold, indicating that DCM™ is not cost-effective. The cost-effectiveness analyses based on improvement in CMAI indicate that while the intervention was more costly, it was also more effective. Incremental cost per unit improvement in CMAI was £289 for intervention versus £67 for control, for the imputed and complete case samples, respectively. However, all cost-effectiveness plane simulations lie above the willingness to pay threshold suggesting that, using the base case analysis, DCM™ is unlikely to be cost-effective. The CEAC confirmed this and indicated that, where λ= £20,000, there is a very low probability that the intervention will be cost-effective.

The process evaluation identified that DCM™ implementation was poorer than expected, with 22.6% (n=7) of care homes not completing one full cycle, 51.6% (n=16) of homes completing only their first expert mapper supported cycle, 12.9% (n=4) completing two full cycles and only 12.9% (n=4) completing the three full, per protocol, cycles to an acceptable level. Mappers, managers, residents, relatives and staff interviewed were able to identify a range of benefits of using DCM™ for residents, staff and for care home practices including improved communication, staff being abler to identify resident needs and provision of more activities. A range of care home level (context, manager support, staff motivation and engagement, mapper skills and qualities), intervention level (understanding of tool and process, complexity and time demands) and trial level (expectations of DCM™ and trial, expert mapper support) barriers and facilitators to implementation were also identified.

Conclusions

This trial indicates that as a care home staff led intervention, DCM™ is not effective or cost effective at reducing agitation or improving quality of life and other care outcomes for residents with dementia living in care home settings. This outcome may be associated with the poor intervention fidelity we experienced during the trial, despite efforts to support implementation, which went beyond standard DCM practice/implementation structures. This suggests the majority of care homes may not provide the right setting conditions for a costly intervention like DCM™ and that externally led models may provide a more practical and resource effective method of implementation. However, further research is needed to evaluate this. Future research should more carefully consider the setting conditions needed for effective psychosocial intervention implementation and appropriate models for delivering interventions, given the available resources and cultural and organisational challenges of implementing complex interventions in care home settings.

Trial registration

This trial is registered as ISRCTN82288852

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Chapter 1: Introduction

1.1. Scientific background

Of those living with dementia in the UK, 38% reside in a care home [1] and at least 80% of people living in care homes have dementia. [2] In 2017 there were over 16000 care homes registered in England, including around 11,900 residential homes, 4500 nursing homes and [3], the majority of which provide care for older people. Concerns have consistently been raised about care home quality. [4, 5] Improvement in care quality and staff knowledge and skills has been a consistent UK government research and practice development priority for nearly a decade [6-9] . Poor quality care is associated with poor outcomes for people with dementia including an increase in behaviours staff find challenging (BSC).[10, 11] Developing an informed and effective care homes workforce is a strategic component of improving care quality, [6, 12] however, there remains limited robust evidence regarding effective evidence-based staff training and practice development interventions for care homes providing care for people with dementia. [13, 14] Furthermore, it is often difficult to achieve the widespread implementation into real-world practice, of evidence-based training interventions developed in the context of research. [14, 15]

Dementia Care Mapping™ (DCM™) [16, 17] is a whole home, practice development intervention, that has been widely used in health and social care settings nationally [18] and internationally, [19] to support the embedding of person-centred care in practice. There is good evidence of its use in practice settings as a quality audit and improvement tool. [20-29] This trial was designed to provide robust evidence, on the effectiveness and cost effectiveness of DCM™ as an intervention to support care homes to sustainably transfer learning from person-centred care training (PCCT) into care practice. The outcomes of the trial aimed to determine whether DCM™ could provide a solution for achieving widespread implementation of an approach to training and practice development, which is practical for use in routine health and social care.

1.1.1 Behaviours staff may find challenging (BSC)

The behaviours that may be expressed by people with dementia in care home settings such as agitation, aggression, restlessness, hallucinations, delusions, depression, anxiety and apathy, may be experienced by staff as challenging to support. [30] These BSC are also known as ‘neuropsychiatric’ or ‘behavioural and psychological symptoms of dementia’ (BPSD). We have chosen to use the term BSC rather than BPSD as it reflects a more person-centred terminology that better emphasises the bio-psycho-social causes of such behaviours. It also represents the terminology used by relatives and staff in care home settings. Up to 90% of people living with dementia experience one or more of these

behaviours during the course of their condition [30] and BSC are reported in up to 79% of care home residents at any one time. [31] BSC also cause distress to the people with dementia experiencing them, [32] are associated with reduced quality of life [33, 34] and have a negative impact on the well-being of other residents. [35] BSC also have significant associated costs [36, 37] including increased risk of hospitalisation, [38, 39] Accident and Emergency use [37] and production of excess disability; meaning functional abilities of people decline more quickly than is otherwise expected. [37] Therefore, reducing BSC has the potential to improve the quality of life of people with dementia living in care homes as well as reduce costs of providing care to this group.

Agitation is the most common, [31, 40] distressing to the person with dementia [32] and the most difficult to manage [41] BSC in care home settings. Agitation includes aggressive behaviours, physically non-aggressive behaviours and verbal agitation, [42] including pacing, spitting, verbal aggression, constant requests for attention, hitting, kicking, pushing, throwing things, screaming, biting, scratching, intentional falling, hurting self and others, making sexual advances and restlessness. [43] The presence of these behaviours puts the person who is agitated at risk of triggering aggressive responses from other residents [44] and causes distress for other residents, the person's family and staff. Rates of over 60% of nursing home residents with dementia displaying agitation are reported, [45, 46] making it an extremely common as well as potentially harmful BSC for the people experiencing it, other residents and staff.

The presence of agitation is reported as highly challenging, compared to other BSC, in terms of clinical management.[41] Agitation places increased burden on care staff [47, 48] who feel less confident in dealing with situations where residents are agitated than in their management of other BSC. [49] There is an association between a person with dementia experiencing agitation and fewer visits from relatives, experiencing social isolation [48] and poorer quality of life. [33] The frequency of agitated behaviours, the difficulties staff have in their management and the potential risks they pose to the person, other residents and staff, means that drug treatments such as antipsychotics and other psychotropic medications may frequently be prescribed as a first line management approach. However, links of antipsychotics to stroke and excess deaths [50] mean their reduced use is an ongoing priority. [4, 9] There is a concern that the mandated reduction in antipsychotic prescribing may in turn lead to the prescription of other psychotropic drugs as an alternative. [51, 52] despite lack of evidence of efficacy. Investigating psychosocial approaches to reduce the incidence of agitation and to support staff with BSC is therefore a research priority. [5]

Agitation and other BSC are not an inevitable consequence of dementia. Agitation is often exacerbated by the poor care practices and environment surrounding the person with dementia [53] as well as by poorly managed physical health and pain. [41, 54] They often reflect an expression of unmet needs by a person with dementia in response to inadequate understanding of a person's needs or poor quality care. [4, 54, 55] This is often related to lack of stimulation and engagement for the person with dementia. [56] For example, Brodaty et al [57] found significant variability between care homes in terms of the proportions of residents within each setting who displayed BSC, indicating a care home level effect that may include both admissions criteria and care practices. Likewise, Weber et al [58] report a significant reduction in BSC when people with dementia attended a therapeutic day hospital programme compared to when at home, again indicating the impact of the psychosocial environment. The presence of agitation within individuals with dementia in care home settings is, therefore, likely to be associated with organisational aspects of care and the care culture. [54] Therefore, the use of psychosocial interventions that address the quality of care practice [4, 59-61] are recommended, with agitation being a key treatment target area for people with dementia in care homes. [62]

1.1.2 Person-centred care

Person-centred care is an effective psychosocial approach in dementia care, [63] considered a best practice approach to reducing agitation and other BSC. [59] Person-centred care means providing a supportive social environment within a care setting where people with dementia are valued, treated as individuals, and staff are encouraged to see the world from their perspective. [59, 64] Person-centred care, therefore, involves evaluating and responding to the unique needs of each person with dementia and offering an individualised approach. The National Institute for Health and Care Excellence and Social Care Institute for Excellence (NICE/SCIE) dementia guideline [59] recommends individualised, holistic or person-centred assessment and care planning, with regular review and individually tailored and monitored psychosocial interventions for BSC. Delivery of care that is person-centred is associated with a reduction in agitated behaviours [65] and BSC more generally [61] and reduced use of anti-psychotics. [63, 66, 67] Bird et al [68] found that multifaceted, individualised interventions lead to significant reductions in BSC. Therefore, the most useful interventions to effect change identify individual causes of BSC and suggest appropriate person-centred solutions. [68-70] This approach is reliant on staff having the required knowledge, skills and confidence in delivery of person-centred care. Provision of person-centred support is an element of the common induction standards [71] for all social care workers in England. Provision of at least

basic training to staff on person-centred care is expected within all care homes in England [59] and is a regulatory requirement. [72] Currently, there are no widely implemented, quality criteria for person-centred care training (PCCT) and content, approaches, quality and efficacy of PCCT vary considerably across the sector. [73] Effective PCCT can produce immediate practice benefits, [65, 67] however due to the variability of the amount, content and quality of PCCT staff receive across the sector, knowledge, skills and staff confidence levels in relation to delivery of person-centred care remain a concern. [49, 74] Research indicates standardising PCCT is unlikely to address these issues [14] and therefore, evidence-based approaches to help staff sustainably embed PCCT into practice are required. [15]

Whilst effective PCCT can produce immediate practice benefits, evidence suggests, that PCCT alone might not sustain change over time [13, 65, 67, 75] and that PCCT needs to be accompanied by an additional intervention to support ongoing change. [66, 76] For example, Fossey et al [66] employed PCCT alongside a comprehensive 10-month focussed intervention for training staff (FITS) including ongoing staff training and support. At post-test antipsychotic medication use had decreased by over 40% in the intervention group. Chenoweth et al [63] provided PCCT to two staff members who then disseminated person-centred care practice across the site. Researchers provided additional individualised care planning and ongoing telephone support during a 4-month intervention period. At 10-months post-randomisation, agitation levels were significantly lower than in the usual care control sites. A limitation of both of these studies is that it is unclear whether PCCT, additional support or both caused the effect. Evidence of efficacy of PCCT after a longer follow-up period is limited, [13] however, Moniz-Cook et al. [67] found the benefits of PCCT alone were not sustained at one-year. The PCCT programmes evaluated thus far indicate that embedding additional support alongside the training intervention is required to produce sustained benefits. [15, 77, 78] Implementing evidence-based health care interventions in real world practice is a recognised challenge, with barriers to implementation of research-designed interventions reported across all areas of practice. [79-81] Current successful interventions that combine staff training with ongoing support, such as the FITS, [66] are resource intensive requiring regular ongoing input from a specialist practitioner and have not yet been possible to implement widely in everyday practice. [82] Interventions that provide staff with knowledge to support BSC that are cost-effective and feasible to implement are required. Any such intervention will need to accommodate the varying amounts, content and quality of PCCT that is a feature of the sector. DCM™ is an intervention that may address this issue.

1.1.3 Dementia Care Mapping™ (DCM™)

DCM™ [16, 17] is an established, routine care home/NHS practice development intervention, recommended in the NICE/SCIE dementia guideline [59] that is regularly used for ensuring a systematic approach to providing individualised person-centred care. DCM™ is an observational tool, set within a practice development cycle used to support the sustained implementation of PCCT in dementia care practice. [83] Following initial formal training of care staff to use the tool, application includes five phases: briefing, observation, data analysis and reporting, feedback and action planning. A detailed overview of the DCM™ intervention is provided in section 2.5.2. This cycle is repeated every 4-6 months to monitor and revise action plans. DCM™ implementation therefore, requires no external input over the long term and is thus potentially less resource intensive and more closely aligned with real world dementia practice than other interventions aiming to address BSC. [66]

Whilst DCM™ has been used in dementia care for nearly 20 years including in care home settings, [25, 84-87] and has strong face validity within the practice field, [88] there is limited robust evidence of its effectiveness in relation to clinical outcomes such as reduction of BSC. Reported benefits of DCM™ include the improvement of well-being in people with dementia, [22, 27, 89] helping staff consider care delivery from the point of view of the person with dementia, the production of evidence to underpin action planning that in turn motivates staff and increases their confidence to deliver person-centred care. [87, 88]

1.2 Evidence of the effects of Dementia Care Mapping™

There are only six published studies, which have examined the benefits of using DCM™ for improving clinical outcomes in care homes; two pilot studies employing a pre-test/post-test design, [90, 91] one quasi-experimental controlled trial [92] and three cluster RCTs. [63, 93, 94] None were carried out in the UK. At the time of submission of the grant application for this trial only the two pilot studies [90, 91] and one of the RCTs had been published. [63]

A pilot study conducted in the Netherlands [91] utilising a One-Group Pre-test/Post-test design found DCM™, used alone, reduced verbal agitation and anxiety in people with dementia. It also improved care staff feelings of connection with clients. A pre-test/post-test design pilot study [90] conducted in three Australian care homes, found DCM™ led to improvements in the quality of staff interactions and reductions in agitation and depression, compared with three control homes. A quasi-experimental controlled trial conducted in Germany, [92] compared outcomes at 6- and 16-months to baseline. Nine nursing homes units, located in nine nursing homes owned by the same group were allocated not at random to one of three arms; no intervention control group (n=3), DCM™ experienced intervention group (n=3) and DCM™ intervention group (n=3). The DCM™ experienced group had been exposed to two

externally delivered DCM™ cycles annually over a number of years. The DCM™ intervention group had no previous exposure to DCM™, but had expressed an interest in undertaking the method. Two staff members from both intervention groups received DCM™ training and were requested to implement three DCM™ cycles over 18-months. The control group received an intervention based on training staff about quality of life, followed by QoL assessment using a standardised tool, of all care home residents at least every 6-months. The study found no significant differences between the two intervention groups and control, or the two intervention groups on QoL or BSC.

The first cluster RCT evaluating the efficacy of DCM™ was conducted in Australia [63] in 15 care homes randomised equally between three arms (usual care (control), person-centred care training (PCCT), DCM™) and included 289 people with dementia (18% loss to follow up at 10-months). The trial found that at 10-months post randomisation, DCM™, when used alone, was associated with significantly reduced agitation and falls in people with dementia compared to control and PCCT and reduced staff feelings of burnout. [95] A three-arm cluster RCT [93] was also conducted in 15 care homes in Norway, randomising equally between control group, person-centred care framework implementation and DCM™. The study recruited 446 people with dementia (29% loss to follow up at 10-months). It found significant reductions in overall neuropsychiatric symptoms as measured by the Neuropsychiatric Inventory (NPI), in agitation and psychosis as measured by the NPI sub-scales and a significant improvement in quality of life compared to the usual care control. Both trials had explanatory designs involving researcher-led cycles of DCM™ with variable degrees of input from trained care home staff, restricting generalisability of the results, since usual implementation of DCM™ is practitioner-led. A Dutch cluster RCT conducted in 34 units, across 11 care homes compared DCM™ to usual care control. [94] It recruited 434 residents (35% loss to follow up at 12-months) and found no difference in residents' agitation between the DCM™ intervention and control homes. Positive staff outcomes were found in the intervention group including significantly fewer reported negative emotional reactions and significantly more positive reactions towards people with dementia. The trial authors identified potential DCM™ intervention fidelity issues, indicating less than desirable implementation in some clusters. All three RCTs were exploratory and each only included two full cycles of DCM™ before final follow-up, with follow-up periods of only 10-12 months post-randomisation, reducing the time for potential change and impact to be realised.

Results of these existing studies are mixed in terms of reported efficacy of DCM™. The studies that included researcher-led cycles of DCM™ (Australia, Norway) showed efficacy for some outcomes, whereas studies with care home staff led cycles of DCM™ have shown no benefits of DCM™ (Netherlands, Germany). A recent systematic review of DCM™

implementation [96] found limited research in this area, with implementation found to be challenging across a number of the published studies. There was some consensus that appropriate mapper selection, preparation and ongoing support during DCM™ implementation, alongside effective leadership for DCM™ within an organisational context of commitment to delivery of person-centred care, could support better implementation.

In summary limitations of existing studies include:

- Relatively small number of clusters (Australia, Germany) or small numbers of care homes containing multiple clusters (Netherlands, Norway);
- Use of DCM™ alone rather than alongside PCCT in accordance with UK best practice guidelines [83] (Australia, Netherlands), reflecting the context within each country at the time of the trial, for example in Australia where PCCT was the exception rather than assumed good practice;
- Only two full cycles of DCM™ before final follow up limiting the potential for impact, based on the length of time that changes within care home practice can take to implement and thus demonstrate potential resident benefits (Australia, Norway, Netherlands);
- Follow up period of no more than 12-months post randomisation, reducing the time for potential change and impact to be realised (Australia, Norway);
- Explanatory trial design (Australia, Norway) involving researcher-led cycles of DCM™ with variable degrees of input from trained care home staff, potentially limiting staff ownership of the DCM™ process, implementation of any action plans and longer-term sustainability of DCM™ use. This also restricts generalisability of the results to usual implementation of DCM™ in care practice, which is practitioner-led;
- No formal, published process evaluation (Australia, Norway);
- Studies conducted in Australia, Norway, Germany and the Netherlands where care-funding, policy, context, regulations and processes are different to the UK.

Despite promising results on the potential efficacy of DCM™ in care home settings, the conduct of these trials in countries where usual care practices, funding and systems are different and where DCM™ was implemented differently to its use in the UK, means their results cannot be directly transferred. A definitive RCT evaluating the effectiveness and cost effectiveness of DCM™ for helping staff to implement person-centred care in UK care home settings, building on this previous work, was needed to inform future UK care home practice.

1.3 Rationale for the research

The knowledge intended to be gained from this trial, beyond that within existing RCTs was:

- Utilisation of a pragmatic trial design reflecting the conditions of DCM™ implementation in usual practice in UK care home settings, compared to the explanatory designs of the previous trials. In particular, trained care home staff rather than researcher-led cycles of DCM™ implementation were utilised. The trial design, size and statistical power allowed definitive conclusions to be drawn regarding effectiveness of DCM™ as an intervention in usual practice within UK care home settings.
- Previous RCTs had conducted only one or two DCM™ cycles with a follow-up period of a maximum of 12-months. In this trial it was intended that care homes implement three cycles of the DCM™ intervention with follow-up over a period of 16-months. This is beneficial since some anticipated practice changes, for example to underlying care culture, are likely to require time to implement. Also given annual staff turnover rates of around 30% [97] in care homes potentially leading to longer term implementation challenges, a longer follow-up period was necessary to investigate whether longer term effects and sustainability could be achieved within this context.
- A full economic evaluation within this pragmatic trial design was included, offering a definitive position on cost-effectiveness. Only one of the previous trials conducted an economic evaluation and given its explanatory design and conduct in a funding system different to the UK, the findings cannot be confidently generalised.

The design of this trial built on existing explanatory trials, to offer a definitive assessment of the effectiveness and cost-effectiveness of DCM™ as a standard clinical intervention in care home settings.

1.4 Aims and Objectives

The aim of the DCM™ EPIC cluster-randomised controlled trial was to evaluate the clinical and cost-effectiveness of DCM™ implemented in addition to usual care (intervention) compared to usual care (control) for people with dementia living in care homes in the UK.

It aimed to answer the following primary and secondary research questions:

1.4.1 Primary research question:

Is the intervention:

(i) more effective in reducing agitation in residents with dementia as measured by the total Cohen-Mansfield Agitation Inventory (CMAI) score and

(ii) more cost-effective than the control,

16-months following randomisation of care homes?

1.4.2 Secondary research questions:

Is the intervention more effective than control, at 6 and 16-months post-randomisation at:

(i) reducing BSC in people with dementia over time?

(ii) reducing the use of antipsychotic and other psychotropic drugs in residents with dementia?

(iii) improving mood and quality of life in residents with dementia?

(iv) improving care home staff well-being and role efficacy?

(v) improving the quality of staff/resident interactions over time?

Other questions the trial sought to explore related to:

(vi) the safety profile of the intervention as assessed by the number and types of adverse events;

(vii) any differential predictors of the effects of the intervention, and

(viii) the process, challenges, benefits and impact of implementing the intervention.

Chapter 2: Trial design and methods

2.1 Trial design

This section reports the trial design and procedures at the commencement of trial recruitment. The original trial protocol is published elsewhere. [98] Subsequent amendments to the original trial protocol, after trial commencement, are highlighted throughout this section and then reported in detail in section 2.10.

This trial was a pragmatic, multi-centre, cluster-randomised controlled trial of Dementia Care Mapping™ plus usual care (intervention) versus usual care alone (control) in residential, nursing and dementia care homes across West Yorkshire, Oxfordshire and South London, for people with dementia.

Due to greater than expected loss to follow-up during the trial, a design change was approved to move from a closed-cohort to an open-cohort design, with additional residents recruited at 16-month follow-up and the cross-sectional sample of residents used within the primary analysis (see section 2.10). The cross-sectional sample of residents was used in the primary statistical analysis (and a secondary health economic analysis), defined at baseline and 16-months respectively as all residents registered at care home randomisation and at 16-months. The closed-cohort sample of residents was used in the primary health economic analysis (a supportive statistical analysis and all analyses of 6-month outcomes), defined simply as all residents registered at care home randomisation.

Since DCM™ is aimed at changing practice across the whole care home setting and it is not possible to limit the potential effects to the care provided to only a sample of people with dementia living in the home, a cluster design was justified. This influenced the decision to consider two important sources of clustering: cluster-randomisation and DCM™ treatment provision, with care homes nested within treatment arms. Due to this we anticipated that the clustering effect would vary across arms, with a higher ICC in the intervention arm. Therefore, an unequal allocation of care homes on a ratio of 3:2 to intervention and control respectively was implemented. An integral cost-effectiveness analysis and a nested qualitative process evaluation were included.

2.2 Ethical approval, research governance and study oversight

Ethical approval for the study was granted by NRES Committee Yorkshire & The Humber - Bradford Leeds on 14th February 2013, REC ref 13/YH/0016. Care home insurance and

indemnity applied to trained mappers who implemented the intervention within the care home setting. Appropriate site-specific approvals were obtained from the three participating hubs; Yorkshire (Bradford Teaching Hospitals NHS Foundation Trust), Oxford (Oxford Health NHS Foundation Trust) and London (Guy's and St Thomas NHS Foundation Trust). The trial was registered with the International Standard Randomised Controlled Trial Register (ISRCTN) reference 82288852. Day to day management of the trial was undertaken by a Trial Management Group (TMG) comprised of the co-applicants, trials researchers and staff and a patient and public involvement representative. This group met twice before the official start of the project, monthly during trial set-up and then bi-monthly or quarterly subsequently. Updates on trial progress were provided by e-mail between meetings. A Lay Advisory Group was established and contributed to TMG decisions (see section 2.13).

Trial steering committee

The trial was overseen by a Trial Steering Committee (TSC), comprised of five independent members (three academic members, one patient and public representative and one care home representative). The TSC monitored trial recruitment, retention, timelines, intervention adherence, data return and quality and considered new issues. It also provided advice and approval for changes to the protocol or trial procedures. It met approximately 6-monthly throughout the trial.

Data Monitoring and Ethics Committee

An independent Data Monitoring and Ethics Committee (DMEC), comprised of four academic members met approximately 6-monthly during the trial. They reviewed unblinded data, recruitment, retention, intervention implementation and safety by group. The DMEC also undertook annual review of any Serious Adverse Events (SAEs).

2.3 Participants

It was intended that 750 residents with dementia from a random sample of 50 care homes would be recruited as well as participants' relatives and care home staff.

2.3.1 Care Home eligibility, recruitment and consent

2.3.1.1 Care home eligibility

To be eligible for the trial a care home was required to:

1) Have a sufficient number of permanent residents with dementia (based on a formal diagnosis or Functional Assessment Staging of Alzheimer's Disease (FAST) score of 4+) eligible to participate, in order to achieve a minimum of 10 residents registered to the trial prior to care home randomisation;
2) Have a manager or nominated person agreeing to sign up to the trial protocol as research lead for the duration of the project;
3) Have agreed to release staff for DCM™ training and subsequent mapping processes;
4) Be within the trial catchment area.

Care homes were not eligible for the trial if:

1) They were subject to Care Quality Commission (CQC) enforcement notices, admission bans or relevant moderate or major CQC compliance breaches;
2) They were receiving other special support for specific quality concerns, such as being currently subject to, or had pending, any serious safeguarding investigations, or receiving voluntary or compulsory admissions bans, or local commissioning special support due to quality concerns;
3) They had used DCM™ as a practice development tool within the 18-months prior to randomisation or were planning to use DCM™ over the course of trial involvement;
4) They were currently, recently or were planning to take part, in another trial that conflicted with DCM™ or data collection.

Where a care home was a large multi-site or multi-floor establishment, one or two units with the largest percentage of residents with dementia, or where the manager felt DCM™ implementation would be most beneficial, were selected to participate as one home.

2.3.1.2 Care home recruitment

Catchment areas for each recruitment hub (Leeds Beckett University, Kings College London, Oxfordshire Health NHS Trust) were established based on post-code districts/boroughs in West Yorkshire, South London and Oxfordshire respectively. All care homes in the catchment areas were identified and screened for initial eligibility via publicly available information (home type, number of beds, CQC status). Care homes deemed eligible were randomly ordered within catchment areas and divided into batches. The first batch of homes from each hub were sent the Care Home Information Sheet (see *Supplementary Material*) by post. A researcher then contacted the care homes by telephone within one to three weeks to

determine interest in taking part. If a care home expressed interest in taking part, the Researcher conducted initial eligibility screening ahead of visiting to determine full eligibility and to initiate care home consent and management permissions (see *Supplementary Material*). If the researcher was unable to make contact with the care home following several attempts, a decision was made to cease attempting to contact. Once all care homes within a batch had been contacted, or deemed uncontactable, the next batch was approached until sufficient homes were recruited.

2.3.1.3 Dementia training audit and provision of dementia awareness training

As person-centred care is considered best practice within UK care homes [59] it was expected that homes would have routinely provided staff with appropriate PCCT. [72] As the quality of PCCT is variable across the sector in the UK, to ensure that each care home met at least minimum dementia awareness training standards, a training audit was developed by the research team and its content and minimum standards required in the trial are reported elsewhere. [99] The training audit was completed in each care home prior to baseline data collection. The researcher completed this via review of training records and discussions with the home manager and/or other relevant staff (e.g. training lead). Where homes fell below the minimum standard they received a half-day dementia awareness course modified in consultation with service users, from an existing resource developed by Bupa Care Services and the University of Bradford. [100] The course was delivered by an experienced trainer/mentor who coached a member of the care home staff to be able to onward deliver to additional staff. Care homes were expected to deliver the training to at least 20% of permanent direct care staff prior to baseline data collection and to complete paperwork detailing how many staff members received the training and when. Based on CQC data, [101] we expected up to 20% of homes to require this dementia awareness package.

2.3.2 Resident eligibility, recruitment and consent

Residents were recruited to the trial at baseline, prior to care home randomisation. Further residents were recruited at 16-months following a design change to the study, due to larger than anticipated loss to follow-up (see *section 2.10.2*).

2.3.2.1 Resident eligibility

At baseline residents were eligible for the trial if they:

1) Were a permanent resident in the care home and not present for receipt of respite or day-care;
2) Had a formal diagnosis of dementia or a score of 4 or higher on the Functional Assessment Staging of Alzheimer's Disease (FAST) [102] (indicating mild to severe

dementia) as rated by the home manager or another experienced member of staff;
3) Were appropriately consented (in accordance with Mental Capacity Act 2005 [103] and clinical trials guidance on informed consent [104, 105]);
4) Had an allocated member of staff willing to provide proxy data;
5) Had sufficient proficiency in English to contribute to the data collection required for the research.

At baseline residents were not eligible for the trial if:

1) They were known by the care home manager and/or relevant senior staff member to be terminally ill, e.g. formally admitted to an end of life care pathway;
2) They were permanently bed-bound/cared for in bed;
3) They were currently in, or had recently taken part in, or were planning to take part in, another trial that conflicted with DCM™ or with the data collected in the trial.

2.3.2.3 Resident screening

The researcher with the care home manager and/or a relevant member of senior staff, screened all care home residents to identify eligible people with dementia to be approached to take part in the trial. The basic demographics of all residents and their eligibility or reasons for ineligibility at screening were recorded, using only the screening number,

2.3.2.4 Resident informed consent

In accordance with the Mental Capacity Act 2005, [103] all eligible residents were assumed to have capacity to consent unless assessed otherwise. The manager/senior staff member approached each eligible resident and sought their permission for the researcher to speak with them. If the resident had capacity and gave verbal consent to speak to the researcher, this was documented and the researcher approached them to discuss the study. If the resident was deemed to lack capacity to make this decision, then the process for appointing a consultee was followed (see *section 2.3.2.4.2*).

The researcher approached each resident who had capacity and agreed to speak to them, to explain the trial using the appropriate documentation and to undertake a further documented assessment of capacity to give informed consent. The resident was provided with the Resident Information Sheet (see *Supplementary Material*) and at least 24-hours later, they were given the opportunity to ask any further questions and then, for those with capacity, formal consent to participate in the trial was sought. If the resident was deemed by the Researcher at any point to lack capacity to consent, the process for appointing a consultee was followed (see *section 2.3.2.4.2*).

2.3.2.4.1 Consent for those with capacity

Residents who were able to give informed consent were asked to sign, or make a mark on, the trial consent form (see *Supplementary Material*). For those who were not able to sign, a witness confirmed that informed consent had been given. Given the progressive nature of dementia, a further capacity assessment was conducted at each data collection point by the researcher to assess continued capacity. In the case of residents who lost capacity during the trial, appropriate guidance on consent in the light of changed capacity was followed [106], involving appointment of a consultee (see *section 2.3.2.4.2*). Where a resident had capacity and consented to taking part in the trial, consent to approach his/her main carer (relative/friend) was sought, regarding their participation as a proxy informant.

2.3.2.4.2 Consent for those without capacity

Where a resident was assessed to lack capacity to give informed consent a 'Personal Consultee' was appointed to give advice on the resident's wishes. This was usually a relative or close friend. Where the resident had no close family or friend able or willing to act as Personal Consultee, a member of staff in the care home who knew them well but who was not actively involved in any elements of the research process (e.g. as a mapper or in giving proxy data on the resident), was appointed as a 'Nominated Consultee'.

If the proposed Personal Consultee was present in the care home, they were approached by the researcher and given all the appropriate documentation (see Supplementary Material) in person and asked for written consent to hold their personal details to enable the researcher to directly contact them thereafter. The proposed Personal Consultee was given at least 24-hours to talk to the resident and other relatives/friends about the resident's wishes. The personal consultee was then asked to return the declaration form by post, within a week, expressing their advice on the resident's wishes regarding taking part in the trial. If the Personal Consultee was not present in the care home, the documentation was sent to them by post, via the care home, on the researcher's behalf. Details of how to contact the researcher should they wish to discuss the role were provided. For both methods of approach, if the declaration form had not been returned after a week, a follow up reminder was sent by post by the researcher informing the Personal Consultee that a Nominated Consultee would be identified if no response was received within a week. If after a further week the declaration form had not been returned the process of appointing a Nominated Consultee was followed.

A Nominated Consultee identified by the manager was approached using the appropriate documentation (see *Supplementary Material*) to discuss the resident's potential involvement in the trial with the resident, other staff members who knew them well and any

relatives/friends. The Nominated Consultee was then asked to complete the declaration form providing advice on the resident's wishes.

Personal and Nominated Consultees were advised that they could approach the researchers at any time to indicate if they felt the person they were representing had changed their mind about participating in the trial, and to withdraw them from participation. Given the frailty of the population who may be serving as Personal Consultees, a review of Personal Consultees' capacity was undertaken by the researcher via the care home manager at 6- and 16-month follow-up, where feasible.

2.3.3 Staff roles, eligibility, recruitment and consent

2.3.3.1 Staff roles

There were five staff roles within the trial, some which were mutually exclusive (Table 1):

i) To act as a Nominated Consultee for residents (see *section 2.3.2.4.2*);
ii) To provide data on standardised measures relating to their role (see *section 2.3.3.2*);
iii) To provide proxy informant data on residents they know well (see *section 2.3.3.3*);
iv) To become a trained DCM™ mapper (see *section 2.5.2.1*);
v) To participate in the trial's process evaluation (see *section 2.9*).

Table 1: Role Summary

	Nominated Consultee	DCM™ mapper	Proxy informant
Nominated Consultee		X	X
Staff measures	X	✓	✓
Proxy informant	X	X	
DCM™ mapper	X		X
Process evaluation	X	✓	✓

2.3.3.2 Staff measures

To be eligible to complete a staff measures booklet, staff were required to be a permanent, contracted, agency or bank member of staff at the time of data collection and have sufficient proficiency in English. Consent to participate in this role was assumed through staff return of the booklet. The staff measures booklets and accompanying information sheets (see *Supplementary Material*) were distributed to all eligible staff members at each data collection visit by the researcher, or care home manager. Booklets were returned anonymously by the

staff member either via a sealed envelope to a locked box located within the care home or posted directly to the research office in the stamped return envelope provided.

2.3.3.3 Proxy informant eligibility, recruitment and consent

To be eligible to act as a proxy informant and provide proxy data on a resident, staff had to be a permanent or contracted member of staff who knew the resident well. Bank or agency staff were not eligible for this role. Potential proxy informants were identified by the care home manager/senior member of staff using the appropriate trial documentation (see *Supplementary Material*). Where possible the same proxy informant was used for each resident throughout the trial, although this was not always possible due to staff turnover, annual leave and shift patterns.

2.3.4 Relative/friend eligibility, recruitment and consent

Where possible a relative or friend who visited the care home regularly was identified for each participating resident, to provide proxy data. The relative/friend proxy was identified either in discussion with the resident or the care home manager/senior member of staff. They could also act in the role of Personal Consultee. To be eligible to provide proxy data, relatives/friends were required to visit the resident at least once per week over the last month, be willing to provide data either by telephone or post during the data collection week and to have sufficient proficiency in English to contribute to the data collection required. Relatives/friends were approached either in person by the care home manger or researcher or by post, depending on visiting patterns and times using the appropriate trial documentation (see *Supplementary Material*).

Relative/friend recruitment took place at baseline and continued at 6-month follow-up in some homes until December 2015 when the decision to cease further recruitment was made, due to low overall relative/friend recruitment. Data continued to be collected from consented relatives/friends throughout the trial. Their continuing eligibility for participation was reassessed at each subsequent data collection point because of changing patterns of visiting over time. Where relative/friend proxies withdrew from the trial, additional participant relatives/friends were not recruited.

2.4 Registration, Randomisation and Blinding

2.4.1 Registration of residents

Residents recruited at baseline were registered with the Clinical Trials Research Unit (CTRU) University of Leeds following care home recruitment, training review (see *section 2.3.1.3*) eligibility confirmation, obtaining informed consent and resident-level baseline data collection, but prior to care home randomisation. Following a design change (see *section 2.10*) additional residents were recruited at 16-months and were registered with the CTRU after confirmation of eligibility, informed consent and collection of their resident-level data.

2.4.2 Randomisation, stratification and blinding

Immediately following baseline, once all residents, staff and relatives/friends were recruited and registration complete, care homes were randomised using the 24-hour automated randomisation system at the CTRU. Care homes fulfilling eligibility criteria were randomised on a 3:2 basis, to receive either intervention or control. A computer generated minimisation programme was used, [107] incorporating a random element to ensure arms were balanced for the following care home characteristics:

- Home/unit type (general residential/nursing, specialist dementia care);
- Size (large>=40 beds, medium/small<40 beds);
- Provision of dementia awareness training by research team (yes, no);
- Recruiting hub (West Yorkshire, London, Oxford)

To maintain blinding of trial researchers collecting data within care homes, randomisation was performed by CTRU Data Management, who were therefore not blind to treatment allocation. Following randomisation, the CTRU informed the care home manager of the treatment allocation, by phone call or e-mail. The Intervention Lead was notified of homes allocated to intervention, so that arrangements could be confirmed for training with consented mappers and contact with the DCM™ expert mapper initiated. Researchers were not informed of treatment allocation and agreed procedures were applied to maintain blinding throughout the trial. Other CTRU staff were only informed of treatment allocation if this was required to undertake their role. All occurrences of unblinding and the reasons for/method of unblinding were recorded.

As researchers were blinded they were unaware of the identity of trained mappers. Therefore, a text message was sent to mappers in the intervention homes by CTRU trial management staff, ahead of data collection at 6- and 16-months, to remind them not to provide proxy informant data if requested to do so.

2.5 Procedure

2.5.1 Usual care (both arms)

Usual care was defined as care routinely delivered within the setting, and was continued in all participating care homes with no restrictions imposed on current practices or on homes undertaking additional development or training. The exception was that control arm homes were required not to implement DCM™ during the trial period. Details regarding any changes in usual care practice during the course of the trial (e.g. new staff roles, change of ownership, new practice initiatives or training programmes) were documented by the researcher at follow-up visits.

To facilitate a person-centred primary care response to BSC should care homes seek support, all General Practitioners (GPs) who served each care home were provided with generic best practice guidance about the implementation of person-centred care and managing BSC, irrespective of whether the residents they provided services to were participating in the trial. We did not inform individual GPs about which residents were participating in the trial.

2.5.2 Dementia Care Mapping™ (intervention arm)

The intervention followed standard procedures as set out in the DCM™ manual and guidance. [17, 108] Two staff members from each intervention care home were trained to use DCM™, followed by implementation of (ideally) three standard DCM™ cycles (each comprising of briefing; observation; data analysis, reporting and feedback; and action planning), in accordance with the British Standard best practice guideline. [83] In addition, care homes were provided with fidelity guidelines which included standardised templates for recording attendance at briefing and feedback sessions and for DCM™ reporting and action planning. Other mechanisms for ensuring adherence to intervention and supporting mapper engagement were implemented including, support from a DCM™ expert mapper during cycle one (see *section 2.5.2.5*) and sending SMS reminders to mappers ahead of each cycle.

2.5.2.1 Mapper identification, eligibility and consent

Two staff in each home were identified by the manager as suitable to be trained in use of DCM™ (mappers). To ensure timely progression from care home randomisation to DCM™ training, and to avoid selection bias, two mappers were identified in every consenting home at care home recruitment and their informed consent to undertake the mapper role was

gained. To be eligible staff had to be a permanent or contracted staff member, have the right skills and qualities as assessed by the home manager against a mapper role descriptor provided by the research team (see *Supplementary Material*), agree to implement DCM™ per protocol and to take part in the process evaluation, if required.

Potential mappers were initially approached by the manager with reference to the written mapper role description. Once verbal consent was obtained, the researcher discussed the role and responsibilities of mappers again with reference to the role descriptor and mapper information sheet, before gaining their written informed consent (see Supplementary Material). If a mapper withdrew or left the care home before the end of the trial, where feasible, another suitable member of staff was identified, consented and trained using a similar procedure, to ensure continuity of DCM™ implementation in the home.

2.5.2.2 Training

Following randomisation, care homes allocated to intervention received DCM™ training as soon as their mappers were able, depending in part upon the course schedule.

All trial mappers attended a standard four-day DCM™ training course held in Bradford or London and provided by the University of Bradford. It included an assessment of competency in use of DCM™. One further attempt at the assessment for attendees failing to achieve a pass mark at the first attempt, was permitted. The course trainers were informed which attendees were EPIC trial mappers in advance. They provided data as to which mappers had successfully completed and passed the course.

2.5.2.3 Implementation

Following completion of the formal, assessed training course, implementation of DCM™ commenced, comprising a practice development cycle of: briefing the staff team; observation over a number of hours; data analysis, reporting and feedback to the staff team; and action planning. Re-mapping at regular intervals forms part of the standard process, to monitor progress and set new action plans. Intervention homes were scheduled to complete their first cycle at 3-months post randomisation (or as soon as practicable), their second cycle at 8-months and their final cycle at 13-months. Ahead of each mapping cycle the trial manager at CTRU contacted mappers individually via SMS to remind them of the upcoming cycle. Paper documents were posted to them to prompt completion of the cycle.

2.5.2.3.1 Briefing

Mappers were asked to run at least one briefing session 1-2 weeks prior to undertaking the mapping observations. Briefing sessions informed the care home staff about DCM™ and the

process of implementation and provided an opportunity for staff to ask questions and for mappers to address any staff concerns.

2.5.2.3.2 Observation

Mappers used the standard DCM™ procedure. They were asked to observe as many individuals, up to a total of five, as they felt confident to, for up to six consecutive hours on a single day if possible. Alternatively, they could observe for as long as possible on consecutive days up to a total of six-hours. A detailed description of the DCM™ tool is published elsewhere [83, 109] and summarised here: every 5-minutes the mapper records two pieces of information about each person they are observing, a Behaviour Category Code (BCC) and a Mood/Engagement (ME) Value. There are 23 possible BCCs for the mapper to choose from, and they capture what the person with dementia is doing within that 5-minute period. The ME Value encapsulates the associated mood and engagement level of the person with dementia and is chosen from a 6-point scale (+5, +3, +1, -1, -3, -5). A set of rules is used to determine which BCC and ME to code. The mapper also records instances when a person with dementia is 'put down' by a care worker, known as personal detractions (PDs), and examples of excellent care, called personal enhancers (PEs). These are recorded as and when they occur. Since DCM™ is grounded in person-centred care, for reasons of privacy and dignity, observations only take place in communal living areas, such as the lounge, dining room and corridors. Mappers do not observe in bedrooms or bathrooms.

2.5.2.3.3 Data analysis, reporting and feedback

For the purposes of trial data analysis, reporting and feedback were considered as a single phase, rather than the two separate phases of implementation described in the DCM™ literature. Once the data had been collected they were analysed by the mappers and presented in a standardised report format for the purposes of feedback to the care team. In the trial a standard template for DCM™ reporting was given to the mappers by the research team (see Supplementary Material). DCM™ feedback sessions provide an opportunity for mappers to share their observations with the staff team and for collective discussion about good care practices and areas for improvement. In the trial mappers were requested to run one or more feedback sessions with as many of the staff team as possible, within one-month of conducting the observations.

2.5.2.3.4 Action planning

Action plans of ways to improve care were then produced. As part of the feedback session, or in a subsequent meeting, staff and mappers were asked to jointly develop agreed,

achievable group (care home level) and individual resident level action plans containing short, medium and longer term goals they wished to implement. Mappers were asked to monitor progress on these actions during the next mapping cycle.

2.5.2.4 Resident consent for mapping

Prior to mapping, residents were selected to be mapped through discussions between the care team and mappers, during the briefing session or on the day of mapping. Mappers followed DCM™ guidance, which states that residents may be selected for observation due to reflecting a range of abilities or having particular care needs staff members have difficulties meeting or understanding. Residents selected for mapping observations did not need to be consenting trial participants, since DCM™ was implemented as a whole home intervention. Consent was gained verbally by the mappers, from the resident or in discussion with their relative prior to observations taking place, in accordance with the usual consent process utilised in DCM™. Any resident data collected as part of the DCM™ process, subsequently used for monitoring intervention fidelity, or for any other purposes in the trial, was anonymised by the mappers before being sent to the research team.

2.5.2.5 DCM™ Expert mapper support for cycle one

This pragmatic trial aimed to ensure that DCM™ implementation reflected what is possible in a typical UK care home, maximising relevance to practice. However, the first cycle of mapping was supported by an expert in use of DCM™ (DCM™ expert mapper), provided by the research team. This is not standard practice as trained mappers would usually engage in DCM™ without further support following training completion. However, it was implemented in the trial to support implementation fidelity across clusters (see also *section 2.9*), provide coaching for care home mappers, to encourage implementation and to support establishment of inter-rater reliability of DCM™ coding between trained mappers in each care home. The DCM™ expert mapper worked alongside the mappers during their first DCM™ cycle, spending three days in the care home supporting establishment of inter-rater reliability on DCM™ coding frames, briefing, mapping observations and delivery of the feedback and action planning session. Two additional days of desk-based support were provided on preparation of briefing documentation, the feedback report and action plans. Telephone and e-mail support for DCM™ implementation, from the DCM™ Intervention Lead was available to all intervention homes thereafter, if required.

2.6 Outcomes

2.6.1 Primary endpoint

The primary endpoint was agitation at 16-months following randomisation measured by the Cohen-Mansfield Agitation Inventory (CMAI), as rated by staff proxy. The Pittsburgh Agitation Scale (PAS) and a modified observational CMAI (CMAI-O), rated by independent researchers provided a means of assessing concurrent validity, addressing the issue of potential detection bias, based on the inability to blind staff to intervention allocation status.

2.6.2 Health economic endpoints

The primary health economic endpoint was cost per quality-adjusted life year (QALY) at 16-months. A secondary endpoint was cost per unit of improvement in CMAI at 16-months. Both of these adopted the health and personal social service provider perspective.

2.6.3 Secondary endpoints

Secondary endpoints relating to residents were:

- Behaviours Staff find Challenging (NPI);
- Mood (NPI);
- Quality of Life (QUALID, QOL-AD, DEMQOL, EQ-5D-5L);
- Prescribed Medication;
- Safety (SAEs, Safeguarding).

Secondary endpoints relating to staff were:

- Sense of Competence in Dementia Care Staff (SCIDS) Scale.

Secondary endpoints relating to homes were:

- Quality of Interactions Schedule (QUIS).

Furthermore, intervention fidelity was assessed. All other data are potential mediators or moderators of the treatment effect. Measures, collection time-points and method of completion are summarised in Table 2.

To ensure a consistent data set was available for each resident at each time-point, the main informant for the primary outcome and for proxy completed secondary outcomes was a staff proxy informant. These data were supplemented, where possible, by information provided by the resident (where able) and their relative/friend (where available).

Table 2: Summary of data collected

Assessment	Method of Completion (completed with/on)	Purpose	Level	Timeline			
				Screening	Baseline	6- months	16- months
Resident Demographics	Researcher Assessment (CM, CR)		Individual		X	X	X
Cohen Mansfield Agitation Inventory (CMAI)	Researcher Interview (SP)	Primary endpoint	Individual		X	X	X
Cohen Mansfield Agitation Inventory Observational (CMAI-O)	Independent Researcher Observations (R)	Independent assessment of concurrent validity of CMAI for detection of potential bias	Individual		X	X	X
Pittsburgh Agitation Scale (PAS)	Independent Researcher Observations (R)	Independent assessment of concurrent validity of CMAI for detection of potential bias	Individual		X	X	X
Neuropsychiatric Inventory (NPI-NH)	Researcher Interview (SP)	Secondary endpoint	Individual		X	X	X
DEMQOL Proxy	Researcher Interview (SP and RF)	Health economics endpoint	Individual		X	X	X
EQ 5D 5L/EQ 5D 5L-proxy	Researcher Interview (R and RF and SP)	Health economics endpoint	Individual		X	X	X
QUALID	Researcher Interview (SP and RF)	Secondary endpoint	Individual		X	X	X
QOL-AD (care home)	Researcher Interview (R)	Secondary endpoint	Individual		X	X	X
Healthcare Resource Use	Researcher Assessment (CR)	Health economics endpoint	Individual		X	X	X
Prescription Medications	Researcher Assessment (CR)	Secondary endpoint	Individual		X	X	X
Resident Comorbidities	Researcher Assessment (CR)		Individual		X	X	X
Clinical Dementia Rating (CDR)	Researcher Interview (SP)	Process measure	Individual		X	X	X
Functional Assessment Staging (FAST)	Researcher Interview (SP)		Individual		X	X	X
General Health Questionnaire (GHQ-12)*	Self-Completed (S)	Secondary endpoint			X	X	
Sense of Competence in Dementia care Staff (SCIDS)	Self-Completed (S)	Secondary endpoint			X	X	X
Quality of Interactions Schedule (QUIS)	Researcher Observations (R,S)	Process measure	Cluster		X	X	X
Care Home Demographics	Researcher Interview (CM)		Cluster		X	X	X
Environmental Audit Tool (EAT)	Researcher Observations (CH)	Process measure	Cluster		X	X	X
Group Living Home Characteristics (GLHC)	Researcher Assessment (CH)	Secondary endpoint	Cluster		X	X	X
Assessment of Dementia Awareness and Person-Centred Care Training (ADAPT) audit	Researcher Assessment (CM, CR)	Pre-baseline benchmarking for provision of additional person-centred dementia awareness training and usual care monitoring	Cluster	X		X	X
Safety Reporting	Researcher Assessment (CM)	Safety			Monthly following Randomisation		
RUSAE Report	Researcher Assessment (CM)	Safety			As highlighted.		

Key: CM – Care Home Manager, CH – Care Home Observations, CR – Care Home Records, R – Resident, S – Staff, SP – Staff Proxy Informant, RF – Relative/Friend Proxy Informant

Note* Collection of GHQ data from staff was ceased during trial – see section 2.10

2.6.4 Resident Measures

2.6.4.1: Primary Outcome Measure:

Cohen Mansfield Agitation Inventory (CMAI) [42, 43]

The CMAI measures 29 agitated or aggressive behaviours. [110] The frequency of each symptom is rated on a seven-point scale (1-7) ranging from “never” to “several times an hour”, based upon observations over the previous two-weeks. A total score is obtained by summing the individual frequency scores, yielding a total score ranging from 29 to 203. The CMAI has good psychometric properties [111] when used in a care home setting. Data from previous similar studies provides expected points change to inform the sample size calculation. The CMAI was completed via researcher interview with the staff proxy informant, in accordance with the CMAI Manual. [43]

Since blinding staff to intervention allocation was not possible, two independent observational measures of agitation were collected to assess potential bias in staff proxy informant completion of the CMAI (see *section 2.6.4.2*). Observation scales have been shown to have good convergence with informant measures of agitation [112]. Observations were completed by an independent blinded researcher who was not involved in any other data collection in the care home.

2.6.4.2 Agitation measures (supportive outcomes)

Cohen Mansfield Agitation Inventory - Observation (CMAI-O) [113]

The CMAI-O was developed by the trial team, with the permission of the CMAI’s author, to provide an observational measure of agitation. It is rated on a four-point scale (1-4) ranging from “never” to “several times an hour”, based upon observations over one day. The CMAI-O data collection was completed on participating trial residents in communal areas between approximately 10:00- 12:00 and 14:00-17:00 (dependent on meal times in each care home). A copy is available from the authors on request.

Pittsburgh Agitation Scale (PAS) [114]

The PAS is an established observational rating of agitation. The scale has good reported reliability and validity. [114] Observations are conducted for between 1 and 8 hours. PAS data were collected on participating trial residents in communal areas between 10:00-12:00 and 14:00-17:00.

Neuropsychiatric Inventory Nursing Home (NPI-NH) [115]

The NPI-NH records a broader range of BSC including delusions, hallucinations, agitation/aggression, depression/dysphoria, anxiety, elation/euphoria, apathy/indifference, disinhibition, irritability/lability, aberrant motor behaviour, sleep and night-time behaviour disorders and appetite/eating disorders. The NPI-NH is a 12-item version designed for use with nursing home/care home populations, and has good reported reliability and validity. [115]

2.6.4.3 Quality of life

DEMQoL-Proxy [116]

The DEMQoL-proxy is a quality of life (QoL) questionnaire designed specifically for use in people with dementia. It has 32 items, covering mood, behavioural symptoms, cognition and memory, physical and social functioning and general health. It is administered by interview with a carer (formal or family) of the person with dementia. The DEMQoL-proxy has acceptable psychometric properties for measuring QoL in dementia [117] and is modelled to enable the derivation of preference-based indices (utility values), the latter of which were employed in the secondary cost-utility analyses. [118]

EQ-5D-5L/EQ-5D-5L Proxy [119]

EQ-5D is an accepted standardised, five-item measure of health outcome that provides a single index value for health status [120] covering: usual activities, self-care, mobility, pain and anxiety/depression, each with five response options (no problems, slight problems, moderate problems, severe problems and unable to do task). Both the self-report and proxy versions were used in the trial.

Quality of Life in Late Stage Dementia (QUALID) [121]

The QUALID is an 11-item scale that rates the presence and frequency of QoL indicators over the previous seven days using proxy report. It is a reliable and valid scale for rating quality of life in people with moderate to severe dementia and has good internal consistency, test-retest reliability and inter-rater reliability. [121]

QOL-AD (care home) [122]

The QOL-AD is a 13-item self-report measure of quality of life with good reported internal reliability, test-retest reliability and convergent validity. [122] It is reported to be reliable in use with people with mild to severe dementia. [123-125] The adapted version of the QOL-AD [126] is a 15-item questionnaire developed for use in care homes and uses simple language and a

four-response answer which is consistent across all questions (poor, fair, good, excellent). It includes minor changes to the standard QOL-AD scale to ensure relevance to those living in long-term care (e.g. amendment of wording of existing items, removal of questions on management of money and marriage status and addition of questions relating to relationships with staff, ability to take care of oneself, ability to live with others and ability to make choices). It has good reported internal consistency. [126]

2.6.4.4 Demographics, health and healthcare resource use

Resident demographics

Standardised demographic information (sex, date of birth etc) was collected by the researcher via interview with the care home manager or other senior member of staff and review of the resident's care records.

Healthcare resource use

This measure was adapted from one developed for a care home feasibility trial. [127] The measure captured use of primary and secondary care including hospital-based care (e.g. hospital and A&E visits and stays), community-based care (e.g. GP visits and contact with other healthcare professionals such as physiotherapists and psychiatrists) and other costs (e.g. adapted beds and other aids) incurred during the previous three-months.

Prescription medications

Prescription of medications within categories of interest (e.g. antipsychotic, benzodiazepine, non-benzodiazepine anxiolytic, non-benzodiazepine anti-psychotic, memantine, antidepressant, cholinesterase inhibitor, anti-convulsant, mood stabiliser, pain relief) and administration of these if prescribed on an as required (PRN) basis, was recorded on a standardised CRF. This was completed by the researcher through review of residents' medication records for the previous month.

Resident comorbidities

These were collected using a standardised CRF through researcher review of residents' care records.

2.6.4.5 Dementia severity

Clinical Dementia Rating Scale (CDR) [128]

The CDR is a well utilised, standardised scale for rating the severity of dementia from no cognitive impairment to severe or advanced dementia. [129] Impairment on six cognitive categories is rated and an algorithm is used to calculate the overall severity rating. Severity

is rated by a trained assessor via informal interview/conversation with the person, or with a proxy who knows the person well. In this study the CDR was completed by the researcher through interview with a staff proxy who knew the resident well.

Functional Assessment Staging (FAST) [102]

The FAST is a scale designed to record the functional severity of dementia. Scores range from 1 (no dementia) to 7 (severe dementia) with levels 6 and 7 each having five sub-levels. It is particularly designed for use in more moderate to severe dementia. It is completed by proxy report from a caregiver. [102]

2.6.5 Staff Measures

2.6.5.1 Staff work stress

General Health Questionnaire (12-item) (GHQ-12) [130]

This is a measure of stress/psychological well-being used in the general population. It has good reported psychometric properties. [131] It contains 12-items related to mental health, each scored on a four-point scale of frequency of symptoms or behaviours ('less than usual' to 'much more than usual'). Due to poor return rates collection of GHQ-12 data was ceased during the trial (see *section 2.10* for further details).

2.6.5.2 Job or role efficacy

Sense of Competence in Dementia Care Staff (SCIDS) [132]

The SCIDS is a user-friendly, self-complete, 17-item scale measuring staff members' competence in caring for people with dementia, across four sub-scales (Professionalism, Building Relationships, Care Challenges, Sustaining Personhood). Each item is rated on a four-point scale of confidence ('Not at all' to 'Very Much'). It has acceptable internal consistency and test-retest reliability. [132]

2.6.6 Organisational Measures

2.6.6.1 Care quality

Quality of Interactions Schedule (QUIS) [133]

The QUIS is an observational measure of the quality and quantity of staff interactions with residents during care delivery, at a care home level. It records five types of interactions

(positive social, positive care, neutral, negative protective, negative restrictive) and has reported adequate inter-rater reliability and sensitivity. [134] The QUIS was completed via researcher observation, using a time-sampling technique in each setting. In accordance with QUIS guidelines [133, 135] observations of interactions at 5-minute intervals, were conducted in communal areas in the care home and recorded summarised into 15-minute intervals. One-hour observations were completed at two time-points (AM and PM) over two days within the same week (7-day period) in accordance with Care Home activity (i.e. morning coffee break) in the most populated communal area in the home. For the purposes of analysis in this trial, the proportion of interactions that were positive (positive social and positive care) was used.

2.6.6.2 Care home environment and characteristics

Care Home Demographics Questionnaire

This questionnaire, designed by the study team, collected organisational data regarding each care home (size, type, ownership, geography, staff turnover, staff ratios, resident demographics, etc.) and its manager (qualifications, length of time in post, leadership style etc.).

Environmental Audit Tool (EAT) [136]

The EAT is an instrument with reported adequate reliability and validity used to differentiate between the quality of the physical environment in various types of dementia care facilities. [136] It was completed by the researcher with the assistance of a staff member if required.

Group Living Home Characteristics Questionnaire (GLHC) [137]

This is a measure of the style of care being delivered in the home. It examines how 'home-like' care delivered is. It includes four-subscales (physical environment, residents, relatives/other visitors, staff) each containing at least three related statements answered according to a five-point scale ('Never' to 'Always'). It was completed by the researcher.

Assessment of Dementia Awareness and Person-Centred Care Training (ADAPT) audit [99]

See *section 2.3.1.3.*

Safety and RUSAE reporting

See *section 2.11.*

2.7 Sample size

The sample size was calculated to detect a moderate standardised effect size of 0.4 on the primary outcome: the between-group difference in mean CMAI scores at 16-months. We assumed the standard deviation (SD) would be similar to that observed in a recently completed trial in UK care homes (7.5 points). [66] The moderate effect size translated to a minimum difference of 3 points. If greater variation in CMAI scores was observed, (SDs ranging from 15 to 20 points as reported by Zuidema et al [138]), then for the same effect size a difference of 6 to 8 points could be detected, respectively. A difference of 8 points on the CMAI is seen as indicative of real behavioural change. [138] Fifty care homes, each recruiting 15 participants provide 90% power at a 5% significance level to detect a clinically important difference of 3 points (SD 7.5 points), assuming 25% loss to follow-up (as seen in Chenoweth et al. [63]) and an inflation factor of 2.0 (i.e. cluster size of 11 participants available for analysis after loss to follow-up and an intracluster correlation coefficient (ICC) no greater than 0.1 [66]).

As provision of care is a further source of clustering, and the ICC was anticipated to be higher in the intervention arm (based on clinical opinion), an allocation ratio of 3:2 was used, giving 30 (450) and 20 (300) care homes (residents) in the intervention and control arms respectively, 50 (750) overall.

During the trial, the TMG, DMEC and TSC monitored loss to follow-up. This was higher than the anticipated maximum of 25%, mainly due to death rates. In order to preserve statistical power close to 90%, and our ability to detect effect size of 0.4 SDs, maintain validity and increase the generalisability of the trial, we recruited additional, newly-eligible, consenting residents from the randomised care homes at 16-months post randomisation and performed a cross-sectional analysis of the data (see *section 2.10*).

2.8 Statistical and health economic methods

A comprehensive *Statistical and Health Economic Analysis Plan* was developed and approved following the approval of the design change. All analyses were performed once, at final analysis in SAS v9.4 or Stata v14.

A CONSORT (Consolidated Standards of Reporting Trials) flow diagram has been used to display care home and resident pathway from registration to final follow-up (see *section 3.1*).

2.8.1 Analysis populations

The principal analyses were intention-to-treat, including all randomised care homes and all registered residents, regardless of whether they received or adhered to their allocated intervention. A further supportive analysis was planned of 'compliers', defined as care homes that would have received at least one cycle of DCM™ to an acceptable level (all components of the cycle are completed) had it been offered to them. Other thresholds of compliance we considered were exploratory. Safety was summarised on the closed-cohort sample of residents since we were unable to obtain timely NHS Digital data on the cross-sectional sample. The samples of staff and relative/friends providing data (other than staff proxy data) were so small that analyses based on them are descriptive and provided in the Appendix only (see Appendix 1, Table 31).

2.8.2 Missing data

In general, if there were no instructions in the manual on how to handle missing items (for PAS, NPI-NH, QUALID, SCIDS and EAT), prorating was used if fewer than 25% of items were missing, (based on adopting a more conservative approach than that proposed by Staquet et al [139]), otherwise the score was assigned as missing. As the proportion of residents with notable missing primary outcomes was low, we prorated for simplicity despite assumptions underlying prorating not always being met.

The primary intended method for handling missing scale data in the cross-sectional analyses was to analyse complete cases, under the assumption that data are missing completely at random (MCAR). For completeness, we also report a sensitivity analysis using multiple imputation, under the assumption that cross-sectional data are missing at random (MAR). If the MCAR assumption was found not to hold true, then the primary analysis would use the multiple-imputed data, assuming data are missing at random (MAR).The proportion of residents missing in analyses of the closed-cohort sample was sizeable at 6-months and substantial at 16-months. As death and moving care home were expected to be the most important predictors of missing closed-cohort data, we expected this data would be missing not at random (MNAR). We considered a range of approaches to handling missing closed-cohort data (see Table 10 and Tables 47 and 48), but report a tipping point analysis [140] for the primary analysis, which indicates the assumptions that would be required about the missing data to change the conclusions.

For completeness, we also report an analysis using multiple imputation, under the assumption that closed-cohort data are missing at random (MAR), which assumes residents

registered at care home randomisation do not die during the duration of the trial. The same variables were included in the imputation models, apart from the baseline questionnaire scores; baseline questionnaire score used in the imputation model was always the same as the outcome questionnaire. The imputation model was done separately for different analysis population, in the cross-sectional, baseline variables were care home summaries, whereas in the closed-cohort, individual level baseline information was used.

2.8.3 Screening, baseline, treatment and outcome summaries

The numbers of care homes approached, screened, eligible, consenting and participating, along with the numbers of residents in the closed-cohort sample and the cross-sectional sample were summarised in a CONSORT flow diagram. Reasons for exclusion and the characteristics of screened residents were also presented overall and across samples.

Baseline characteristics of care homes, care home managers and residents (closed-cohort and cross-sectional samples) were summarised overall and for intervention and control. In accordance with the TIDieR checklist, [141] summaries of treatment receipt were given by intervention component for DCM™ and by parallel-group for usual care.

Baseline, 6- and 16-months outcomes were summarised for the intervention and control and additionally for residents in the closed-cohort and cross-sectional samples at 16-months.

2.8.4 Primary effectiveness analysis

The continuous primary outcome of agitation (CMAI score) was analysed on the cross-sectional sample of residents using a linear two-level heteroscedastic regression model that allowed the cluster and resident-level random effects to vary by arm. The model adjusted for minimisation factors (care home type, size, provision of dementia awareness training and recruiting hub) and average care home-level baseline characteristics (dementia severity via CDR, age and CMAI score) as fixed effects. These variables were pre-specified in the protocol, age was added as an additional covariate. Unadjusted and adjusted ICCs, estimates and corresponding 95% confidence intervals were presented, by arm. A negative mean difference in outcome favours the intervention. The primary analysis model was decided a priori in the Statistical Analysis Plan before the data were un-blinded and without reference to the data. It was consistent with/followed on from the trial design.

2.8.5 Sensitivity effectiveness analyses

The robustness of the conclusions of the primary effectiveness analysis was assessed via a number of sensitivity analyses. The primary effectiveness analysis was repeated:

- With an additional covariate categorising care homes by whether they were recruited pre or post eligibility criteria change;
- Including care home size as a continuous covariate;
- Assuming clustering is homogeneous across arms;
- Using the observational CMAI (CMAI-O) and PAS scores in place of the CMAI;
- Using the closed-cohort sample in place of the cross-sectional sample, allowing dementia severity, age and CMAI score to be included as covariates at the resident-level.

2.8.6 Supportive effectiveness analyses

The treatment effect among 'compliers' was estimated using a series of complier average causal effect (CACE) models. Our main supportive analysis defined 'compliers' as care homes that would have received at least one cycle of DCM™ to an acceptable level if it had been offered. Other thresholds were exploratory. CACE treatment estimates were obtained from two-stage least square instrumental variable regressions (using Stata command ivreg), using robust standard errors to allow for clustering effects. The model adjusted for the same baseline variables as the primary analysis model with the addition of binary variable 'treatment received' (number of DCM cycles received to pre-specified level).

For our mediation analysis, we used a parametric causal mediation approach to allow for interactions between mediators and treatments, which the typical Baron and Kenny [142] approach does not. We reported the natural indirect effect, which is the effect on outcomes of having the mediator present compared to it not being present, for a number of pre-specified intermediate variables (potential mediators). Analysis was done on an ITT basis on cross-sectional cohort. Each mediator was analysed separately assuming there was no unobserved confounding in treatment-outcome, mediator-outcome and treatment-mediator relationships and that any mediator-outcome relationship confounders were not affected by treatment allocation. We used parametric regression models using Stata the paramed command. A linear regression model was fitted for the outcome variable. Logistic regression was used for the mediator variable. In the multiple imputation we additionally included the potential mediators.

In our moderator analyses, we explored whether the treatment effect differed depending on pre-specified baseline characteristics of either the care home or the resident. The primary analysis was repeated, including each potential moderator, alongside the interaction between treatment and the potential moderator. Analyses was performed on the ITT cross-sectional sample, subject to the availability of data for each potential moderator.

2.8.7 Secondary effectiveness analyses

Secondary analyses were undertaken using the same principles as the analysis of the primary outcome. For secondary outcomes (behaviours staff find challenging, use of antipsychotic drugs and other psychotropic drugs, mood, resident quality of life, staff role efficacy, care quality and the quality of staff/resident interactions), three analyses were performed:

1. Cross-sectional at 16-months;
2. Closed-cohort at 6-months;
3. Closed-cohort at 16-months.

The same covariates were included as for the primary analysis (for closed-cohort analyses, individual resident-level covariates were used as appropriate). Cluster-specific linear two-level heteroscedastic regressions were fitted where outcomes were continuous (resident quality of life). Population-average logistic regressions were fitted, using generalised estimating equations (GEE), where outcomes were binary (behaviours staff find challenging, use of antipsychotic drugs, mood).

2.8.8 Safety analysis

The number and proportion of residents in the closed-cohort who died from any cause between randomisation and 16-months was summarised by arm. The cause and place of death was also reported. The number of hospital admissions per resident, mean number of hospital admissions per resident, average length of hospital admission, overall number of hospital admissions reported and admissions by ward type was summarised by arm and overall. No formal statistical comparison was undertaken between arms.

2.8.9 Health Economic analysis

The economic evaluation was a within-trial analysis. We chose not to develop a decision-analytic model for the evaluation. While a model may have been useful in extrapolating any

costs and health benefits beyond the end of the trial, we felt that the measure of future effectiveness would be highly uncertain and would require additional assumptions (e.g. about the duration of effect). The analysis followed the reference case guidance for technology appraisals set out by the National Institute for Health and Care Excellence (NICE). [143] The primary analysis was a cost-utility analysis and presents outcomes as quality-adjusted life years (QALYs) using a health and personal social service provider perspective (whilst some of these costs might in practice be paid for by residents themselves, this was not accounted for in the analysis because it was deeded not to have any impact on the incremental costs of the DCM intervention). A secondary cost-effectiveness analysis based on cost per unit of improvement in CMAI was also conducted.

2.8.9.1 Deviations from the SAP

The following deviations from the SAP were decided upon during data analysis. The primary health economic analysis assumed that the local authority pays for the provision of care for residents (NHS and social care perspective). We had planned to conduct an analysis where we assumed that some proportion of residents paid for their own care home stay. Following further discussions with the research team it was decided to remove this element. The justification for this was that care homes are paid even when residents are hospitalised and hence the source of payments for residency would not impact results.

In the SAP we stated that: “The validity of reports will be assessed by correlating scores between EQ-5D and those on the alternative measures (QUALID, QoL-AD) and by exploring the ability of the measure to distinguish between known groups (for example, based on CDR).” This was not included as part of the required analysis within the original grant application. This analysis is still planned as additional methodological research. For the trial analysis we took the pragmatic approach and based the primary analysis on staff proxy measures since this was by some margin the most complete data.

2.8.9.2 Resource Use and Costs

Unit costs for health service staff and resources were obtained from national sources such as the Personal Social Services Research Unit (PSSRU), [144] the eMIT national database [145] and NHS reference cost database [146] (see Appendix 1 Table 66 for a summary of unit costs).

2.8.9.3 Cost of DCM™ intervention

The DCM™ intervention consisted of two components: i) delivery and receipt of DCM™ training; and ii) implementation of the DCM™ process in care homes.

It was assumed that both components would require DCM™ mappers in the trial (two per intervention site) to take dedicated time away from their usual care duties during the working day. The amount of time required for the DCM™ training course was four days. The estimated amount of time required for the DCM™ process is reported in existing DCM™ guidelines [83], based on the experiences of experts using DCM™ in practice settings. Data were also collected during the trial in order to assess the validity of these estimates and, where this was shown to exceed the assumed average, the impact of any additional staff time was assessed in sensitivity analyses. It was assumed that additional time was not required for other care home staff to attend DCM™ briefing and feedback sessions, but that these were arranged at handover and other convenient times for staff to attend as part of their usual duties.

In order to calculate the total cost of staff time, an hourly wage was estimated for a typical DCM™ Mapper. This incorporated data from the trial on the proportion of DCM™ Mappers in particular roles (e.g. a home care worker and a care home manager) and data published by the PSSRU on the hourly wages (or annual salaries converted to hourly wages using standard methods) of workers in these roles. Where relevant wage data was not available from PSSRU, we reviewed alternative sources, including recent job advertisements.

Additional costs of the delivery and receipt of DCM™ training included the course fees, training materials, accommodation, meals, subsistence and travel. These were estimated using information from the DCM™ course provider and data on the costs incurred in running the trial. A further additional cost of implementing the DCM™ process in care homes was the consultancy fees, travel and subsistence expenses incurred through employment of external DCM™ expert mappers to support the intervention implementation and fidelity during the first DCM™ mapping cycle in each of the intervention sites. The primary analysis assumed that the intervention was delivered as planned and all cycles were implemented and costed. A sensitivity analysis costed only the cycles that had been partially or fully implemented.

The primary analysis assumed that the Local Authority payed for the provision of care home care for residents. As such these costs were included in the healthcare provider (NHS) and social care cost perspective.

2.8.9.4 Healthcare resource use

Data on healthcare resource use incurred during the previous 3-months were collected for each resident at baseline, 6- and 16-months. Medication use during the past month was captured at the same time points (see *section 2.6.4.4*).

2.8.9.5 Quality of Life/Utility

Quality of Life was measured in the trial at baseline, 6- and 16-months using the EQ-5D-5L, completed by care home residents, and the EQ-5D-5L-Proxy, completed by staff and relatives. [120] A recently-generated UK general population tariff [147] was used to calculate the utility scores and a (5L to 3L) mapping algorithm was used as a sensitivity analysis. [148]

Utility values were also calculated using the DEMQOL-Proxy tool (DEMQOL-PROXY-U), which was completed by staff and relatives. A UK population tariff was used to calculate utility scores. [118] The main cost-utility analyses were based on the EQ-5D-5L utility, but sensitivity analyses were conducted based on DEMQOL-Proxy-U.

Taking a pragmatic approach, we elected to base the primary analysis on EQ-5D-5L data from the staff proxy at all three time-points as this represented the most complete set of responses. However, we conducted a sensitivity analysis employing resident completed EQ-5D-5L data where it was available at all three time-points. Where this was not available we used data from relative proxies (if available at all three time-points) and, finally, when this was unavailable, from staff proxies.

2.8.9.6 Analysis

The primary economic analysis was a cost-utility analysis over 16-months presenting incremental cost-effectiveness ratios (ICER) for intervention versus control, with effects expressed in terms of QALYs. As the clinical efficacy analyses used agitation as the primary endpoint, a secondary cost-effectiveness analysis based on change in CMAI over 16-months was also conducted.

Total QALYs were calculated using an area under the curve approach between adjacent utility measure completions using EQ-5D-5L and DEMQoL-Proxy utilities captured at baseline, 6- and 16-months. If residents died their utility value was assumed to be zero and their data were retained in the analyses. Quality of life was assumed to change from last completion value to zero in a linear fashion.

Total costs were estimated using the resource use questionnaires at 6- and 16-months. It was assumed that reported resource use during a 1-month (for medications) or 3-month (other costs) period remained constant between time points in the trial (e.g. the 10-month period between follow-up at 6- and 16-months). To capture the costs incurred prior to death, a daily cost was estimated based on each resident's previous resource consumption (at baseline or 6-months) and applied until the date of death.

Incremental costs and QALYs (or CMAI) were estimated using a Seemingly Unrelated Regression (SUR) approach which consisted of a system of regression equations that can recognise the correlation between individual costs and outcomes:

Model 1 (cost):

$$TotalCost_i = \alpha_i + \beta\ RandTrt_{ch} + \varepsilon_i$$

Model 1A (cost sensitivity analysis):

$$TotalCost_i = \alpha_i + \beta_1\ RandTrt_{ch} + \beta_2\ T0\_Costs_i + \beta_3\ T0\_CDR_i + \beta_4\ T0\_Age_i + \varepsilon_i$$

Model 2 (qalys):

$$TotalQALY_i = \alpha_i + \beta_1\ RandTrt_{ch} + \beta_2\ T0\_QALY_i + \beta_3\ T0\_CDR_i + \beta_4\ T0\_Age_i + \varepsilon_i$$

Where T0 = baseline, CDR = CDR score

In addition to controlling for baseline QALYs, which differed at baseline, for consistency, with the statistical analysis age and baseline CDR score were also included (Model 2 above). Although costs were not significantly different at baseline, these same baseline characteristics were included in the SUR for costs in a sensitivity analysis.

Incremental cost-effectiveness ratios (ICERs) were calculated both for cost per QALY gain and cost per unit improvement in CMAI score. We used the NICE willingness to pay per incremental QALY threshold (£20,000 = Lambda [λ]) to determine whether the intervention was cost-effective. Interventions with an ICER under £20,000 per QALY are generally considered cost-effective. There is no such willingness to pay threshold to aid the interpretation of changes in CMAI but we framed this in the context of other study results.

Discounting at the NICE preferred rate of 3.5% per annum for costs and effects were conducted for values post 12-months (i.e. for the final 4-months of the trial).

2.8.9.7 Net benefit analysis

A net benefit regression framework was also employed to allow parametric analysis of the incremental costs and benefits of the intervention. Net monetary benefit is calculated using individual-level total costs, total QALYs and the cost-effectiveness threshold (λ=£20,000):

NMB = (λ*QALYs) – Costs

Linear regression models were used to regress treatment allocation on individual-level (i for I individuals in the trial) estimates of NMB, whilst controlling for other observable trial arm imbalances (e.g. dementia severity, agitation levels or socio-demographics):

$$NMB_i = \alpha_i + \beta\, RandTrt_{ch} + \delta\, \boldsymbol{X}_i + \varepsilon_i$$

Where RandTrt is the treatment allocation and **X** is a vector of observable characteristics.

We also examined heterogeneity in the treatment effect by compliance at the care home level in a multi-level model accounting for clustering at the care home level:

$$NMB_i = \alpha_i + \beta\, \boldsymbol{CH}_{ch} + \delta\, \boldsymbol{X}_i + \varepsilon_i$$

Where **CH** is a vector of three groups of intervention arm care homes, grouped according to the number of cycles in which the care home had completed all four components of the intervention (this is defined as an 'acceptable' level in the statistical analysis see *section 2.9.7*):

= 0 if care home had completed no cycles to an acceptable level
= 1 if care home had completed one cycles to an acceptable level
= 2 if care home had completed two or three cycles to an acceptable level

Control arm care homes were in the reference category and the coefficient (β) is a measure of incremental net benefit associated with a particular group of care homes.
To be consistent with the statistical analysis, we also conducted a CACE analysis on net monetary benefit which is designed to account for the potential endogeneity of compliance using a two staged least squares instrumental variables approach.

2.8.9.8 Missing data

We ran the resident-level analysis on complete cases (CCA) initially which required data on total QALYs (based on various EQ-5D-5L or DEMQOL measures, depending on the analysis) and total costs. However, due to the extent of missing data, the primary analysis was based on data where missing values were imputed using multiple imputation (MI). This assumed that the data were missing at random. The first stage of the imputation process used mean imputations to estimate the baseline values of each EQ5D5L, DEMQOL-Proxy measures, CMAI score and time-invariant characteristics (age/date of birth at baseline), following guidance in a paper by Faria et al. [149]

Second, Multiple Imputations by Chained Equations (MICE) was used to impute missing EQ5D-5L, DEMQOL-Proxy measures (index values rather than individual items) and CMAI score at 6-months and 16-months and individual components of total costs at all three time-points. The number of individual components of total costs (n=15) used in the imputation process was decided, taking a pragmatic approach. As a general rule, at each time-point, high cost and common resource items (e.g. hospital visits and stays) were imputed individually and less common items were imputed on a bundled basis.

The number of imputations (n=48) reflected the ratio of missing: complete data. We accounted for clustering within care homes. Rubin's [150] rules were used to combine parameter estimates of the multiple imputations

2.8.9.9 Cross sectional cohort analysis

The change in the trial to an open-cohort design meant that additional data for some residents were available at 16-months, despite them not being in the trial at baseline or 6-month follow-up. For the primary analysis, we only used data from those residents consented into the trial at baseline (the original-cohort). However, in order to be consistent with the statistical analysis, an additional analysis was conducted incorporating the costs and QALYs for those residents providing data only at 16-months (the cross sectional-cohort).

Where data on both costs and EQ-5D was only available at 16-months in the cross-sectional cohort, we imputed the total cumulative costs and total QALYs for the whole trial period using a two-stage imputation process. First, mean values of the total costs and total QALYs generated in the imputations described above (n=48) were used to replace the missing data on total costs and total QALYs in the closed cohort. Second, data on total costs and total QALYs for each individual in the closed cohort (n=726) (including the values that had been imputed in the first stage) were used to impute the total costs and QALY data for all individuals in the cross-sectional cohort, using the MICE method and Rubin's rules described above, accounting for recorded data at 16-months, including costs and quality of life. This enabled calculation of an ICER for the cross-sectional cohort. Since this approach relied on an unusual two stage imputation process for individuals who had no recorded data at baseline, the results should be considered illustrative only and treated with due caution. This approach also relied on an assumption that survival was independent of the intervention and time spent in the care home since residents providing data at 16-months only would have survived until 16-months had they been in the care home for that duration.

2.8.9.10 Sensitivity analyses

Deterministic sensitivity analysis of the ICER was undertaken to test the robustness of the results to changes in the analytical approach and to assumptions made. For example, we re-ran analyses exploring the impact on results of different approaches to costing, handling missing data and of employing alternative utility capture methods.

A non-parametric bootstrapping analysis was also conducted to determine the level of sampling uncertainty around the ICER estimates by generating 10,000 estimates of incremental costs and benefits, using the combined estimates of the multiple imputed datasets (n=48) using Rubin's [150] rules, and accounting for clustering in care homes. The bootstrapped estimates were used to generate the cost-effectiveness plane and the cost effectiveness acceptability curve (CEAC). [151]

2.9 Process evaluation and assessment of treatment implementation

2.9.1 Aims and research questions

The process evaluation was designed to examine the process, challenges, benefits and impacts of the trial, in order to identify the processes and factors associated with degrees of successful and unsuccessful intervention implementation.

The aims of the process evaluation included:

- Describing adherence to the required components of the intervention and the quality (or fidelity) of intervention delivery.
- Understanding staff, residents' and relatives' perceptions of the impacts of the intervention
- Understanding the barriers and facilitators to implementing DCM™ in practice

The process evaluation answered research questions aligned to the Medical Research Council guidelines on process evaluations [152] and included implementation, mechanisms of impact and context.

1. What was implemented?
    a. What was the process of setting up the intervention in each care home?
    b. If, and how, did this differ from the intended process as outlined in the protocol?

c. How many cycles of DCM™ were delivered in each care home? (Dose + Reach)

d. To what extent did each cycle in each care home meet the planned delivery as set out in the protocol? (Fidelity + Reach)

e. If and how did care homes deviate from delivery of the intervention as set out in the protocol?

2. How did participants react to the intervention?

    a. What were mappers', managers', residents', relatives' and staffs' experiences of the intervention and its implementation?

    b. What were mappers', managers', residents', relatives' and staffs' perceptions of the impact of the intervention?

    c. Did the intervention have any perceived, unexpected impacts or consequences?

    d. For perceived impacts, through what mediators/processes did each group perceive the intervention to have operated?

    e. Did the intervention or its mechanisms of impact operate in any unexpected ways?

3. What contextual factors shaped if, and how, the intervention was implemented or worked?

    a. What were the perceived barriers and facilitators to intervention implementation, mechanisms of impact and perceived impact from the perspective of mappers, DCM™ expert mappers, managers, staff, residents and relatives?

    b. How did care homes that demonstrated different degrees of intervention implementation manage and address barriers and facilitators to intervention implementation?

The process evaluation and implementation assessment was intended to support refining and improving of intervention efficacy and the sustainable implementation of the intervention over time, if the intervention was found to be effective. [153]

2.9.2 Design of the process evaluation

A mixed methods approach to data collection was used involving quantitative and qualitative components to embed the process evaluation as part of the main trial dataset.

The quantitative data included assessment of levels of adherence and fidelity in each home utilising data provided by the mappers from each care home at each cycle. These data included details on the 'dose' and quality of DCM™ use in relation to briefing (number of briefing sessions held and proportion of care home staff receiving briefing), mapping cycles (number of mapping sessions, numbers of residents observed, length of mapping period and number of mappers taking part) feedback sessions (number of feedback sessions held and proportion of care home staff receiving feedback) and DCM™ and action planning documentation (successful completion of standard mapping documents during each cycle using the standard templates provided, and the number of action plans developed per resident and at home level).

The qualitative data were collected from a subset of 18 intervention homes using semi-structured interviews with residents, the care home manager, mappers, staff, relatives and residents. Homes that had achieved varying degrees of success with DCM™ implementation (no full cycles, at least one full cycle, two or more full cycles) were purposefully selected in order to explore the factors associated with successful and unsuccessful implementation. Although selection of care homes took place before the final follow-up data collection point, the process evaluation interviews took place after all outcome data had been collected in each home (i.e. at the end of the 16-month follow-up data collection). Semi-structured interviews were also conducted with the DCM™ expert mappers, to explore their experience of supporting the implementation of DCM™ within the intervention homes. To enable links between the qualitative and quantitative data, researchers undertaking the qualitative data collection were provided with implementation data by the CTRU from the first two cycles in the home prior to the interviews.

2.9.3 Sampling for the quantitative and qualitative data collection

For the quantitative data analysis, frequency data from the mapping cycles in all intervention homes were used to assess dose, adherence and fidelity, and to understand variation in levels of DCM™ implementation across the homes.

For the qualitative data collection, purposive sampling was used to select a sub-set of 18 homes, which had achieved varying degrees of success with DCM™ implementation to explore factors associated with this in greater detail. Due to the staggered recruitment of care

homes and the need to set up the process evaluation data collection dates with home managers ahead of time, participating homes had to be identified before all three cycles of mapping were due to have been completed. These homes were stratified into three equal groups (6 per group) according to whether they were deemed to be likely to be 'successful implementers' (more than two cycles completed), 'partial implementers' (1-2 cycles completed) or unsuccessful implementers' (less than one cycle completed) of DCM™.

Homes that differed according to key characteristics with the potential to affect DCM™ implementation, including location of homes (6 from each hub), size (large >=40 vs medium/small <40), and type of home (nursing, dementia, general residential), were also accounted for in the sampling.

2.9.4 Participant eligibility

Residents from homes taking part in the process evaluation were eligible if they were deemed to have capacity to consent and were able to take part in a brief interview. Staff were eligible to take part if they were a permanent or contracted member of staff. Relatives/friends were eligible if they had visited the home at least once a month during the trial.

Identifying staff and relatives/friends to approach was undertaken in conjunction with the home manager and included identification of the staff who had played a key role in intervention delivery. All potential participants were provided with verbal and written information about the interview, were given time to consider taking part, and signed a consent form if willing to participate (see Supplementary Material). Mappers had already provided consent to take part in the process evaluation as part of their initial consent to become mappers.

2.9.5 Data collection, transcription and storage

All researchers were trained in qualitative interviewing ahead of data collection to ensure consistency of approach. Resident interviews were brief, using a conversational style informed by a flexible interview schedule. Staff and relative/friend interviews were conducted using a semi-structured format informed by a topic guide. The interviews focused on experiences of DCM™ implementation, with prompts to encourage interviewees to discuss the various stages of DCM™ implementation, the successes, challenges and impacts of implementation, and any changes required to improve DCM™ implementation or impact in

the care home, as well as future plans for DCM™ within the care home. Mappers who had left the home during the trial were not interviewed. Relatives/friends of resident participants who had died during the trial were not contacted regarding the process evaluation interviews. Interviews were conducted within the care homes, in a private room with no other individuals present and an alternative method of telephone interviews was offered to all relatives/friends (see *Supplementary Materials* for copies of interview topic guides).

The interviews were audio recorded using a digital audio recording device and were professionally transcribed by a researcher independent to the study. Any potentially identifying information about the participants was anonymised or removed during transcription. Audio files were securely transferred in encrypted format and stored securely on computers in University offices.

2.9.6 Data analysis

Data analysis utilised a Framework Analysis approach. [154] Initial data analysis by all researchers involved in data collection informed the development of a coding matrix which guided and created a structure for further data analysis. The focus of the coding matrix (and therefore the data analysis) was on experiences of utilising and implementing DCM™, with a focus on identifying patterns and variations in implementation, barriers and facilitators to implementation, and the impacts of DCM™ implementation. The coding matrix helped to assimilate the development of coding categories between the team of researchers who undertook the analysis. Each transcript was independently analysed by two researchers to ensure key themes were identified. Development of the coding categories continued throughout data analysis, informed by the emerging themes and analytic thoughts of the researchers. Codes and themes were compared and contrasted across homes and between different types of respondents to develop an in-depth, nuanced and contextualised understanding of the implementation and impacts of DCM™.

The quantitative data that informed the process evaluation (measures of adherence and fidelity in each home) were collected and analysed as part of the main trial dataset (as described in *section 2.8.3*). Findings from the quantitative data were integrated with the qualitative data to provide an in-depth understanding of DCM™ implementation, and the issues surrounding implementation.

2.9.7 Measurement of adherence

Adherence to the prescribed processes for intervention delivery was monitored from randomisation to check that both mappers attended DCM™ training on time and passed the assessment. At each expected round of mapping, adherence to the processes was monitored to check that mappers delivered all components of the DCM™ cycle as intended and to the required quality (fidelity) and three full cycles (dose). Anonymised copies of all observation data collection sheets, feedback reports and action plans were collected to assess fidelity. Data was also collected from the DCM™ expert mapper about cycle one completion, following their support of mappers through their first cycle of mapping. For the purposes of the trial DCM™ was considered as comprised of four required components: 1) briefing, 2) observation, 3) data analysis, reporting writing and feedback, 4) action planning.

Care homes were classified according to their compliance with the intervention at each cycle as 'Acceptable', 'Partial' or 'None' compliance.

For a cycle to be classified as:

i) Acceptable, the care home must have completed all four components;

ii) Partial, the care home had completed one to three components;

iii) None, the care home had completed none of the components.

If paperwork was not received for specific components and the researchers had been unable to ascertain verbally from mappers whether particular cycle components had been completed, the following rules were used to determine whether a component had been completed:

- If there was paper documentation for observation, it was assumed that briefing also took place (at least 2 components were completed);

- If there was paper documentation for feedback, it was assumed briefing and observation took place (at least 3 components were completed);

- If there was paper documentation for action planning, it was assumed that briefing, observation and feedback took place (all components were completed).

Assessment of the quality of each component was also conducted where paperwork had been returned including: whether all the required DCM™ coding frames and accompanying qualitative notes had been used during mapping; if the standard feedback report format had been used and all parts of this completed (group data summary and individual data summary

for each resident); and whether the standard action planning template had been used and if there were action plans developed at a care home level and for each resident mapped.

2.10 Summary of changes to project protocol

Ten substantial amendments to the protocol and associated trial documentation were made during the trial.

2.10.1 Internal pilot

An initial two homes were recruited to the study early to permit internal piloting and review of trial processes, procedures, measure and tools ahead of recruitment of further care homes. Data from these homes were included in the trial. Changes to the original project protocol, implemented following this pilot are reported in detail in the published protocol [98], in Table 3 and the Appendix (see Appendix 2).

2.10.2 Design change

Our original sample size estimation, to detect a clinically important difference of 3 points (SD 7.5) in the primary endpoint of agitation using the CMAI questionnaire assumed a 25% loss to follow-up at 16-months after care home randomisation. If loss to follow-up was higher than anticipated (but no greater than 35%), our intended sample size of 750 residents still provided more than 85% power at a 2-sided 5% significance level to detect a moderate effect size, equating to 0.4 SDs.

Through monitoring loss to follow-up within the trial, we determined by November 2015 that the rate would exceed our lower limit of 25%. Using data from care homes randomised into the trial up to the 27th November 2015, we predicted that loss to follow-up at 16-months would be in the range of 32% to 48%, see Appendix 3, Figures 10 and 11. As such, continuing the trial as planned would not provide sufficient power for statistical analysis of the primary endpoint. An amendment to the trial design was required to ensure the results of trial were robust and generalizable. Based on consideration of all the available options, we proposed recruiting additional residents at follow-up (i.e. move to an “open cohort” design)

Table 3: Summary of substantial amendments to the protocol as associated trial documentation

Amendment number	Date	Summary of amendment
SA1	10/1/2014	Modification to method and content of health resource data to be collected including from medical records and NHS Digital (previously Health and Social Care Information Centre)
SA2	22/4/2014	Modifications to care home information sheet to improve clarity and provide additional information following review by the PPI panel
SA3	26/6/2014	Modifications to: care home recruitment process; resident, staff and relative eligibility criteria; screening of proxy informants; clarification of mutually exclusive staff roles; translation of trial documentation; amendment of assessment measures to be used; process for completion of independent assessments; monitoring of DCM™ implementation; relative/friend withdrawal; resident safety monitoring; establishment of a DMEC; information included on participant information sheets and consent (mapper, staff proxy and resident including consultees) documents; and development of a short form of the resident information sheet.
SA4	10/9/2014	Personal Consultee introductory letter and reminder; and relative/friend proxy informant introductory letter approved.
SA5	15/1/2015	GP letter to accompany guidance on antipsychotic prescribing approved
SA6	15/1/2015	Change of sponsor; modification to care home eligibility criteria; modification to resident eligibility criteria; modification to randomisation stratification criteria.
SA7	22/10/2015	Modification to requirements for witnessing resident consent; addition of text message reminders for mappers; and modifications to participant information sheets and consent forms
SA8	4/2/2016	Detail added to the protocol on conduct of the process evaluation; modifications to staff measures booklet; modification to continued attempts to recruit relative/friend proxy informants post-baseline; and modifications to participant information sheets.

SA9	15/4/2016	Change to open cohort design, additional recruitment of resident participants at 16-month follow up and associated changes to trial documentation approved; modification to staff proxy informant consent processes; modification regarding requirements to check care home indemnity insurance; introduction/modification of documents to support process evaluation and to proposed process evaluation methods and processes; and modification to process for assessing ongoing capacity of Personal Consultees.
SA10	25/7/2016	Modification to data collected during process evaluation; additional text messages to remind mappers about mutually exclusive staff roles.

(See Appendix 3). All those consenting to take part (residents already participating in the trial and consented at baseline, as well as additional residents consenting at 16-months), provided data at 16-months.

The key impact of this design change was to increase the size of the cohort at follow-up to maintain the power of the trial and its ability to detect the effect size of 0.4 with 90% power, see Appendix 3, Table 67.

2.10.2.1 Sample size calculations

With an estimated 48% loss to follow up, we expected to lose 360 residents before 16-month follow-up, resulting in data at all three time-points from 388 residents. All the other parameters – significance level, 2-sided test, ICC of 0.1 remained the same. Consideration was given to recruiting only a proportion of eligible residents at each home at 16-months).

Three possible scenarios of additional recruitment were considered (an average of 3 additional residents per care home; recruiting 35% of residents lost at follow up in each care home; replacing only 25% of residents lost to follow up in each care home) and all provided sufficient power to detect the effect size of 0.4 (89%, 91%, 90% power respectively). The TMG, oversight committees (TSC and DMEC) and funder agreed that imposing a recruitment ceiling at 16-months would be open to selection bias, and that statistical power and the ability to generalise could be limited. Recruitment processes could also be protracted due to allowing time for decision-making via personal consultee i.e. should this be a refusal to take part, further resident-consultee dyads would then need to be approached, so considerably lengthening the recruitment process, researcher workload and thus cost.

Researchers were therefore, instructed to recruit as many residents as possible in order to minimise bias. Numbers were monitored to ensure at least three extra residents from each remaining care home were recruited.

Benefits of the design change were:

a) ability to detect intervention effects at the care home level (as the intervention is aimed at the whole care home);

b) conclusions could be generalised to a broader population of residents (i.e. not just to those still residing in the care home 16-months following randomisation);

c) we would be able to analyse the data for a cross-sectional (i.e. open cohort) and closed cohort (longitudinal) design;

d) we minimised selection bias by providing an objective criterion for inclusion (all eligible consenting residents);

e) recruitment processes were resource-efficient since all eligible residents were approached to participate at a single time-point; and

f) we would be less reliant on assumptions around imputation for missing data.

As well as maintaining power and increasing generalisability, the agreed design change incurred minimal additional cost.

Three of the authors (RW, AF, CS) have since secured additional funding from the Medical Research Council [155] to conduct a methodology 'bolt on' to EPIC around the use of open-cohort designs in clinical trials. This recognises the importance of considering alternative trial designs for the conduct of studies in populations with potential large loss to follow-up rates.

2.10.2.2 Resident eligibility (16-months post randomisation)

The following inclusion criteria were applied for additional residents recruited at 16-month follow-up: a permanent resident within the care home or unit(s) taking part in the trial; had a formal diagnosis of dementia or scored 4+ on FAST [102] rated by the home manager or another experienced member of staff; and had sufficient proficiency in English to contribute to the data collection required for the research. Residents were not eligible if they: were already a DCM™ EPIC Trial participant; declined (personally or via Personal or Nominated Consultee) trial participation at baseline; moved to the care home (or participating EPIC unit) less than three-months prior to screening; were known by the care home manager and/or relevant senior staff member to be terminally ill, e.g. formally admitted to an end of life care pathway; were permanently bed-bound/cared for in bed; and were taking part in or had recently taken part in another trial that conflicted with the DCM™ intervention or with data collection for the DCM™ EPIC trial.

2.11 Resident safety

Given the intervention was at the care home level, was very low risk and non-invasive, and that trial consent was for data collection, minimal reporting of safety data was required. Given the trial population was care home residents with dementia, adverse events (AEs) were expected as part of usual care and therefore, only data on adverse events serious in nature (SAEs) were collected on consented trial residents.

A serious adverse event (SAE) was defined as an untoward event which resulted in death, was life threatening, required or prolonged existing hospitalisation, was significantly or permanently disabling or incapacitating, or was otherwise considered medically significant by a clinician. It was expected that residents would be admitted to hospital in the event of an SAE, therefore the safety reporting form collected information on hospitalisation, including reason, duration, and outcome. All deaths occurring from the date of consent up to the last data collection visit were recorded on a trial death form and reported electronically to CTRU within one working day of becoming aware. These data were collected by the researcher, monthly via a phone call to the care home manager/research lead from point of randomisation to completion of 16-month follow-up. Summaries of SAEs were reviewed annually by the trial DMEC.

Any SAE occurring to a resident which, in the opinion of the care home manager/lead and Chief Investigator, was related to research procedures and was unexpected, required reporting to the main Research Ethics Committee (main REC).

2.12 Safeguarding

It was possible the researchers might observe poor or potentially abusive practice while visiting care homes participating in the trial. The definition of abuse detailed in the Department of Health [156] guidance was utilised. In the case of observing suspected abuse the relevant Local Authority Safeguarding Adults processes were followed following discussion of the incident between the researcher and the recruitment centre lead/Chief Investigator.

2.13 Patient and Public Involvement

Patient and Public Involvement (PPI) was embedded in both the design and conduct of the trial, through both lay advisors on the investigator team and a Lay Advisory Group (LAG). The main focus was ensuring that PPI input was meaningful and a PPI strategy was written at the beginning of the trial to outline how their contribution was envisaged.

2.13.1 Lay advisors

Three dedicated lay advisors were part of the investigator team, one individual as a member of the TSC and two as members of the TMG (one of whom was also a co-applicant). These

individuals provided a user perspective on the design and conduct of the trial. They attended regular meetings throughout the trial and ensured that the TMG considered issues of importance to people living with dementia, their families and people working in care homes. Examples of advice included simplification of participant information and provision of assistance to the researchers to do this, and suggestion that a short, pictorial version of the resident information sheet was developed. These individuals also reviewed newsletters before they were circulated, making suggestions such as increased font size to improve accessibility of these to families of people living in care homes. The lay advisors collaborated on the development and writing of a trial summary which was prepared for care home managers. They also supported preparation of this section on PPI involvement.

2.13.2 Lay Advisory Group

The LAG was recruited through a partnership agreement with the Alzheimer's Society, who hosted the LAG meetings. The LAG consisted of eight members comprising a person living with dementia, relatives of people living with dementia, the Manager of a care home, a person working for a Care Organisation and a representative from the Alzheimer's Society. The LAG met three times during the process of the trial to discuss progress, initial results and dissemination strategies. A fourth meeting was held to discuss final trial outputs in February 2018, following completion of the trial in December 2017.

Alongside attendance at LAG meetings, individuals provided review of trial documents such as information sheets and consent forms prior to ethical approval being sought. Individuals from the group also reviewed the intervention protocols. All trial newsletters were reviewed by the LAG prior to distribution. Members of the LAG had the opportunity to review the publication plan and be involved with all publications arising from the study. The decision on whether to be involved in each publication was based on if, as a group, members considered that it would be beneficial for a PPI representative to be involved and if it was relevant for them to provide input.

The LAG was responsible for devising the non-academic dissemination strategy for the trial. Such avenues for dissemination included practitioner articles, a lay article for the Alzheimer's Society magazine, infographics and radio interviews as well as dissemination on social media. The LAG will continue to be involved in the design and dissemination of these publications including the design of the trial results summaries and posters for care home and individual trial participants (i.e. residents, relatives/friends, staff members etc.).

Chapter 3: Results

3.1 Recruitment and randomisation

3.1.1 Cluster recruitment

The number of care homes randomised, and residents registered, are summarised in Figure 1 by treatment arm, at baseline, 6- and 16-months following randomisation for the original cohort and the cross-sectional sample.

A total of 335 care homes were screened for entry into the trial. Of these, 241 randomly sampled care homes were approached and 94 homes expressing interest were formally assessed using the eligibility criteria. Of the 63 eligible care homes, 51 consented to take part and, following one consent withdrawal, 50 care homes were randomised into the trial (21 from Yorkshire, 15 from London and 14 from Oxford, see Appendix 1, Table 26). Nineteen care homes (38.0%) were randomised to control and 31 (62.0%) to intervention. Care homes were randomised over 16-months from October 2014 until January 2016.

3.1.2 Resident participant flow and recruitment

3.1.2.1 Original cohort

A total of 1564 residents were screened for eligibility from consenting care homes, 1069 (68.4%) were eligible, 781 (73.1%) were consented, 743 (95.1%) were registered, and 726 (97.7%) were consented and registered at the point of care home randomisation. The reasons for exclusion from the trial are summarised overall and by hub in the *Appendix 1, Table 27*. Residents in the original cohort were registered over 15-months from October 2014 until December 2015.

3.1.2.2 Additional resident recruitment at 16-months

Following the approved design change, a further 1444 residents were screened from 48 care homes at 16-months post-randomisation (see *Appendix 1, Table 27*). This included all already participating residents and those who had declined to take part when approached at baseline, who were then recorded as ineligible, alongside participants failing to meet other eligibility criteria. The first two care homes randomised did not screen additional residents as agreement for the design change was received after these care homes had completed 16-month follow-up. Of the 1444 residents, 421 were eligible, 266 consented and 261 residents were subsequently registered (99 residents in control homes and 162 in intervention homes).

A lower proportion of residents in London were ineligible due to being permanently bed-bound or terminally ill.

There was a higher proportion of ineligible residents of those screened (due to not having a formal diagnosis of dementia), and consent refusals in the intervention compared to control arm (see *Appendix 1, Table 28*). The additional residents were screened over 11-months from June 2016 until May 2017.

3.1.2.3 Cross-sectional sample

Overall at 16-months, a total of 675 residents were included in the cross-sectional sample: 414 residents from the original cohort who reached 16-months and 261 additionally-recruited residents. There were regional differences between hubs in resident ethnicity and funding type, with London reporting the lowest proportion of white residents and Oxford reporting the highest proportion of Local Authority funding (see *Appendix 1, Table 29*).

3.1.2.4 Investigation into potential recruitment bias of additional residents

As the additional residents for the cross-sectional sample were recruited following care home randomisation, age, gender, ethnicity, length of stay in care home and funding type were compared for all screened and registered residents (see Table 4). Overall, there was a shorter length of stay in the additional cohort compared to the original cohort, as was expected. Of the 726 residents included in the original cohort, 145 (20.0%) consented themselves; 263 (36.2%) were consented by a Personal Consultee and 318 (43.8%) by a Nominated Consultee (see *Appendix 1, Table 30*). In contrast, of the 261 residents recruited at 16-months, 58 (22.2%) consented themselves, 73 (28.0%) were consented by a Personal Consultee and 130 (59.8%) by a Nominated Consultee. There was no difference by arm in the proportion of residents who consented for themselves, but a higher proportion were consented by Nominated Consultees in the intervention arm (87, 53.7%) relative to the control arm (43, 43.4%).

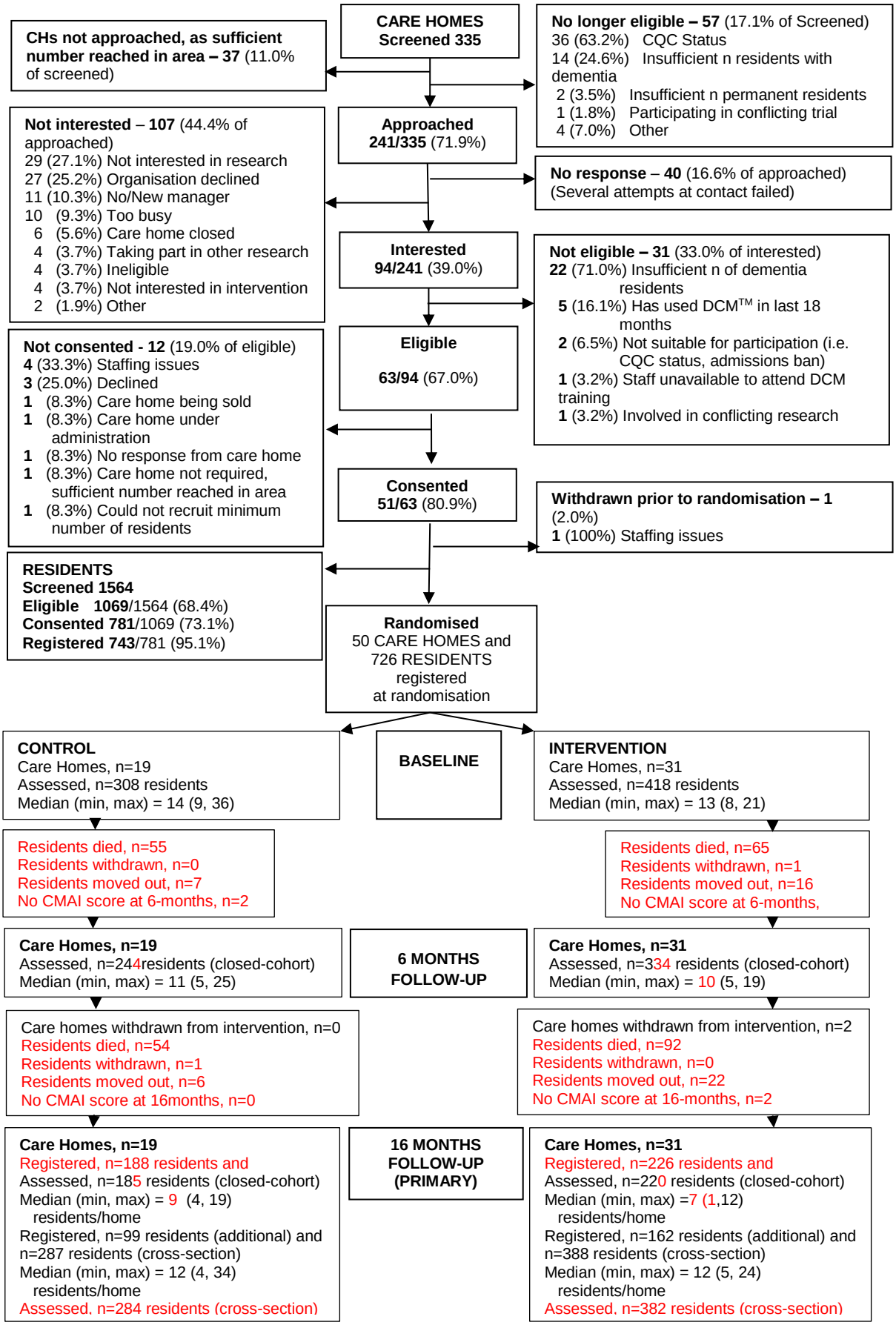

Figure 1 Care Home and Resident CONSORT Diagram

Table 4 Characteristics of Screened Residents Overall and by Arm

	Original Cohort				Additional					
	Screened	Registered			Screened*			Registered		
	Total (n=1564)	**Control (n=308)**	**Intervention (n=418)**	**Total (n=726)**	**Control (n=275)**	**Intervention (n=602)**	**Total (n=877)**	**Control (n=99)**	**Intervention (n=162)**	**Total (n=261)**
Age at registration (years) Mean (SD)	85.1 (8.18)	85.2 (7.37)	85.9 (7.83)	85.6 (7.64)	85.1 (7.51)	85.1 (8.36)	85.1 (8.10)	84.6 (7.69)	85.9 (8.09)	85.4 (7.95)
Length of stay in care home (years) Mean (SD)	2.3 (2.48)	2.3 (2.14)	2.4 (2.47)	2.3 (2.34)	1.3 (1.84)	1.7 (2.29)	1.6 (2.17)	1.2 (1.01)	1.5 (1.72)	1.4 (1.50)
Sex Female N (%)	1140 (72.9%)	244 (79.2%)	292 (69.9%)	536 (73.8%)	202 (73.5%)	423 (70.3%)	625 (71.3%)	68 (68.7%)	118 (72.8%)	186 (71.3%)
Ethnicity N (%) Missing										
White	1483 (94.8%) 26	302 (98.1%)	400 (95.7%)	702 (96.7%)	271 (98.5%) 2	575 (95.5%) 4	846 (96.5%) 6	99 (100.0%)	158 (97.5%)	257 (98.5%)
Other	55 (3.5%)	6 (1.9%)	18 (4.3%)	24 (3.3%)	2 (0.7%)	23 (3.8%)	25 (2.9%)	0 (0.0%)	4 (2.5%)	4 (1.5%)
Funding type N (%)										
Local Authority	741 (47.4%)	128 (41.6%)	224 (53.6%)	352 (48.5%)	113 (41.1%)	291 (48.3%)	404 (46.1%)	52 (52.5%)	74 (45.7%)	126 (48.3%)
Continuing Healthcare	115 (7.4%)	28 (9.1%)	20 (4.8%)	48 (6.6%)	5 (1.8%)	16 (2.7%)	21 (2.4%)	1 (1.0%)	1 (0.6%)	2 (0.8%)
Self-funded	555 (35.5%)	133 (43.2%)	156 (37.3%)	289 (39.8%)	94 (34.2%)	224 (37.2%)	318 (36.3%)	33 (33.3%)	75 (46.3%)	108 (41.4%)
Local Authority and self-funded	69 (4.4%)	17 (5.5%)	17 (4.1%)	34 (4.7%)	26 (9.5%)	42 (7.0%)	68 (7.8%)	13 (13.1%)	12 (7.4%)	25 (9.6%)
Missing	84 (5.4%)	2 (0.6%)	1 (0.2%)	3 (0.4%)	37 (13.5%)	29 (4.8%)	66 (7.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

*Excluding those already participating in EPIC or those that were screened at baseline but refused consent.

3.1.3 Staff recruitment

There was a very poor return rate of staff questionnaire booklets (see *Appendix 1, Table 31*) despite the changes made to encourage return rates i.e. removal of the GHQ12 and personal data (see *section 2.10*). Following consultation with oversight committees, it was agreed that persistence with obtaining staff data was important as the intervention was designed to effect a 'whole-home' change. However, due to low return rates, planned statistical analyses could not be conducted.

3.1.4 Relative/friend recruitment

At baseline, 197 relatives/friends were registered to the trial with 96 in the control arm and 101 in the intervention arm. This reflects a larger proportion in the control arm given the 2:3 randomisation allocation. The total number of relatives/friends registered to the trial reduced at 6-months (n=170, control=85, intervention=85) and 16-months (n=118, control=63, intervention=55) (see *Appendix 1, Table 32*) as might be expected with the high loss to follow-up rates. It was agreed by the oversight committees that, given the low percentage of data received, these data would not be useful when undertaking statistical analyses, with the exception of some of the health economic analyses (see *section 2.8.9*). New relative/friend informants were therefore not identified at follow-up. Where relatives/friends agreed to take part at baseline, we continued to request their follow-up data.

3.2 Baseline data

3.2.1 Care Home characteristics

At baseline, on average the intervention arm homes were larger than control. However, the average proportion of permanent residents with dementia was higher in the control arm. Care home managers had similar work experience and training across both arms (Table 5)

A slightly higher than anticipated number of care homes (n=13, 26%) [99] needed PCCT training ahead of baseline data collection due to not meeting minimum criteria on the ADAPT audit tool.

Table 5 Baseline care home and care home manager characteristics

	Control (n = 19)	Intervention (n = 31)	Total (n = 50)
Unit type (N (%) missing) - General residential/nursing home	11 (57.9%) 0	20 (64.5%) 0	31 (62%) 0
- Specialist dementia care home/unit	8 (42.1%) 0	11 (35.5%) 0	19 (38%) 0
More than one unit (N (%) missing)	3 (15.8%) 0	3 (9.7%) 0	6 (12%) 0
DCM™ was used between 18-months to 5 years (N (%) missing)	11 (57.9%) 0	20 (64.5%) 0	31 (62%) 0
Residents' meeting held within the last 6-months (N (%) missing)	17 (89.5%) 0	30 (100%) 1	47 (95.9%) 1
Relatives' meeting held within the last 6-months (N (%) missing)	18 (94.7%) 0	29 (96.7%) 1	47 (95.9%) 1
Number of beds in the care home (Mean (SD) missing)	28.8 (8.97) 2	36.8 (14.28) 1	33.9 (13.1) 3
Number of permanent residents (Mean (SD) missing)	30 (11.27) 0	32.9 (14.02) 1	31.8 (12.98) 1
Percentage of permanent residents with dementia (Mean (SD) missing)	83.1 (21.21) 0	74.2 (22.48) 1	77.7 (22.21) 1
Percentage of self-funded residents (Mean (SD) missing)	52.8 (28.12) 0	37.9 (21.12) 1	43.7 (24.89) 1
Cost of a self-funded place per year (£) (Mean (SD) missing)	44553 (13291) 0	41638 (13003) 1	42768 (13056) 1
Average resident:staff ratio daytime (Median (Range) Missing)	5.2 (3.0, 8.8) 0	4.7 (2.5, 10.5) 1	4.8 (2.5, 10.5) 1
Average resident:staff ratio night time (Median (Range) Missing)	9.5 (3.3, 17.5) 0	9.7 (2.9, 15.3) 1	9.7 (2.9, 17.5) 1
Care Home manager			
Time in current role (Median (Range))	2.5 (0.3, 37.0)	2.9 (0.3, 25.0)	2.6 (0.3, 37.0)
Length of time worked in care homes (N (%))			
Up to 10 years	3 (15.8%)	7 (22.6%)	10 (20.0%)
More than 10 years	16 (84.2%)	24 (77.4%)	40 (80.0%)
Length of time in a manager role (N (%))			
- Up to 2 years	3 (15.8%)	7 (22.6%)	10 (20.0%)
- Up to 5 years	5 (26.3%)	4 (12.9%)	9 (18.0%)
- Up to 10 years	2 (10.5%)	5 (16.1%)	7 (14.0%)
- More than 10 years	9 (47.4%)	15 (48.4%)	24 (48.0%)
Manager dementia training/education			
Previously trained as a dementia care mapper by UoB	3 (15.8%)	4 (12.9%)	7 (14.0%)
Dementia specific qualification	4 (21.1%)	10 (32.3%)	14 (28.0%)
Dementia covered in one part of a qualification	10 (52.6%)	18 (58.1%)	28 (56.0%)
Attended a dementia specific training course	19 (100.0%)	31 (100.0%)	50 (100.0%)

Table 6 Resident characteristics

Original cohort at baseline		**Control (n = 308)**	**Intervention (n = 418)**	**Total (n = 726)**
Age at randomisation Years (Mean (SD) missing)		85.3 (7.38) 0	86 (7.83) 0	85.7 (7.64) 0
Gender Male (%)		64 (20.8%)	126 (30.1%)	190 (26.2%)
Number of comorbidities per resident (Median (Range))		2 (0, 10)	2 (0, 14)	2 (0, 14)
Selected comorbidities*	Anxiety	34 (11.0%)	23 (5.5%)	57 (7.9%)
	Depression	62 (20.1%)	55 (13.2%)	117 (16.1%)
	Psychosis	16 (5.2%)	24 (5.7%)	40 (5.5%)
	Sleep disturbance	6 (1.9%)	7 (1.7%)	13 (1.8%)
	Delirium	3 (1.0%)	2 (0.5%)	5 (0.7%)
FAST stage (out of completed scores)		**(n=306)**	**(n=391)**	**(n=697)**
1		2 (0.7%)	0 (0.0%)	2 (0.3%)
2		2 (0.7%)	0 (0.0%)	2 (0.3%)
3		1 (0.3%)	1 (0.3%)	2 (0.3%)
4		39 (12.7%)	56 (14.3%)	95 (13.6%)
5		26 (8.5%)	48 (12.3%)	74 (10.6%)
6		166 (54.2%)	214 (54.7%)	380 (54.5%)
7		70 (22.9%)	72 (18.4%)	142 (20.4%)
Cross-section at 16-months		**Control (n = 287)**	**Intervention (n = 388)**	**Total (n = 675)**
Age at randomisation Years (Mean (SD) missing)		83.7 (7.77) 0	85.2 (7.79) 0	84.6 (7.81) 0
Gender Male (%)		71 (24.7%)	110 (28.4%)	181 (26.8%)
Number of comorbidities per resident (Median (Range))		2 (0, 7)	3 (0, 12)	2 (0, 12)
Selected comorbidities*	Anxiety	26 (9.1%)	27 (7.0%)	53 (7.9%)
	Depression	64 (22.3%)	66 (17.0%)	130 (19.3%)
	Psychosis	11 (3.8%)	21 (5.4%)	32 (4.7%)
	Sleep disturbance	2 (0.7%)	5 (1.3%)	7 (1.0%)
	Delirium	2 (0.7%)	2 (0.5%)	4 (0.6%)
FAST stage (out of completed scores)		**(n=284)**	**(n=384)**	**(n=668)**
4		22 (7.7%)	35 (9.1%)	57 (8.5%)
5		20 (7.0%)	21 (5.5%)	41 (6.1%)
6		168 (59.2%)	238 (62.0%)	406 (60.8%)
7		74 (26.1%)	90 (23.4%)	164 (24.6%)

*not mutually exclusive

3.2.2 Resident characteristics

In the closed-cohort, the mean resident age at randomisation was similar between intervention and control arms (85.3 years in control, 86.0 years in intervention) (Table 6). A higher proportion of residents in the intervention were male (126, 30.1%) compared to control (64, 20.8%) and the median number of comorbidities was two in both arms, with the proportion of residents with no comorbidities similar across arms.

In the cross-sectional sample, control residents were slightly younger compared to intervention residents (83.7 versus 85.2 years respectively). There was a higher proportion of residents with no reported comorbidities in control compared to intervention. Similar levels of dementia severity were observed in both arms, as measured by the FAST, although a lower proportion of residents had moderately severe to severe dementia (FAST stage 6-7) in the closed-cohort (74.9%) compared to the cross-sectional sample (85.4%) due to worsening of dementia of residents in the closed-cohort over time.

3.3 Treatment summaries

3.3.1 Control

Organisational and staff changes reflecting usual care at a care home level are summarised in Table 7 for both arms, each compared to the previous time point. A higher proportion of care homes had experienced management changes in the intervention arm at 6-months, and a higher proportion of care homes had new staff roles introduced in the unit in the intervention arm. At both follow-up points, a higher proportion of intervention care homes achieved or completed standard quality assessments (e.g. ISA). Compared with control homes a smaller proportion of intervention care homes reported having staff with higher-level dementia-specific qualifications at 6-months, but by 16-months a higher proportion of intervention homes reported staff with higher-level dementia-specific qualifications.

3.3.2 Intervention

Adherence to the intervention is reported by cycle and number of components completed (i.e. briefing; observation; analysis, reporting and feedback; and action planning) in Figure 2 (see *Appendix 1, Table 33* for further detail on adherence by care home), with the furthest reported component through the DCM™ cycle presented. Based on documented evidence, 16 (51.6%) of care homes in the intervention arm completed only one cycle to an acceptable level, 4 (12.9%) completed two cycles to an acceptable level and 4 (12.9%) completed all three cycles to an acceptable level. Seven care homes (22.6%) did not complete a full

intervention cycle, with three (9.7%) of these not completing any of the intervention components. Further intervention component summaries are in Appendix 1 (see *Tables 34-40 and Figure 7*). Due to challenges in getting return full adherence data from care homes, it was not possible to ascertain how many care home staff had engaged with the DCM process during each cycle and thus to assess intervention 'dose' in terms of reach.

Table 7 Summary of changes in usual care

	At 6-months (from baseline)			At 16-months (from 6-months)		
N (%) Unknown	**Control (n=19)**	**Intervention (n=31)**	**Total (n=50)**	**Control (n=19)**	**Intervention (n=31)**	**Total (n=50)**
Any organisational changes	4 (21.1%)	6 (19.4%)	10 (20.0%)	4 (21.1%)	6 (19.4%)	10 (20.0%)
Any care home management changes	5 (26.3%)	12 (38.7%)	17 (34.0%)	8 (42.1%)	13 (41.9%)	21 (42.0%)
Any new staff roles	1 (5.3%)	6 (19.4%)	7 (14.0%)	3 (15.8%)	7 (22.6%)	10 (20.0%)
Any new projects or initiatives	5 (26.3%)	9 (29.0%)	14 (28.0%)	6 (31.6%)	12 (38.7%)	18 (36.0%)
Any new voluntary measures to improve standards	1 (5.3%)	3 (9.7%)	4 (8.0%)	0 (0.0%)	3 (9.7%)	3 (6.0%)
Any standard quality assessments achieved	3 (15.8%)	9 (29.0%)	12 (24.0%)	2 (10.5%)	6 (19.4%)	8 (16.0%)
Currently subject to any CQC notifications	2 (10.5%)	6 (19.4%)	8 (16.0%)	1 (5.3%)	1 (3.2%)	2 (4.0%)
PCC training available in unit	18 (94.7%)	29 (93.5%)	47 (94.0%)	16 (84.2%) 1	31 (100.0%)	47 (94.0%) 1
Staff with higher level dementia-specific qualification	10 (52.6%)	12 (38.7%) 1	22 (44.0%) 1	10 (52.6%)	20 (64.5%)	30 (60.0%)

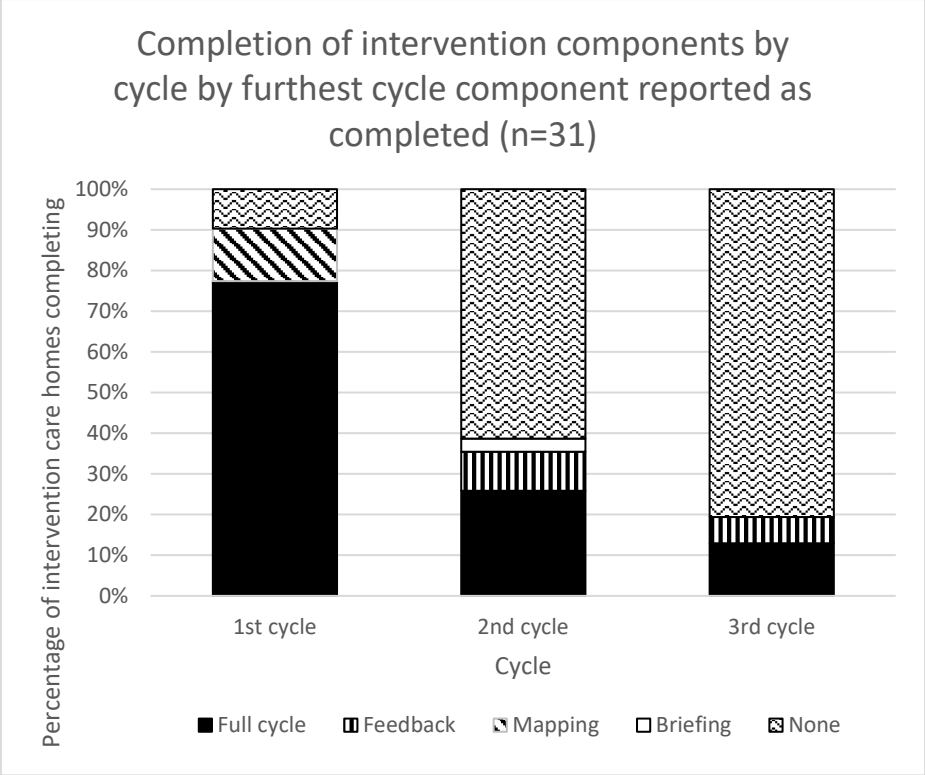

Figure 2: Completion of intervention components by cycle

3.4 Losses and exclusions after randomisation

3.4.1 Withdrawals

Two care homes in the intervention arm withdrew from further trial treatment but not from further data collection in months 11 and 12, respectively. One resident from the closed-cohort withdrew consent for all data collection in the intervention arm (withdrawn by personal consultee in month 2). There were four staff-proxy withdrawals, one in each arm at 6- and 16-months follow-up. There were four relative/friend withdrawals, one in the control arm (at 16-months follow-up) and three in the intervention arm (one at 6-months and two following 16-months follow-up).

3.4.2 Protocol violations

There were two care home eligibility violations identified and reported in first two-months following randomisation (one in each arm). Both related to changed CQC status, between recruitment and randomisation. In both cases, the chief investigator agreed to the care homes continuing in the trial and were included in the ITT analysis. Five staff eligibility violations were reported in the intervention arm, involving individuals who undertook both mapper and staff-proxy roles.

3.4.3 Resident deaths in closed cohort

Seventeen resident deaths occurred between care home registration and randomisation (See *Appendix 1, Table 41*); the remaining 726 residents constitute the original cohort. Overall, there were 272 (37.5%) deaths reported between randomisation and the end of 16-month follow-up in the original cohort, 111 (36.0%) in the control arm and 161 (38.5%) in the intervention arm (however, of these, primary outcome data was available for 2 (1.8%) in the control arm and 4 (2.5%) in the intervention arm). The majority of residents died in the care home (224/272, 82%), 89/308 (80.2%) in the control and 135/418 (83.9%) in the intervention arm. The mean proportion of deaths per care home in the control was 0.36 (SD=0.12) and 0.39 (SD=0.14) in the intervention arm.

3.5 Clinical effectiveness of the intervention

3.5.1 Analyses of the primary outcome

Analyses were conducted on the cross-sectional sample (primary) and the closed-cohort. Unadjusted scores are presented in Table 8 for the primary outcome (staff-proxy completed CMAI) and change in unadjusted scores from baseline is presented graphically in Appendix 1, Figures 8 and 9. At baseline, the mean CMAI total score was higher in control (48.4 points) compared to intervention (45.4 points) homes. In the closed-cohort at 6-months, the gap had closed, with means being 44.9 points and 43.6 points respectively in control and intervention homes (148/726 (20.4%) residents were lost to follow-up however). By 16-months, the gap had widened again in the closed-cohort (although by this time 321/726 (44.2%) residents were lost to follow-up), with means of 46.4 points and 41.4 points respectively in control and intervention care homes. The gap was slightly narrower in the cross-sectional sample (9/675 (1.3% lost to follow-up), with means of 46.1 points and 42.8 points in the control and intervention homes respectively. Differences in means between the control and intervention homes are therefore small in both resident samples, largely arising from changes carried through from baseline.

All 675 residents in the cross-sectional sample at 16-months were included in the primary analysis, 666 of which had complete data. There was no evidence of a difference in agitation levels between arms. The mean difference in total CMAI score from the two-level heteroscedastic linear regression model fitted to the multiply-imputed data (assuming data were MAR) was -2.11 points, lower in the intervention arm than in the control (adjusted means 45.47 points in control; 43.35 points in intervention, 95% CI -4.66 to 0.44, p=0.104). The unadjusted ICC was zero in the control and 0.058 in the intervention arm, but the adjusted ICC was zero in the control and 0.001 in the intervention arm, indicating that between-cluster heterogeneity in the intervention arm was explained by the covariates in the

model. Using the complete cases, the mean difference was -2.19 points lower for intervention compared to control homes (95% CI -4.81 to 0.43), the adjusted ICC was zero in both treatment arms, indicating that the treatment effect was neither clinically meaningful or statistically significant at the 5% level (p=0.099) (see *Appendix 1, Table 45*). The primary analysis is summarised in Table 10.

3.5.1.1 Supportive and sensitivity analyses

Unadjusted scores for the observational CMAI (CMAI-O) and PAS scores outcomes using in place of the CMAI by resident sample and time-point are presented in Table 9 (cross-section) and Appendix 1, Tables 42 (closed cohort), 43 and 46-47 (complete cases). A similar pattern of differences was found for these supportive outcomes completed by the blinded independent researcher. The mean CMAI-O scores were consistently very slightly higher in the afternoon than in the morning. The same is the case for PAS scores. Loss to follow-up was higher for these supportive outcomes (about 276/726=38.0% at baseline, 358/726=49.3% at 6-months, and 495/726=68.2% and 310/675=45.9% at 16-months in the closed-cohort and cross-section respectively) than for the primary outcome.

The sensitivity and supportive analyses are summarised in Table 10 and Appendix 1, Table 44, respectively. The key sensitivity analysis simplified the model fitted to ensure complete convergence and was added post-hoc. Sensitivity analyses on the CMAI for the subset of residents included in the analyses of the CMAI-O and PAS were also added post-hoc. The equivalent analyses on the complete cases are provided in Appendix 1, Tables 18 to 20. The key sensitivity analysis and the first three planned sensitivity analyses supported the results found in the primary analysis.

Sensitivity analyses of the CMAI-O and the PAS indicated a potential over-estimation of the treatment effect from the primary analysis, as the mean differences are reduced when a blinded independent observation is made (analyses in rows 4a and 4c Table 10). However, we would expect the CMAI-O and PAS to potentially under-estimate agitation levels since they are conducted over only two observations periods in a single week, in public areas of the home during restricted daytime hours. The staff-proxy rating is made over two weeks and includes consideration of agitation during personal care, evening and the night-time. The sensitivity analysis conducted on the closed-cohort gave a mean difference of -3.25 (95% CI -6.13 to -0.37, p=0.027), apparently contradicting the conclusion of the primary analysis. However, the sensitivity analysis is not robust, as it relies on multiply imputing data for 45% of the sample. It has a different interpretation too, as this is the treatment effect estimated for residents who remain the in the care home from baseline to 16-months. A sensitivity analysis

Table 8 Unadjusted CMAI scores by resident sample and time-point

Unadjusted CMAI scores[a] by resident sample and time-point						
				Closed-cohort		
Mean (SD) Missing	Control (n = 308)		Intervention (n = 418)		Total (n = 726)	
Baseline Total score	**48.4 (19.53)**	**2**	**45.4 (15.95)**	**2**	**46.7 (17.6)**	**4**
Subscales:						
Aggressive behaviour	14.3 (8.10)	2	12.6 (6.28)	2	13.3 (7.16)	4
Physically non-aggressive	11.6 (6.47)	8	11.3 (6.08)	10	11.4 (6.25)	18
Verbally agitated	10.4 (6.23)	5	9.9 (5.94)	2	10.1 (6.06)	7
Other	12 (4.58)	0	11.5 (3.73)	2	11.7 (4.12)	2
6-months Total score	**44.9 (16.75)**	**64**	**43.6 (14.32)**	**84**	**44.2 (15.39)**	**148**
Subscales:						
Aggressive behaviour	13.3 (7.21)	64	12.4 (6.14)	84	12.8 (6.62)	148
Physically non-aggressive	10.5 (5.88)	68	10.6 (5.28)	100	10.6 (5.54)	168
Verbally agitated	9.4 (5.42)	64	9.6 (5.42)	87	9.5 (5.42)	151
Other	11.7 (3.95)	64	11 (3.26)	84	11.3 (3.58)	148
16-months Total score	**46.4 (16.54)**	**123**	**41.4 (14.73)**	**198**	**43.7 (15.76)**	**321**
Subscales:						
Aggressive behaviour	14 (7.66)	123	12.3 (5.9)	196	13 (6.8)	319
Physically non-aggressive	11 (5.82)	124	9.2 (4.85)	205	10 (5.38)	329
Verbally agitated	9.7 (5.55)	123	9 (5.63)	197	9.3 (5.60)	320
Other	11.8 (4.05)	123	10.8 (3.08)	199	11.3 (3.59)	322
				Cross-section		
Mean (SD) Missing	Control (n = 287)		Intervention (n = 388)		Total (n = 675)	
16-months Total score	**46.1 (16.78)**	**3**	**42.8 (15.79)**	**6**	**44.2 (16.29)**	**9**
Subscales:						
Aggressive behaviour	13.7 (7.93)	3	12.2 (5.87)	4	12.9 (6.86)	7
Physically non-aggressive	11 (6.01)	4	9.9 (5.36)	15	10.4 (5.67)	19
Verbally agitated	9.8 (5.79)	3	9.7 (6.16)	5	9.7 (6.00)	8
Other	11.5 (3.73)	3	11 (3.49)	7	11.2 (3.60)	0

[a]CMAI overall, range 29-203, higher score indicates higher frequency of agitated behaviour. CMAI subscales: Aggressive behaviour (range 9-63), Physically non-aggressive behaviour (range 6-42), Verbally agitated behaviour (range 5-35) and Other behaviour (range 9-63).

Table 9 Unadjusted observational CMAI and PAS scores for by time-point - cross-sectional cohort

Unadjusted CMAI-O[a] and PAS[b] scores by time-point - cross-section						
	AM			PM		
	Control	**Intervention**	**Total**	**Control**	**Intervention**	**Total**
Mean (SD) N completed	**(n = 287)**	**(n = 388)**	**(n = 675)**	**(n = 287)**	**(n = 388)**	**(n = 675)**
16-months CMAI-O Total Score	**31.1 (3.8) 156**	**30.5 (3.3) 209**	**30.8 (3.5) 365**	**31.4 (3.8) 148**	**31.1 (3.9) 206**	**31.2 (3.9) 354**
Subscales: Aggressive behaviour	9.3 (0.9) 156	9.3 (1.0) 209	9.3 (1.0) 365	9.3 (1.1) 148	9.3 (1.2) 206	9.3 (1.1) 354
Physically non-aggressive	6.7 (1.4) 156	6.5 (1.5) 209	6.6 (1.4) 365	6.9 (1.5) 148	6.8 (1.9) 206	6.9 (1.8) 354
Verbally agitated	5.8 (2.2) 156	5.5 (1.5) 209	5.6 (1.8) 365	5.8 (1.9) 148	5.7 (1.7) 206	5.7 (1.8) 354
Other	9.3 (1.0) 156	9.2 (0.7) 209	9.2 (0.8) 365	9.3 (0.9) 148	9.3 (0.9) 206	9.3 (0.9) 354
16-months PAS score	1.1 (1.9) 156	0.8 (1.7) 209	0.9 (1.8) 365	1.2 (1.9) 148	0.9 (1.8) 205	1.0 (1.8) 353

[a]CMAI-O: scores 29-116, higher score indicates more frequent agitated behaviour, [b]PAS: range of 0-16, with higher scores representing higher levels of agitation

on the closed-cohort assumed data are missing not at random (MNAR). This explores the impact of assumptions about the missing data, looking at a range of plausible and potentially implausible scenarios in which there was a shift in the CMAI at 16-months of up to 40 points either way for residents that died, withdrew or moved away. This assumes that the scores for all residents with missing data would have shifted by the same number of points. The conclusions of the closed-cohort analysis remain unchanged for shifts of -40 to 5 points from the average CMAI at 16-months for those who died and any shift for those who withdrew (see *Appendix 1, Table 48*).

Supportive analyses of the closed-cohort at 6- and 16-months (see *Appendix 1 Table 44*) indicate that there were no differences in CMAI, CMAI-O or PAS scores at 6-months, and no differences in CMAI-O and PAS scores at 16-months. Overall, these analyses confirm that the intervention is not superior to the control.

A complier average causal effect (CACE) analysis of the cross-sectional sample, comparing care homes in the intervention arm that completed at least one cycle to an acceptable level with care homes that would have completed at least one cycle had the intervention been offered to them, gave a mean difference in CMAI score at 16-months of -2.5 points (95% CI -5.4 to 0.4, p=0.089). This indicates that the ITT estimate from the primary analysis is not dissimilar to the effect of completing at least one cycle to an acceptable level. The 95% confidence intervals are wider compared to the primary analysis and the CACE estimate is not statistically significant at the 5% level (p=0.089) (Table 11). The exploratory CACE analyses using other definitions of adherence indicate that the treatment effect may increase if care homes complete at least two DCM™ cycles to an acceptable level compared to completing only one cycle. While these analyses are suggestive of a dose-response relationship in which supporting adherence to the second and third cycle might result in a clinically meaningful effect, this would need to be confirmed by further research.

The change in unadjusted CMAI scores for the care homes between baseline and 16-months is presented by intervention adherence (the number of cycles completed to an acceptable level) in Figure 3. There was considerable variation in CMAI score changes between care homes completing zero, one, two and three acceptable cycles.

Table 10: Primary and sensitivity analyses assuming missing data are MAR – cross-sectional sample

Analysis	Adjusted Mean in Control	Adjusted Mean in Intervention	Estimated Mean Difference	Lower 95% Confidence Limit	Upper 95% Confidence Limit	p-value	Adjusted ICC for Intervention	Adjusted ICC for Control	N
Primary analysis	45.47	43.35	-2.11	-4.66	0.44	0.104	0.001	0.000	675
Sensitivity analyses (cross-sectional sample)									
Key sensitivity analysis (hub omitted from the model)	46.02	43.78	-2.24	-4.91	0.42	0.099	0.010		675
1. Adjusting for before-after eligibility change*	44.82	42.69	-2.13	-4.71	0.45	0.105	0.002	0.000	675
2. Care home size as a continuous variable	45.59	43.21	-2.38	-5.00	0.25	0.076	0.000	0.000	675
3. Homogeneous clustering across arms	45.41	43.32	-2.09	-4.61	0.44	0.105	0.001		675
4a. CMAI-O (AM)	31.00	30.41	-0.58	-1.62	0.45	0.269	0.215	0.006	675
4b. CMAI on subset with CMAI-O (AM)	47.49	43.43	-4.06	-7.55	-0.57	0.023	0.016	0.001	365
4c. CMAI-O (PM)	31.34	31.11	-0.22	-1.52	1.08	0.737	0.220	0.013	675
4d. CMAI on subset with CMAI-O (PM)	47.49	43.43	-4.06	-7.55	-0.57	0.023	0.016	0.001	365
4e. PAS (AM)	0.93	0.73	-0.20	-0.67	0.27	0.402	0.166	0.011	675
4f. CMAI on subset with PAS (AM)	47.49	43.43	-4.06	-7.55	-0.57	0.023	0.016	0.001	365
4g. PAS (PM)	1.17	0.89	-0.28	-0.96	0.41	0.429	0.299	0.018	675
4h. CMAI on subset with PAS (PM)	47.49	43.43	-4.06	-7.55	-0.57	0.023	0.016	0.001	365
5. CMAI at 16-months (closed-cohort)	46.4	43.16	-3.25	-6.13	-0.37	0.027	0.013	0.001	726

*eligibility changed in December 2014 after first two care homes randomised

Table 11: CACE analysis using various scenarios

	Model	Treatment Effect (SE)	95% Confidence Interval	p-value
CACE Analyses (documented and expert evidence), multiple imputation	At least one cycle to an acceptable level	-2.5 (1.5)	-5.4 to 0.4	0.089
	At least one cycle to a partial level	-2.2 (1.3)	-4.8 to 0.3	0.087
	One cycle **only** to an acceptable level	-3.6 (2.2)	-7.9 to 0.8	0.106
	At least two cycles to an acceptable level	-8.5 (5.3)	-18.9 to 2.0	0.112
Complete Case CACE Analyses, sensitivity analyses	At least one cycle to an acceptable level			
	At least two cycles to an acceptable level	-2.6 (1.4)	-5.4 to 0.2	0.068
	At least one cycle to a partial level	-2.2 (1.3)	-4.8 to 0.3	0.087

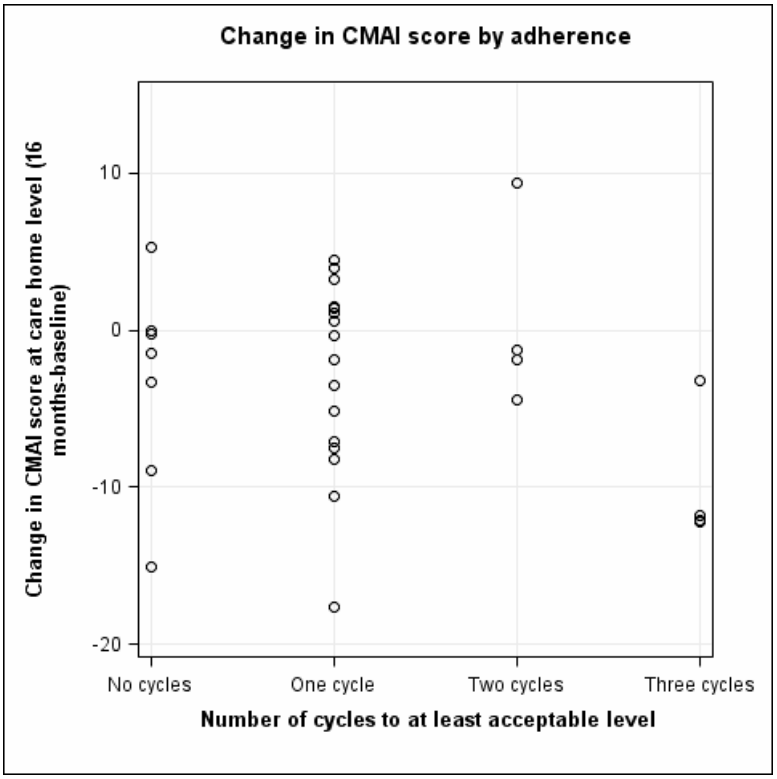

Figure 3 Change in CMAI score between baseline and 16-months by adherence to the intervention

3.5.2 Analyses of the secondary outcomes

Analyses of the NPI-NH, PRN prescription medications, quality of life and quality of staff interactions were conducted on closed-cohort at 6-months and on the cross-sectional sample (primary) and the closed-cohort (supportive) at 16-months. Unadjusted scores are presented in Tables 12, 13, 14 and 15 by resident sample and time-point and Appendix 1, Tables 49-60.

As can be seen in Table 12, at baseline, the proportions of residents experiencing behaviour staff may find challenging to support (BSC) (defined as presence of the following behaviours in the NPI-NH: agitation/aggression, depression/dysphoria, anxiety, apathy/indifference, disinhibition or irritability/lability) were similar across the intervention and control arm. However, the average NPI-NH score was higher in the control than intervention arm. Agitation/aggression was experienced by the highest proportion of residents across all time-points and in both samples. At 16-months, the proportion of residents experiencing BSC was smaller in the intervention arm compared to control for both the cross-sectional and closed-cohort samples. The average NPI-NH score was similar in both arms for both samples, having reduced more in the control arm from baseline.

The percentage of residents prescribed antipsychotics on a PRN basis was low across time-points at less than 1.6% (see Table 13), making it difficult to detect any differences between the arms. Quality of life was primarily measured using the QUALID staff-proxy. Data is presented on the resident-rated QOL-AD and the relative-proxy QUALID, however, this is for comparison only, due to the poor completion rates (see Table 14). There are no notable differences in the QUALID scores provided by staff-proxies at baseline, 6- or 16-months in either resident sample. This pattern is supported by the resident-rated QOL-AD and relative-proxy QUALID.

The proportion of positive interactions as measured by the QUIS (see Table 15) differed between arms at baseline and at 6-months, with a higher proportion of interactions experienced in the intervention; this difference in proportions was not evident at 16-months.

Table 12 Unadjusted NPI-NH scores and behaviours staff find challenging by resident sample and time-point

	Scores Mean (SD) Missing			**Number experiencing the behaviour staff find challenging** completed N (%)		
CLOSED-COHORT	**Control (n = 308)**	**Intervention (n = 418)**	**Total (n = 726)**	**Control (n = 308)**	**Intervention (n = 418)**	**Total (n = 726)**
Baseline Total NPI[a] score	**13 (13.95) 0**	**11.7 (12.35) 0**	**12.2 (13.06) 0**			
Subscales*:				236 (76.6%) 308	325 (77.8%) 418	561 (77.3%) 726
Agitation/Aggression	5.0 (2.85) 2	4.7 (2.86) 0	4.8 (2.85) 2	145 (47.1%) 308	192 (46.0%) 417	337 (46.5%) 725
Depression/Dysphoria	4.1 (2.77) 0	3.6 (2.63) 2	3.8 (2.70) 2	92 (30.0%) 307	129 (30.9%) 418	221 (30.5%) 725
Anxiety	5.2 (3.16) 2	3.9 (2.32) 3	4.5 (2.80) 5	80 (26.0%) 308	98 (23.5%) 417	178 (24.6%) 725
Apathy/Indifference	5.4 (3.30) 1	5.2 (3.07) 1	5.3 (3.16) 2	91 (29.5%) 308	130 (31.2%) 417	221 (30.5%) 725
Disinhibition	5.0 (3.29) 0	3.8 (2.62) 0	4.3 (2.97) 0	51 (16.6%) 308	65 (15.6%) 416	116 (16.0%) 724
Irritability/Lability	5.3 (3.16) 3	4.4 (2.85) 0	4.8 (3.01) 3	117 (38.0%) 308	153 (36.7%) 417	270 (37.2%) 725
6-months Total NPI score	**11.3 (12.35) 0**	**9.7 (10.14) 0**	**10.4 (11.17) 0**			
Subscales*:				186 (76.2%) 244	238 (74.4%) 320	424 (75.2%) 564
Agitation/Aggression	5.4 (3.24) 0	4.4 (2.62) 0	4.9 (2.98) 0	120 (49.0%) 245	125 (39.2%) 319	245 (43.4%) 564
Depression/Dysphoria	3.7 (2.66) 0	3.5 (2.35) 1	3.6 (2.47) 1	63 (26.0%) 242	101 (31.6%) 320	164 (29.2%) 562
Anxiety	4.6 (2.92) 2	4.0 (2.71) 1	4.3 (2.81) 3	47 (19.3%) 244	57 (17.9%) 319	104 (18.5%) 563
Apathy/Indifference	5.7 (3.39) 1	4.3 (2.91) 1	4.9 (3.16) 2	73 (29.9%) 244	116 (36.3%) 320	189 (33.5%) 564
Disinhibition	4.9 (3.08) 0	5.3 (3.44) 0	5.1 (3.23) 0	35 (14.3%) 244	30 (9.4%) 320	65 (11.5%) 564
Irritability/Lability	4.5 (3.12) 0	4.4 (2.89) 0	4.5 (2.99) 0	83 (33.9%) 245	99 (30.9%) 320	182 (32.2%) 565
16-months Total NPI score	**10.4 (9.25) 0**	**7.7 (9.36) 0**	**8.9 (9.4) 0**			
Subscales*:				146 (78.9%) 185	154 (69.4%) 222	300 (73.7%) 407
Agitation/Aggression	4.5 (2.30) 0	4.5 (3.00) 0	4.5 (2.65) 0	82 (44.3%) 185	76 (34.2%) 222	158 (38.8%) 407
Depression/Dysphoria	3.5 (2.09) 1	3.1 (1.87) 1	3.3 (1.99) 2	63 (34.1%) 185	55 (24.8%) 222	118 (29.0%) 407
Anxiety	4.5 (2.28) 0	4.4 (2.83) 1	4.4 (2.56) 1	29 (15.7%) 185	34 (15.3%) 222	63 (15.5%) 407
Apathy/Indifference	5.5 (3.33) 0	5.2 (3.40) 0	5.3 (3.36) 0	73 (39.5%) 185	62 (27.9%) 222	135 (33.2%) 407
Disinhibition	3.6 (2.43) 1	3.6 (2.59) 0	3.6 (2.48) 1	24 (13.0%) 185	24 (10.8%) 222	48 (11.8%) 407
Irritability/Lability	4.5 (2.30) 0	4.0 (2.83) 0	4.2 (2.58) 0	65 (35.1%) 185	66 (29.7%) 222	131 (32.2%) 407
CROSS-SECTION	**Control (n = 287)**	**Intervention (n = 388)**	**Total (n = 675)**	**Control (n = 287)**	**Intervention (n = 388)**	**Total (n = 675)**
16-months Total NPI score	**10 (10.46) 0**	**8.4 (10.25) 0**	**9.1 (10.36) 0**			
Subscales*:				219 (77.1%) 284	269 (70.1%) 384	488 (73.1%) 668
Agitation/Aggression	4.7 (2.48) 0	4.7 (2.67) 2	4.7 (2.58) 2	116 (40.8%) 284	141 (36.7%) 384	257 (38.5%) 668
Depression/Dysphoria	3.5 (2.35) 2	3.2 (2.03) 1	3.3 (2.19) 3	95 (33.5%) 284	105 (27.3%) 384	200 (29.9%) 668
Anxiety	4.0 (2.45) 0	4.0 (2.57) 2	4.0 (2.51) 2	48 (17.0%) 283	72 (18.8%) 384	120 (18.0%) 667
Apathy/Indifference	5.5 (3.41) 0	4.6 (3.06) 0	5.0 (3.25) 0	95 (33.5%) 284	108 (28.1%) 384	203 (30.4%) 668
Disinhibition	3.8 (2.70) 1	4.4 (3.22) 0	4.1 (2.99) 1	35 (12.3%) 284	42 (10.9%) 384	77 (11.5%) 668
Irritability/Lability	4.5 (2.44) 0	4.0 (2.66) 1	4.2 (2.58) 1	94 (33.1%) 284	127 (33.1%) 384	221 (33.1%) 668

[a]A total NPI score, calculated by summing the total score for the first 10 domains (excluding Sleep and Appetite domains) together giving the total NPI score a range of 0 to 120. Higher scores on the NPI are indicative of the resident exhibiting more behaviours that staff find challenging *Number experiencing the behaviour staff find challenging means experiencing any of the behaviours from the listed subscale

All 726 residents in the closed-cohort were included in analyses of the resident-level secondary outcomes at 6-months; all 49 care homes where the QUIS was completed were included in the analysis at 6-months (see Table 16). The odds ratio for the presence versus absence of one or more of the six domains of the NPI-NH describing behaviours that staff find challenging is 0.95 (95% CI 0.61 to 1.48), indicating that there was no difference in the odds of residents experiencing these domains across arms (at a population or cluster-specific level). The odds of residents being prescribed antipsychotics on a PRN basis in the intervention arm was 0.46 times the odds in the control arm. However, the 95% confidence interval (0.09 to 2.24) was wide, which reflects uncertainty from the small number of prescriptions made. The odds of experiencing depression/dysphoria and apathy/indifference in the intervention arm were both approximately 1.32 times the odds in the control arm, however the 95% confidence intervals both overlapped one (0.87 to 2.0 and 0.85 to 2.07, respectively) so differences are not statistically significant. The odds ratio for presence or absence of anxiety was 1.01 (95% CI 0.62 to 1.66), indicating that there was no difference in the odds of residents experiencing anxiety across arms.

The mean QUALID staff-proxy score was 0.74 points lower in the intervention compared to the control (95% CI -1.91 to 0.43), indicating no difference in quality of life between arms. As such, no statistically significant differences were found in the closed-cohort between arms on any resident-level secondary outcome at 6-months. Similarly, there was insufficient evidence that proportions of positive staff interactions with residents, observed using the QUIS, differed by treatment arm.

All 675 residents in the cross-sectional sample were included in the primary analyses and all 726 residents in the closed-cohort were included in the supportive analyses of the resident-level secondary outcomes at 16-months. All 49 care homes where the QUIS was completed were included in its analysis at 16-months (see Table 17). In the cross-sectional sample, the odds of residents experiencing one or more of the six domains of the NPI-NH describing BSC in the intervention arm were 0.72 (95% CI 0.48 to 1.08) times the odds in control, indicating that, although there was no statistically significant difference in the odds of residents experiencing these domains across arms (at a population or cluster-specific level), the trend is in favour of the intervention. In the closed-cohort, the odds in the intervention arm were 0.57 (95% CI 0.34 to 0.95) times the odds in the control, a result that is statistically significant (at a population or cluster-specific level) at the 5% level.

Table 13 Unadjusted PRN prescription medications by resident sample and timepoint

CLOSED-COHORT			
N prescribed (%)	**Control (n = 308)**	**Intervention (n = 418)**	**Total (n = 726)**
Baseline			
Antipsychotic	**5 (1.6%)**	**5 (1.2%)**	**10 (1.4%)**
Non-benzodiazepine hypnotic	2 (0.6%)	4 (1.0%)	6 (0.8%)
Pain relief	109 (35.4%)	123 (29.4%)	232 (32.0%)
6-months			
Antipsychotic	**4 (1.3%)**	**2 (0.5%)**	**6 (0.8%)**
Non-benzodiazepine hypnotic	1 (0.3%)	3 (0.7%)	4 (0.6%)
Pain relief	89 (28.9%)	132 (31.6%)	221 (30.4%)
16-months			
Antipsychotic	**2 (0.6%)**	**2 (0.5%)**	**4 (0.6%)**
Non-benzodiazepine hypnotic	4 (1.3%)	3 (0.7%)	7 (1.0%)
Pain relief	59 (19.2%)	83 (19.9%)	142 (19.6%)
CROSS-SECTION			
N prescribed (%) N Completed	**Control (n = 287)**	**Intervention (n = 388)**	**Total (n = 675)**
16-months			
Antipsychotic	**2 (0.7%)**	**4 (1.0%)**	**6 (0.9%)**
Non-benzodiazepine hypnotic	6 (2.1%)	3 (0.8%)	9 (1.3%)
Pain relief	90 (31.4%)	138 (35.6%)	228 (33.8%)

Frequencies are given out of those in the respective samples, assuming the missing data reflects no prescriptions. No PRN anticonvulsants, no PRN mood stabilisers and no PRN non-benzodiazepine anxiolytics were prescribed for any residents at any time-points.

Table 14 Unadjusted quality of life scores by resident sample and time-point

CLOSED-COHORT			
Mean (SD) N	**Control (n = 308)**	**Intervention (n = 418)**	**Total (n = 726)**
Baseline			
QUALID[a] Staff-proxy	**20.9 (7.19) 308**	**20.1 (6.76) 418**	**20.5 (6.95) 726**
QUALID Relative-proxy	22.5 (7.49) 82	21.6 (6.86) 81	22.0 (7.18) 163
QOL-AD[b] Resident	42.7 (5.13) 155	41.7 (7.11) 189	42.1 (6.31) 344
6-months			
QUALID Staff-proxy	**20.7 (6.88) 245**	**19.3 (6.04) 319**	**19.9 (6.45) 564**
QUALID Relative-proxy	21.6 (7.18) 62	22.1 (8.89) 65	21.8 (8.07) 127
QOL-AD Resident	43.0 (5.09) 92	41.3 (5.97) 137	42.0 (5.68) 229
16-months			
QUALID Staff-proxy	**19.9 (6.38) 185**	**19.5 (6.06) 222**	**19.7 (6.20) 407**
QUALID Relative-proxy	23.0 (6.24) 38	23.1 (8.41) 31	23.0 (7.24) 69
QOL-AD Resident	43.2 (6.17) 65	42.8 (5.47) 81	43.0 (5.77) 146
CROSS-SECTION			
Mean (SD) N	**Control (n = 287)**	**Intervention (n = 388)**	**Total (n = 675)**
16-months			
QUALID Staff-proxy	**19.5 (6.44) 284**	**19.5 (6.20) 384**	**19.5 (6.30) 668**
QUALID Relative-proxy	23.0 (6.15) 39	23.1 (8.41) 31	23.0 (7.18) 70
QOL-AD Resident	43.4 (5.69) 113	42.2 (6.61) 156	42.7 (6.25) 269

[a]QUALID: range 11 to 55, with 11 representing the highest quality of life; [b]QOL-AD: 13 to 52, with higher scores reflecting greater quality of life.

Table 15 Unadjusted QUIS interactions by resident sample and timepoint

Total interactions (% positive) Missing	**Control (n = 19)**	**Intervention (n = 31)**	**Total (n = 50)**
Baseline	2065 (74.9%) 0	2405 (81.7%) 1	4470 (78.6%) 1
6-months	1766 (81.7%) 0	2291 (88.6%) 0	4057 (85.6%) 0
16-months	1578 (83.7%) 0	2320 (83.7%) 0	3898 (83.7%) 0

Table 16 Secondary outcomes at 6-months (closed-cohort)

Secondary Outcome	Analysis	Treatment Effect (Intervention - Control)	Lower 95% Confidence Limit	Upper 95% Confidence Limit	p-value	N
RESIDENT RELATED						
Behaviours staff find challenging	Population-Average Logistic Model (GEE)	0.950	0.612	1.476	0.820	726
	Cluster-Specific Logistic Model (REML)	0.951	0.584	1.547	0.838	726
Antipsychotic medication	Population-Average Logistic Model (GEE)	0.455	0.093	2.236	0.331	726
Mood (NPI Domain)						
Depression/Dysphoria	Population-Average Logistic Model (GEE)	1.320	0.872	1.999	0.190	726
Anxiety	Population-Average Logistic Model (GEE)	1.011	0.617	1.656	0.967	726
Apathy/Indifference	Population-Average Logistic Model (GEE)	1.330	0.853	2.073	0.208	726
Quality of Life						
QUALID (staff-proxy)	Linear Model (REML)	-0.740	-1.910	0.430	0.214	726
CARE HOME RELATED						
Quality of Staff Interactions (QUIS): Proportion of positive interactions	Linear regression	0.039	-0.023	0.101	0.210	49

OR <1 favours intervention

Table 17 Secondary outcomes at 16-months by resident sample

Secondary Outcome	Analysis	Treatment Effect (Intervention - Control)	Lower 95% Confidence Limit	Upper 95% Confidence Limit	p-value	N
CROSS-SECTION – RESIDENT RELATED						
Behaviours staff find challenging	Population-Average Logistic Model (GEE)	0.720	0.479	1.083	0.115	675
	Cluster-Specific Logistic Model (REML)	0.681	0.400	1.158	0.156	675
Antipsychotic medication	Population-Average Logistic Model (GEE)	1.191	0.216	6.559	0.841	675
Mood (NPI Domain)						
Depression/Dysphoria	Population-Average Logistic Model (GEE)	0.757	0.511	1.123	0.167	675
Anxiety	Population-Average Logistic Model (GEE)	1.133	0.670	1.916	0.642	675
Apathy/Indifference	Population-Average Logistic Model (GEE)	0.810	0.525	1.249	0.340	675
Quality of Life						
QUALID (staff-proxy)	Linear Model (REML)	-0.050	-1.120	1.020	0.922	675
CLOSED-COHORT – RESIDENT RELATED						
Behaviours staff find challenging						
	Population-Average Logistic Model (GEE)	0.570	0.343	0.948	0.031	726
	Cluster-Specific Logistic Model (REML)	0.577	0.334	0.996	0.048	726
Antipsychotic medication	Population-Average Logistic Model (GEE)[a]	0.783	0.114	5.368	0.802	726
Mood (NPI Domain)						
Depression/Dysphoria	Population-Average Logistic Model (GEE)	0.592	0.369	0.950	0.030	726
Anxiety	Population-Average Logistic Model (GEE)	1.037	0.588	1.830	0.900	726
Apathy/Indifference	Population-Average Logistic Model (GEE)	0.601	0.380	0.952	0.030	726
Quality of Life						
QUALID (staff-proxy)	Linear Model (REML)	-0.070	-1.260	1.110	0.902	726
CLOSED-COHORT – CARE HOME RELATED						
Quality of Staff Interactions						
(QUIS): Proportion of positive interactions	Linear regression	-0.001	-0.081	0.078	0.972	49

OR <1 favours intervention

[a] Model fitted without adjusting for hub and stratification factors to ensure convergence.

In the individual domains, in the cross-sectional sample, the odds that residents experienced depression/dysphoria or apathy/indifference in the intervention arm were both around 0.76 times the odds in the control arm (95% CI: 0.51 to 1.12 and 0.53 to 1.25, respectively) but this was not statistically significant. In the closed-cohort, however, the odds in the intervention were both around 0.59 times the odds in the control (95% CIs 0.37 to 0.95 and 0.38 to 0.95, respectively) statistically significant at the 5% level in favour of the intervention. As at 6-months, the odds ratios for the presence or absence of anxiety were close to one in both the cross-sectional and the closed-cohort samples, indicating no difference across arms. Overall, although no statistically significant differences were found between arms in the primary cross-sectional sample at 16-months, trends in favour of the intervention in BSC and mood were found in the closed-cohort.

On the staff-proxy completed QUALID there was no difference in mean scores between arms, indicating no difference in quality of life at 16-months. There was no evidence of a difference between treatment arms in the proportion of positive staff interactions with residents observed using the QUIS.

The confidence intervals for residents being prescribed antipsychotics on a PRN basis in the cross-sectional and closed-cohort samples were wide making them difficult to interpret (Tables 16 and 17).

Further summaries of secondary outcomes are in Appendix 1, Tables 49-52, Table 61 (unadjusted scores), Tables 26-30 (output from additional models) and Tables 58-60 (summary of medications).

3.5.3 Analyses of safety

There were no reported unexpected serious adverse events (RUSAE). The majority of care home residents in the closed-cohort did not have any hospital admissions; 231 (75.0%) in the control and 308 (73.7%) in the intervention (see Table 18). On average, hospital admissions lasted 3.7 days in the control and 2.9 days in the intervention arm. The majority of hospital admissions were to general wards.

Deaths are reported in Section 3.4.3 and in Appendix 1, Table 41.

Table 18 Hospital admissions in the closed-cohort

	Control (n = 308)	Intervention (n = 418)	Total (n = 726)
Number of hospital admissions per resident - N (%):			
0	231 (75%)	308 (73.7%)	539 (74.2%)
1	64 (20.8%)	77 (18.4%)	141 (19.4%)
2	11 (3.6%)	25 (6%)	36 (5%)
3	2 (0.6%)	7 (1.7%)	9 (1.2%)
Number of hospital admissions per resident - Mean (SD)	0.3 (0.57)	0.4 (0.71)	0.3 (0.65)
Length of hospital admission (days) - Mean (SD)	3.7 (12.33)	2.9 (9.65)	3.2 (10.86)
Overall number of hospital admissions reported - N (%)	92 (25%)	153 (26.3%)	245 (25.8%)
Admission ward type:			
General	77	132	209
ICU	2	4	6
HDU	0	0	0
Other	9	11	20

4. Cost effectiveness

4.1 Missing data

Figure 4 outlines the data available for the economic evaluation and the level of multiple imputation conducted. Data from 389 (intervention = 214; control = 175) residents were available for the original cohort complete case analysis and 726 (intervention = 418; control = 308) were available for the imputed dataset (and the primary analysis sample).

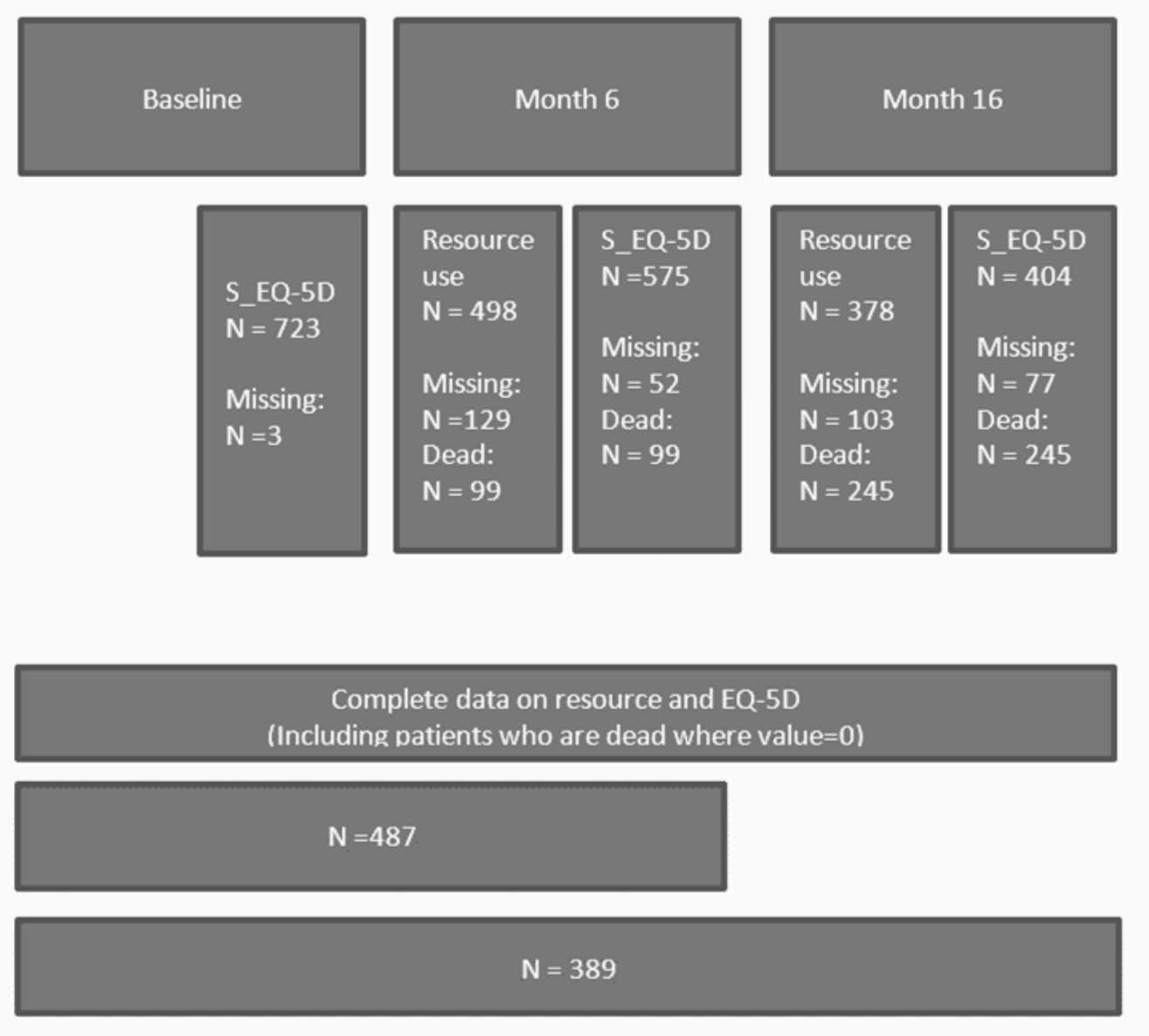

Figure 4: Data completion rates for the complete case sample*

*Baseline resource use not required for complete case analysis

4.2 Costs

The costs of the DCM™ intervention and the assumptions behind this are described in Table 19. These were agreed with the research team and cover the DCM™ training and implementation. The total cost of the DCM™ intervention was estimated to be £421.07 per resident (£9,290.30 per care home). Control arm costs were assumed to be zero.

Table 65 in Appendix 1 includes descriptive statistics on resource use across time-points and by trial arm based on data taken from resident care plans and care home records. Due to changes to the consent requirements to access NHS Digital data between baseline recruitment and the request for a data download at 16-months, we were unable to receive the data and thus were unable to use it to check the accuracy of data on hospital admissions obtained from the care home records. The costs of these are described in Table 20 below. Costs are presented in UK £ sterling (2017 prices). Total costs were £3,539.00 and £2,059.58 on average per resident in intervention and control arms, respectively. T-tests suggest these costs were significantly different for the imputed ($p<0.001$) and complete case ($p<0.05$) samples.

Primary care costs were similar across arms while secondary care costs were noticeably higher in the intervention arm. The intervention arm included a few high cost individuals. There were six residents whose costs exceeded the maximum in the control with long periods of hospital stay or one-to-one care; these were excluded along with seven other high cost individuals (generated in the imputation) in a sensitivity analysis.

Table 19: Costs of DCM™ intervention

Description of costs	£	Key assumptions and sources
Training course fee	£975.00	DCM™ course booking form [157]. Inclusive of lunch, refreshments and course materials.
Accommodation (four nights)	£300.00	Based on review of DCM™ EPIC trial records.
Meals/other subsistence	£70.00	Based on review of DCM™ EPIC trial records.
Travel to/from the course	£100.00	Based on review of DCM™ EPIC trial records.
Staff time	£434.77	Assumed there are four categories of care staff (hourly wage and proportion of staff in each category shown in brackets): home care worker (£7.38, 20%) and senior home care worker (£8.20, 25%) (hourly wages reported in PSSRU 2016 [144]), nurse (£12.45, 20%) (based on £25,902 annual salary for band 5 nurse reported in PSSRU 2016 [144] and converted to hourly rate) and care home manager (£21.63, 35%) (assumed median annual salary of £45,000, based on a review of recent job advertisements). The proportion of staff in each category was based on review of DCM™ EPIC trial records. Assumed course participation required four full working days (eight hours per day).
Delivery and receipt of training (for each DCM™ mapper)	£1,879.77	Assumed two staff trained in each intervention home and that there were no staff in the trial who did not require training (e.g. because they had previously received it). Assumed that there were no last minute cancellations (which may have incurred additional costs if rebooking).
Staff time per mapping cycle for DCM™ mapper	£543.46	Using data on the cost of staff time listed above and assuming that each mapping cycle required five full working days (based on DCM™ Mapper Guidance document and some verification using DCM™ EPIC trial data).
Implementation costs (for each DCM™ mapper)	£1,630.38	Assumed there were three mapping cycles per DCM™ Mapper (conducted in accordance with DCM™ Mapper Guidance based on published standards [83]). Assumed that additional time was not be required for other staff to attend DCM™ briefing and feedback sessions, but that these are arranged at handover or other convenient times as part of usual duties (as per protocol).
Consultancy fees for External DCM™ Expert	£2,100.00	To support intervention implementation and fidelity in the first cycle of DCM™ mapping, assumed to be for five days (£420.00 per day).
Travel and subsistence expenses for DCM™ expert mapper	£170.00	Based on review of DCM™ EPIC trial data.
Implementation costs (for each DCM™ expert mapper)	£2,270.00	Assumed each care home received one full cycle of DCM™ supported by the expert mapper.
TOTAL COSTS		
Per care home	£9,290.30	Assumed 2 DCM™ Mappers and 1 External DCM™ Expert per care home
Per resident	£421.07	Assumed 22.06 residents per care home (calculation based on DCM™ EPIC trial data)

All costs are reported at 2016/17 prices

Table 20: Healthcare resource costs in base case analysis*

Costs (£)	Intervention (n=418)				Control (n=308)			
	Mean	Std Err	Min	Max	Mean	Std Err	Min	Max
Intervention cost	£421.07	N/A	N/A	N/A	£0.00	N/A	N/A	N/A
Primary care costs	£1,522.32	£81.37	£0.00	£19,559.93	£1,568.13	£85.58	£0.00	£8,544.83
Secondary care costs	£1,547.34	£315.41	£0.00	£67,346.67	£436.96	£99.98	£0.00	£14,220.38
Medication costs	£46.40	£3.64	£0.00	£405.38	£53.67	£4.76	£0.00	£459.25
Total cost	£3,539.00	£337.00	£421.00	£73,944.00	£2,059.58	£146.71	£0.66	£18,032.06

*Discounted, closed cohort, EQ-5D 5L, staff completed, with imputation. These values are unadjusted to reflect the true range of costs.

4.3 Utility

Staff proxies represented the greatest proportion of completed quality of life measures. (n = 453; 62%). This was followed by relative/friend proxies (n = 176; 24%) and then resident self-report (n=168; 23%). Table 21 includes the utility values (with multiple imputation) for each trial arm across assessment mode and questionnaire.

The primary analysis was based on the utility values reported in the top row i.e. the imputed EQ-5D-5L completed by staff proxies and scored using the standard UK tariff. Other analyses presented in this study used the alternative utility values reported in other rows of the table. The first four rows show imputed utility scores for EQ5D5L (rows 1-3) and DEMQOL (row 4) whereas the final two rows report the utilities that were used in the complete case analysis (i.e. prior to multiple imputation).

In the primary analysis there was a slight baseline imbalance with the control arm having marginally higher quality of life. As we might anticipate, mean EQ-5D scores declined during the trial over 16-months with resident longevity. There was a trend apparent in most of the approaches that the decline in quality of life was greater in the control arm than in intervention arm. Using all approaches, quality of life was higher in the intervention arm than control arm at 16-months.

The baseline imbalance in quality of life was a relatively consistent finding across assessments and scoring methods. Adjustment for this was made in the calculation of QALYs.

Table 21: Utility values

Assessment*	Baseline						6-months						16-months					
	Intervention			Control			Intervention			Control			Intervention			Control		
	N	Mean	Std Err	N	Mean	Std Err	N	Mean	Std Err	N	Mean	Std Err	N	Mean	Std Err	N	Mean	Std Err
EQ-5D-5L* – Staff MI; Primary analysis	418	.663	.011	308	.676	.011	418	.573	.015	308	.569	.019	418	.421	.018	308	.395	.019
EQ-5D-5L – Staff MI; Death not recoded	418	.663	.011	308	.676	.011	366	.654	.013	261	.672	.015	277	.636	.017	204	.596	.017
EQ-5D-5L* – Staff MI Mapped to 3L	418	.435	.016	308	.469	.019	418	.363	.018	308	.374	.020	418	.262	.019	308	.229	.017
DEMQoL* – Staff MI	418	.759	.006	308	.746	.007	418	.669	.013	308	.623	.016	418	.746	.018	308	.736	.021
EQ-5D-5L* – Staff CCA**	214	.663	.016	175	.682	.018	214	.554	.021	175	.531	.025	214	.364	.025	175	.349	.025
EQ-5D-5L* Patient/Relative or Staff (CCA)	215	.702	.016	176	.716	.019	215	.596	.022	176	.555	.026	215	.383	.025	176	.370	.027

*In these cases deaths were coded as zero; **Only those with completions at all 3 time-points

4.3.1 Cost-effectiveness

Table 22 includes the ICERs for the primary and secondary analyses and for the various sensitivity analyses. In the base case cost-utility analysis, intervention is more costly (by £1,479) and more effective (.024 QALYs) than control. This yielded an ICER of £60,627; well above the £20,000 NICE threshold, indicating that DCM™ is not cost-effective. The complete case analysis had similar costs to the imputed sample but higher incremental QALYs for the intervention. With the exception of the analyses which excluded high cost outliers, the ICERs from various sensitivity analyses (including those which restricted the intervention sample to intervention compliant care homes i.e. those completing at least one cycle) also all exceeded £20,000. These analyses included additional costs associated with the intervention of over £1,600 and an incremental benefit ranging .024 to .036. The cross-sectional cohort analysis yielded lower incremental costs and higher incremental benefits for the intervention than found in the imputed sample.

In the sensitivity analyses which excluded the high cost outliers in the intervention arm (n=6 were excluded from the complete case analysis and prior to conducting MI for an analysis using MI data), incremental costs reduced dramatically and the ICER approached the cost-effectiveness threshold (£36,371/QALY) in the base case and fell below it in the complete case scenario (£10,975/QALY). The ICER also decreased in line with greater intervention compliance. An analysis adjusting for baseline costs yielded an ICER below £25,000 but this was based on a dramatically reduced sample and cannot be considered a robust estimate.

The cost-effectiveness analyses based on improvement in CMAI indicate that while the intervention was more costly, it was also more effective. Incremental cost per unit improvement in CMAI was £289 and £67 for intervention versus control for the imputed and complete case samples, respectively.

Figures 5 and 6 are the cost-effectiveness plane and the CEAC, respectively, for the base case cost utility analysis. The plane indicates the greatest uncertainty lies in the benefits of the intervention. All of the simulations lie above the willingness to pay threshold suggesting that, using the base case analysis, DCM™ is unlikely to be cost-effective. The CEAC confirms this and indicates that, where λ= £20,000, there is a very low probability that the intervention will be cost-effective.

Table 22: Cost effectiveness

Analysis*	Costs					QALYs/Benefits					
	N	Intervention	N	Control	Incremental	N	Intervention	N	Control	Incremental	ICER
Base case											
EQ-5D-5L – Staff MI	418	£3,539	308	£2,060	£1,479	418	.718	308	.708	.024	£60,627
CMAI MI	219	£3,318	185	£2,345	£974	219	-1.767	185	-.557	-3.37	£288.88
Sensitivity analyses											
EQ-5D-5L CCA***	214	£3,380	175	£2,073	£1,307	214	.682	175	.665	.029	£45,674
EQ-5D-5L – Staff MI, implemented cycle costs	418	£3,463	308	£2,060	£1,403	418	.718	308	.708	.024	£57,509
EQ-5D-5L – Staff MI, excluding intervention cost outliers in the imputations	412	£ 3,046	308	£2,060	£533	412	.722	308	.708	.027	£36,371
EQ-5D-5L CCA excluding intervention cost outliers***	208	£2,437	175	£2,073	£364	208	.688	175	.665	.033	£10,975
EQ-5D-5L Staff MI Mapped to 3L	418	£3,539	308	£2,060	£1,479	418	.457	308	.459	.026	£57,208
DEMQoL – Staff MI	418	£3,539	308	£2,060	£1,479	418	.836	308	.799	.032	£45,918
EQ-5D-5L – Staff MI Open cohort**	523	£2,830	394	£1,608	£1,222	523	.577	394	.548	.028	£42,953
DEMQoL – Staff MI Open cohort**	523	£2,830	394	£1,608	£1,222	523	.665	394	.629	.036	£34,234
EQ-5D-5L Staff MI (int arm = only those who completed at least two DCM™ cycles to an acceptable level	100	£2,856	308	£2,060	£ 796	100	.734	308	.708	.026	£30,447
EQ-5D-5L Staff MI (int arm = only those who completed at least one DCM™ cycle to an acceptable level****	328	£3,833	308	£2,060	£1,774	328	.744	308	.708	.044	£40,062
CMAI CCA	129	£2,768	101	£2,424	£344	129	-1.78	101	1.06	-5.12	£67.20[1]
EQ-5D-5L – Staff MI, with adjustment for baseline costs	262	£3,366	225	£1,924	£1,464	262	.732	225	.692	.061	£24,139

All costs and benefits (with the exception of CMAI) occurring in the final 4-months are discounted; **unadjusted as baseline data not collected; [1]Cost per unit change in CMAI no adjustment for baseline costs except where shown; **** Residents residing in care homes in the intervention arm that did not complete any cycles to an acceptable level of compliance, were excluded from the analysis.

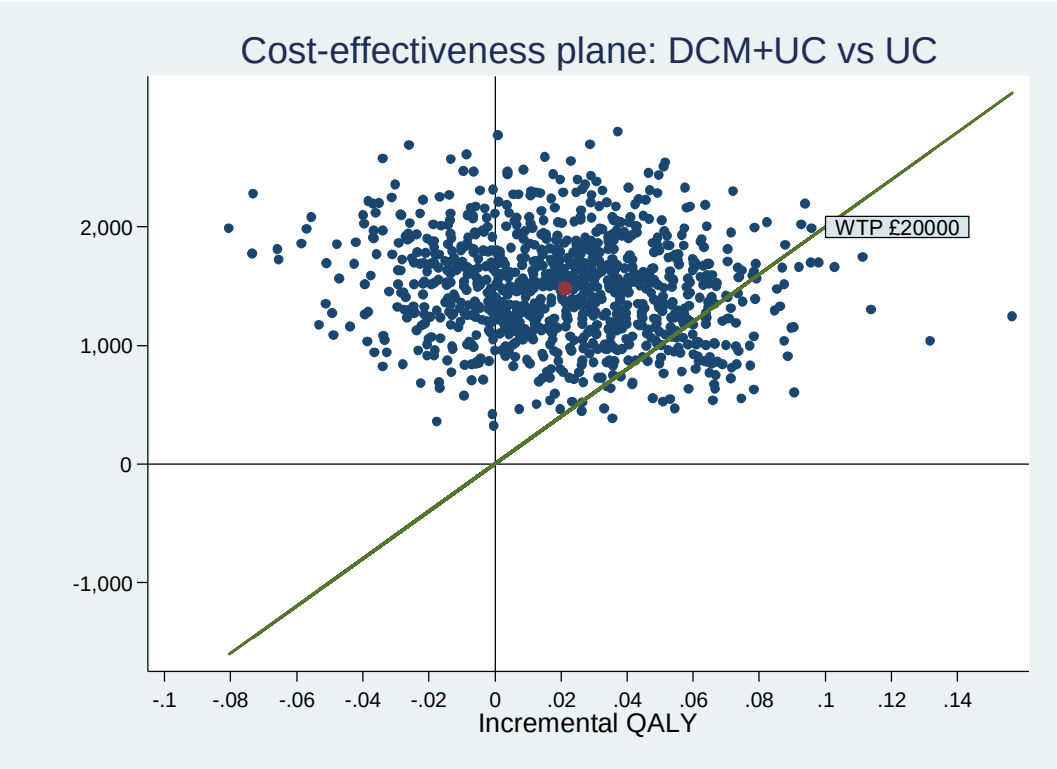

Figure 5: Cost-effectiveness plane

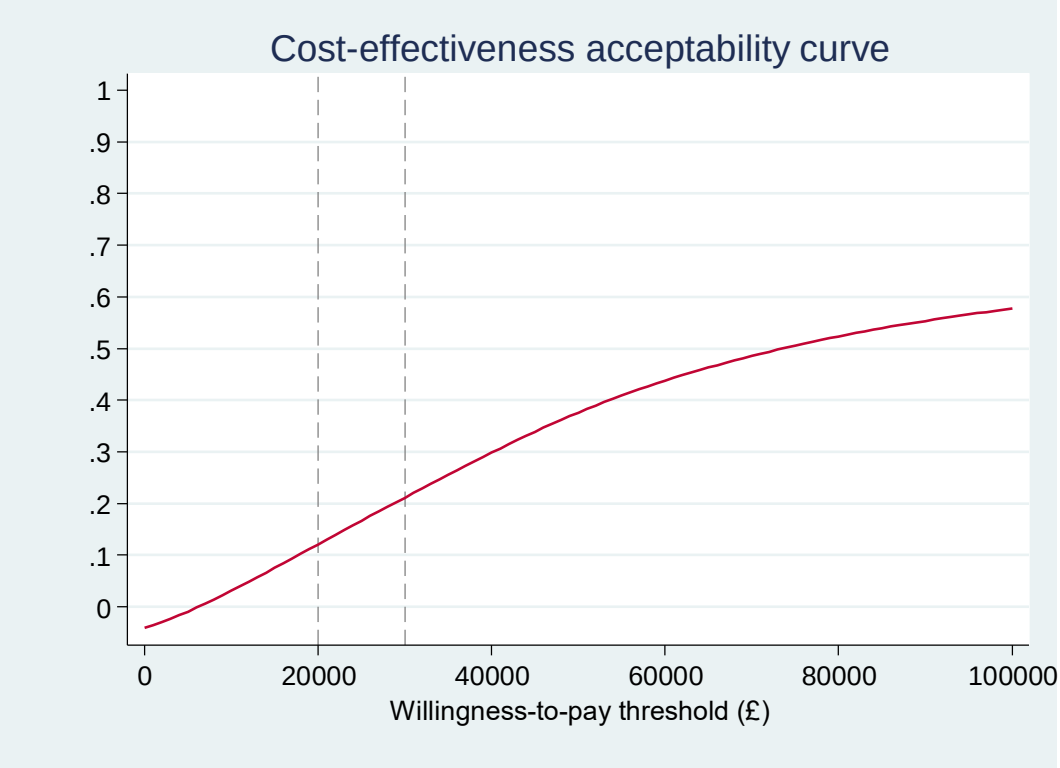

Figure 6: Cost-effectiveness acceptability curve

Table 23 reports the outcomes from the net benefit regression model including the covariates employed in the main statistical model and an interaction between trial arm and compliance indicator variable. The only significant predictors of net benefit were baseline EQ-5D (higher QoL leads to higher net benefit) and CDR (lower values lead to higher net benefit). In this model, neither the intervention nor the compliance*intervention interaction terms are statistically significant. The CACE analysis yielded similar results in that the active treatment variable including only intervention care homes who complied with the intervention (completed at least one acceptable cycle) was not statistically significant.

Table 23: Net Benefit Regression

				N =	726
				Prob > F	0.0000
	Coefficient	**Robust SE**	**P value**	**Lower CI**	**Upper CI**
Constant	5282.33	1726.75	**0.004**	1802.20	8762.46
Treatment*Compliance					
0	-1617.88	840.149	0.061	-3311.72	75.96
1	-1427.81	1159.62	0.225	-3762.80	907.18
2	177.53	1139.85	0.88	-2117.28	2472.34
Date of birth	0.16	0.09	0.115	-0.04	0.35
Baseline EQ-5D	14628.21	1381.11	**0.000**	11847.35	17409.07
Baseline CDR	-807.31	389.57	**0.044**	-1592.07	-22.56
Care home type	-463.22	835.22	0.582	-2144.57	1218.125
Care home size	856.64	1032.51	0.411	-1221.49	2934.77
Care home training	353.93	1107.15	0.751	-1874.86	2582.727
Care home hub					
2	23.62	1359.16	0.986	-2713.0556	2760.31
3	-1152.31	1215.883	0.348	-3599.056	1294.44

Within VCE adjusted for 50 clusters in site

5. Process evaluation

5.1 Participants

In total, 75 interviews were conducted. Of these interviews, 67 were with staff members who had undertaken various roles during the trial. Interviews took place with 17 managers, 25 mappers (2 of which were also managers), and 27 'other' members of staff who reflected a range of roles in the care home and varying degrees of involvement with the intervention. Due to the high losses to follow up and the requirement of having to be able to provide informed consent to participate in an interview, only two residents participated. Six relatives agreed to participate in interviews. Interviews ranged greatly in duration (from 3 - 38 minutes) depending on the interviewee's knowledge and awareness of the intervention.

5.2 What was implemented?

Each care home was requested to implement DCM^{TM} as detailed in the protocol and described above (section 3.3.2). There was considerable variation of implementation across the 31 intervention homes, as well as variable compliance with return of required trial documentation to evidence DCM^{TM} implementation. A range of approaches was used to increase return rates of trial documentation including multiple phone and e-mail remainders being sent by the Intervention Lead and CTRU staff and in some cases un-blinded researchers attending the care home to collect copies of documentation. In some care homes documented evidence of all components of intervention completion (e.g. attendance sheets for briefing and feedback sessions, mapping data, feedback reports, action plans) were not always available even though mappers or managers reported a cycle of mapping had occurred. We made the assumption that undocumented earlier phases of a DCM^{TM} cycle (e.g. briefing session) had been completed if documentation for later phases was provided (e.g. mapping data or feedback report). We also only recorded a component of a cycle as complete if we had documentary evidence for completion of it or a later stage of the process. In some cases, mappers reported verbally to the intervention lead or CTRU staff that a DCM^{TM} cycle or components of it had been completed, but failed to provide documentary evidence of this. Therefore, our final compliance data may be subject to inaccuracies of both under and over reporting of the components of each cycle that actually occurred.

5.2.1 Mapper training and retention

Mapper training was delivered per protocol (within 2-months of randomisation) in 21/31 (68%) homes. There were delays in training mappers from 9 care homes (29%) and no mappers were trained in one home (3%). In two homes (6%) only one mapper was trained

compared to the stipulated two. Withdrawal of one or both of the mappers occurred in 17 homes (55%). The reasons for withdrawal were resignation from the care home, ill-health/long-term sickness, maternity leave, and in one home, both mappers withdrew due to lack of management support to map. At 16-month follow-up 14 homes (45%) had two trained mappers still in post, 7 had one mapper (23%) and 10 (32%) had no mappers. While there was funding to train additional mappers this only occurred in one home due to insufficient time before the end of the trial to train further mappers, being unable to identify a suitable replacement mapper or the consented mapper being unable to attend scheduled DCM™ training due to personal or organisational reasons.

5.2.2 Mapping cycles

As is reported in section 3.2.2 DCM™ implementation was considerably less than the per protocol three acceptable cycles, in the majority of the 31 intervention homes, with only four homes completing three full cycles. The first cycle of mapping was commenced per protocol (within 3-months of randomisation) in 22/31 homes (71%). The DCM™ expert mappers reported spending considerable time contacting care homes to rearrange mapping dates following cancellations by the care home and in prompting production of feedback reports and actions plans during the first supported cycle (see discussion below).

5.3 How did participants react to the intervention?

5.3.1 Experiences of the intervention

As with implementation of the intervention, experiences of the intervention and its success varied between homes, and also between stakeholder groups (e.g. mappers, managers, staff, relatives and residents). Discussion around experiences of the intervention predominantly focused around the impacts of DCM™ and the challenging and facilitating factors experienced when implementing DCM™. Experiences of the intervention are therefore explored under these two broad themes – Section 5.3.2 focuses on perceptions of DCM™'s impact, and Section 5.4.1 focuses on barriers and facilitators to DCM™ implementation and impact.

5.3.2 Perceptions of intervention impact

In keeping with the findings of the statistical analyses (Section 3.5) which identified variability in impacts between care homes, the process evaluation identified variability in how much participants felt DCM™ had an impact within their care home. Examples of positive impacts

are considered below, before moving on to consider examples of when DCM™ was felt to have variable or little impact.

5.3.2.1 Perceptions of impacts for people with dementia

A range of impacts of DCM™ were identified for people with dementia at an individual and home level, as indicated in the key themes below.

5.3.2.1.1 Improved responses to individuals' needs, personalities and interests

A repeated positive experience was the ability of DCM™, and the observational element in particular, to help staff to identify, and so respond to, residents' individual needs, personalities and interests:

> *"One of our gentleman that we did the observation on, we found that he made his own wellbeing by playing with food and chucking it. So then I could go to the chef and say… 'This gentleman plays with his food, what can we do?' We saw him doing it before but because of the mapping it makes you look into it a bit more… He was happier, he'd have a lot more things that he could play with." (50028/10394)*

> *"When you're mapping somebody and you see that they're not joining the group activities you, we thought right let's just try and see if we can do an activity that's just for her." (50069/10475)*

DCM™ was repeatedly cited as enabling individualised tailoring of care and activities which helped staff to better meet residents' preferences, needs and interests. This ability to better identify individual needs extended to groups of residents that staff could find more difficult to care for, as discussed below.

5.3.2.1.2 Improved anticipation, understanding and prevention of complex behaviours

Examples of enhanced identification of individual needs were made in reference to 'behaviour that is challenging', which included agitation (the primary trial outcome measure), aggression and distress:

> *"I'm finding this really interesting because we can just observe all of the behaves of our residents, and then we can just think about this, what can we change? How can*

we make them more happy? …How can we reduce of their really low behaves, which make them distract or distressed?" (50028/10637)

"In terms of challenging behaviours… it became predictable, but then it is preventable through your interventions. The mapping itself helped us identify the individual needs and once that is identified we tried to set up plans and how to deal with or approach the challenge, the behaviour that is challenging." (50011/10160)

Participants repeatedly described how mapping helped to identify, and so to anticipate, preventable patterns of challenging behaviour by recognising antecedents, warning signs and early points of intervention. This supports the trial's hypothesis that DCM™ would have an impact on agitation, although the above quotes suggest that reducing agitation would only have been a focus for residents who were identified by staff or mappers as being agitated, rather than a blanket intervention for all residents.

5.3.2.1.3 Increased quality and quantity of interactions

Alongside impacts at an individual level, staff also spoke of impacts for all residents at a care home level. The impact most frequently referred to was improvements in the quantity and quality of staff-resident and resident-resident interactions:

"You know, they [staff] try and engage with people more." (50010/10095)

"We've got another lady who's end stage dementia who's just been people chatting with her, she's actually started speaking again! Now whether that would have happened anyway I don't know, but she's not spoken for ever such a long time but now odd words are coming out." (Manager 58930)

Increases in staff-resident interaction were repeatedly cited, as in the example above, as having a visual impact on the person's mood:

"Sometimes even one little smile to residents, one little joke, or one interaction can make a big change, for the rest of the day even... It's like our lunchtimes there is around thirty something residents plus six carers in one room, and how someone can still feel lonely, and one interaction can change that." (50028/10637)

"One of our care staff, he just went to her [lady with dementia] with a bright smile and started joking and how that changed her mood! …She was much more brighter, she was much more involved in all the situation." (50028/10637)

These, and other quotes included throughout the process evaluation results, suggest a potential link between increased interaction and activity, as a result of DCM™ implementation, and improved well-being for residents in intervention homes.

5.3.2.1.4 Increased provision of activities and occupation

Alongside improvements in resident interaction, increased provision of social and therapeutic activities and meaningful occupation was another common impact of the DCM™ process. These activities were typically instigated in response to recognition from mapping observations that residents were spending large proportions of their time without these types of stimuli:

> *"My activities budget is off the scale! But at least I know if I do a map now on a particular day I know that there's going to be stuff going on, and I now that if I'm sat there I'm not going to be bored silly." (50069/10475)*

> *"Now we introduce lots of sensory activities… all the residents have got some sort of activities... because we've been observing … and we've been thinking that what could improve their well-being." (Manager 50018)" (50018/10268/10277)*

> *"In the two years that we've been here… the level of stimulus, activities, has grown." (Relative 58747/40007)*

DCM™ highlighted the importance of care provision that not only addressed the physical needs of residents, but also their social and emotional needs and well-being:

> *"I have to say, that first map I was bored silly, and that made me think we are not doing anywhere near enough for these residents. Yes, we're ticking all the boxes in terms of care, they're well looked after, you know, everything is up to date in terms of that person, but what are we doing here to keep their well-being sort of on a good level?" (Manager 50069)*

This quote again suggests a link between increased occupation for residents as a result of DCM™ and improvements in well-being.

5.3.2.1.5 Improved responses to the needs of particular groups of residents

Some staff perceived that DCM™ had a greater impact on certain sub-groups of residents. Residents with more advanced dementia or with more limited verbal communication abilities

were considered, by some staff, to be more likely to benefit from DCM™, since it provided a useful method of identifying their unique needs:

> *"Especially those with end stage dementia, I think they do tend to get more attention possibly than they did before. I think staff are more considerate towards them and give them a bit more empathy... A lot of the residents we have that can still interact… they seem to be already getting quite a lot of attention… I think it has had more impact on the residents that weren't getting the attention, possibly." (59830/40002)*

> *"So many of our residents have severe dementia and, you know, their comprehension is very limited so (Mapper X) helped us in there to make changes." (Manager, 50065)*

Residents who were included in DCM™ mapping, were another group that staff considered to gain particular benefit from DCM™ participation, as their involvement in mapping provided a focus on identifying their care needs.

5.3.2.1.6 Other impacts for people with dementia

Other impacts for people with dementia that were reported by staff included giving people with dementia a voice, and enhancements to the environment and equipment that better met residents' needs at an individual or a care home level:

> *"As we observe them [people with dementia], it gives them a lot of chance and opportunity to express themselves." (50011/10160)*

> *"One lady she couldn't lift up the cup and we decide to change from plastic beaker the two handle, which has helped her a lot." (58747/10447)*

> *"We changed many things, even change the place where they sit. We try to make them comfortable, those who are watching TV, switch off the radio when TV, because the first time [first mapping] it was kind of noise. So we try to make it better." (58747/10447)*

These examples collectively illustrate how DCM™ gave staff the ability to understand experiences of the care home from the perspective of residents with dementia, and so to identify how those experiences might be improved. The ability of DCM™ to uncover the 'emic' perspective of residents is explored further in Section 5.3.2.2 below.

5.3.2.1.7 Summary

As the above examples show, the impacts of DCM™ for people with dementia reported by staff at both an individual and care home level indicate that DCM™ could lead to an increase in staff-resident and resident-resident interaction, an increase in meaningful resident occupation, and an improvement in staff identification of individual residents' needs. Some staff reported that impacts were more likely for particular groups of residents, namely those with more advanced dementia or communication difficulties, or residents who underwent DCM™ mapping.

5.3.2.2 Perceptions of impacts for staff

The perceived impacts of DCM™ for managers, mappers and other care home staff included increased awareness of residents' needs, communication of these needs, and of care quality, and greater confidence among staff in caring for residents with dementia.

5.3.2.2.1 Improved awareness and understanding of residents needs and care quality

Impacts on staff predominantly related to improved understanding of the residents under their care and, as a result, improved awareness of the quality of care being provided in the home:

> *"You don't realise what you're doing sometimes and it makes you look at things to say I wouldn't like that type of thing." (Staff 40005)*

> *"I think the benefits were just along the lines of highlighting to staff a little bit more about the needs of dementia clients." (Manager, 50013)*

Numerous references were made to DCM™ helping staff to better understand and respond to the needs and behaviours of people with dementia, indicating that this was a key impact for staff. DCM™ also provided access to the perspectives and experiences of residents with dementia, and a powerful reminder of the importance of understanding these:

> *"Sometimes you just forget about, you know, the actual person. And to sit in that lounge and that dining room for six hours, you go through what they go through every day. If that isn't the message of Dementia Care Mapping, I don't know what is." (Manager 50069)*

> *"We were looking at it from the residents' point of view, so we could see what they like, what they didn't like." 50031/10456)*

Comments from other staff echo these suggestions that, prior to DCM™ implementation, staff were less cognisant of residents' experiences of care in the home.

5.3.2.2.2 Improved understanding of embodied communication

Improved understanding of *embodied communication* was a repeatedly cited impact. Staff, managers and mappers all referred to an increased awareness of, and response to, non-verbal cues and communication from residents with dementia as a result of DCM™:

> *"We're more attuned to looking for non-verbal cues and very small changes." (Manager, 58930)*
>
> *"It's like offering somebody a drink and then, when you are observing it, actually they're wanting to do it for themselves. So it's watch that hand movement isn't it, and making carers aware." (10181)*
>
> *"…by holding hands or by touch, there is, you can see the difference. The person will be quiet, or they needed that attention." (50018/10268/10277)*

Staff recognition of non-verbal cues of residents' needs was important, as they helped the staff to identify the resident's unique personality, abilities, preferences and requirements. Improving embodied communication was therefore particularly important for residents who rarely or never communicated verbally.

5.3.2.2.3 Increased confidence and positive feedback for staff

Staff were often reported to feel more confident in their care practices as a result of DCM™ taking place in the home:

> *"They're more confident now than they were." (Manager, 50019)*
>
> *"Care assistants are now confident about doing things with the residents in there… I think they're enjoying their jobs more, I think they're enjoying being in that unit more." (Manager, 50167)*

Increases in confidence appeared to stem from several sources. These included feedback from the DCM™ process about the needs of residents, examples of the positive impact on residents when their needs where well met, and increases in confidence which came from DCM™ providing an opportunity to celebrate the sometimes overlooked positive actions of staff:

"Sometimes even though you're seeing the staffs are doing very good things to the residents, sometimes you don't appreciate… you don't get the time to do that…but this was the time that we could be able to appreciate the staff." (50018/10268/10277)

Increases in staff confidence and knowledge could also result from having staff trained as mappers available in the home as a perceived source of expertise and support in relation to problems and approaches to caring for residents with dementia:

"After talking with the mappers it presents a greater awareness of what you need to do with and for your clients." (50010/40010).

"She's (Mapper) got that extra knowledge that she'll go well it could be this, or it could be that." (10666/40015)

The potential increases in staff confidence and knowledge that could arise from having access to the expertise of a mapper within the home suggests that some impact may have been possible in intervention homes which did not actually implement any DCM™ cycles. However, this is not borne out in the main trial results.

5.3.2.2.4 Summary

The most commonly cited impacts of DCM™ on staff were increased awareness and understanding of the needs of residents with dementia, including the embodied communication of residents with limited verbal communication, and increased confidence for staff in providing care for people with dementia.

5.3.2.3 Changes in Care Practices and Culture

Related to impacts on staff, were wider changes in the practice and culture of care across the home. The magnitude of the changes referred to could vary greatly, from small changes to staff behaviours to more significant changes which could require managerial or financial support.

5.3.2.3.1 Smaller, achievable changes to care practices and culture

Relatively small, and thereby achievable, changes in staff behaviour were often considered by participants to make a big difference, despite the relatively little time, cost or effort they took to implement:

"Just tiny little things, for instance, when a staff member walked through the foyer… and acknowledged the residents, their faces lit up. That split second, and even a smile, it made a lot of difference to the residents." (50031/10456)

"Now if I'm dealing with anybody, I have a conversation while I'm washing and dressing them. And that way I'm finding out little bits about them… about their likes and dislikes, what they use to do in their past life." (50015/60002)

Examples of these small, achievable changes often involved staff making better use of the opportunities available to them to interact with residents - for example, as they undertook care tasks or were passing through the home. Despite these examples signifying relatively small changes to practice, they were felt by staff, especially if collectively adopted, to have a significant impact on residents:

"It doesn't have to be a major functional change of the home, these [changes spoken of] are all really, really small things but, holistically and collectively, they make a massive difference." (Manager, 50011)

"The little things can make a big difference for someone who is just, who is not involved in the situation, even in the big group where they are sitting." (50028/10637)

The significance attached to such changes was also an example of the low levels of baseline interaction seen in some homes during the QUIS observations, where residents could spend long periods of time with no one to interact with.

5.3.2.3.2 Larger, formal changes to care practices and culture

Larger changes to more formal care practices and processes were also reported, such as staff inductions, 'in-house' training, and care planning approaches. These changes required more effort to implement and could necessitate support at a managerial level, or agreement across multiple care homes:

"We have made it into a holistic type of care planning, where in again we have brought in person-centred care." (50011/10160)

"The main difference that it's had so far is altering our training, 'X' does our dementia training across both homes, and we also do dignity training between both homes. And we've changed those courses quite a lot, so that it delivers a lot more of the language we learnt across Dementia Care Mapping." (50018/10268/10277)

Changes to care home culture requiring managerial support were also spoken about, for example in relation to shifting prior assumptions held at a home level about talking to residents not constituting 'proper work':

> *"There's this culture shift where it's okay to sit down and have a chat with them [residents], it's okay to be seen to do that... If she [care home owner] saw a carer sitting down [before DCM™] it would be like 'What the hell are you doing? You're being lazy!'. And actually there's a massive shift now, if you walk in and see a carer sitting and joking around with residents, that's a really good responsive service." (Manager, 50011)*

This last example indicates the importance of having senior management understanding and support for the need to change care practices and culture in the home.

5.3.2.3.3 A tool for identifying and evaluating changes to care practices and culture

Many of the responses above indicate that DCM™ was used as a tool to identify areas for improvement across a range of care home practices and processes, including training needs, the quantity and quality of interactions with residents, and care planning. Managers were particularly aware of the potential benefits of DCM™ as a structured tool for identifying and evidencing practice improvements:

> *"Whereas before we would try to improve but we didn't really know how, so it was a bit like running around headless… I think one of the most positive things about mapping is that it gives you a structure to sort of put dementia and dementia care in… So before [DCM™], you sort of, you want to improve but it's very difficult to know how to improve." (Manager, 50018)*

> *"From the cycles that the girls have done, they've identified and can share information with the rest of the employees, to actually improve in any way we can the care that's delivered." (Manager 50031)*

DCM™ was also used as a means of providing evidence of the impact of improvements to care practices, and thus provided a means of both *motivating* and *maintaining* changes to the practice and culture of care:

> *"Until you've sat there for a few hours and actually seen someone gain enjoyment from just holding something, it's something that's very easy to ignore because it's very small. So it [DCM™] meant we could actually start making small changes, people could see the difference." (50018/10268/10277)*

"I've always said it's [sitting and chatting with residents] a legitimate activity, but it is, now it's been pointed out to them that it actually does have an impact on that person's health and well-being, then, you know it's done more." (Manager 58930)

Where managers were also mappers, this facilitated the process of getting senior staff to understand, and provide financial support for, any changes required to care practices in the home. In some instances, significant changes were made to care practices as a result of DCM™ implementation:

"That whole unit is light years away from before it was before you started doing the mapping, before we started the project." (Manager 50167)

5.3.2.3.4 Summary

DCM™ enabled care homes to achieve change in some of the daily care practices of their staff, most noticeably in relation to the level of interactions with residents. Changes were also noted to formal care practices such as approaches to care planning and staff induction and training. DCM™ was perceived to be a useful tool through which the need for these changes was identified, with managerial or across site support required for changes to be made at a care home level.

5.3.2.4 Impacts on Relatives

Some impacts from DCM™ were noted for relatives of residents in the home. The most common impacts cited for relatives were increased involvement in the home and better provision of information by staff to relatives about their family member's care:

"It has involved not just the home staff; it has involved families." (Manager, 50010)

"I found it really interesting for the residents that we mapped to let their families know what we'd noticed … This is what we found when we were going [DCM™], and this is what we're going to do." (Manager, 50069)

There is a suggestion here that impacts may be greater for residents who were mapped, and also for their relatives. It should, however, be noted that these perceived impacts were reported by staff and not by relatives who, as discussed in Section 3.7.4.2.1, could struggle to identify the impacts of DCM™ on themselves:

"I don't know, it's really hard to say… Overall I'm really happy so I can't say there's been anything specific that I've noticed that's any different." (50010/40009)

5.3.2.5 Examples of limited impacts

Although many participants identified positive impacts resulting from the implementation of DCM™ within their home, they sometimes struggled to provide examples or identify specific ways in which change had occurred:

> *"I do think there is an impact there generally yes." (Manager 50010)*

> *Interviewer: "Can you give us any examples of specific action plans that came from the first cycle, which was a while ago?" Participant: "It was ages ago, erm… I can't specifically." (Manager 50011)*

In addition, some participants considered that DCM™ had asserted little influence over care practices in the home or over the experiences of residents:

> *Interviewer: "Has there been any impact, there might not have been, on the residents do you think as the result of mapping?" Participant: "No. No I don't think so." (50010/10096)*

> *Interviewer: "Has there been anything for staff, have they changed kind of their routines at all?" Participant: "Erm, not as a whole, no." (50069/10475)*

It might be expected that staff from homes who implemented less cycles of DCM™ would struggle to identify impacts as a result. This tendency is supported to a degree by the above quotes, all of which came from homes that experienced problems with DCM™ implementation and only completed 1 or 2 cycles of DCM™ as a result. However, participants from homes completing 3 cycles could still struggle to identify definitive impacts from the implementation of DCM™:

> *"I must admit I have seen some improvement but I'm not here every day." Interviewer: "Have you seen improvement for the residents' quality of life as well, do you think?" Participant: "I think so, yeah. Especially those with end stage dementia, I think they do tend to get more attention possibly than they did before." (Mapper 58930)*

> *"We've got another lady who's end stage dementia who's just be people chatting with her, she's actually started speaking again. Now whether that would have happened anyway I don't know..." (Manager 58930)*

> *"I suppose I haven't necessarily seen any real changes, but I was happy in the first place." (Relative 50018-20107)*

Collectively, and in line with the main trial results, the above quotes suggest that implementing DCM™ did not uniformly lead to positive impacts for care home residents or for staff. Issues were also experienced with unexpected, and sometimes negative, impacts and with maintaining positive impacts over time, as is explored next.

5.3.2.5 Unexpected impacts or consequences

A small number of potentially unexpected, and sometimes negative, impacts or inappropriate uses of DCM™ were identified during the interviews.

5.3.2.5.1 Conflict amongst staff

Disagreements over the findings of mapping sessions were reported to lead to conflict amongst staff in one home, although these differences were subsequently resolved:

> *"There was arguments as well, because you know they say sometimes that you don't see the residents and how they are being… and we cleared everything and they did take it in a positive way eventually!" (50018/10268/10277)*

Although this was the only reference made to arguments, some other homes also reported initially negative responses from staff to DCM™ feedback, highlighting the importance of ensuring that staff understand the DCM™ process and the importance of providing feedback which celebrates positive examples of care as well as highlighting areas for care improvement.

5.3.2.5.2 Fear of scrutiny from past negative experiences

As a result of a home beginning to use DCM™, some staff felt scrutinised and fearful, predominantly due to past negative experiences of other forms of care scrutiny, such as CQC inspections:

> *"In most cases when it [feedback on care] happens it's a negative experience because there's inspectors from various organisations, so I think it wasn't until we started giving feedback and there was quite a bit of positives in there that the staff really engaged with the process." (50018/10268/10277)*

> *"The staff… it didn't matter how much time we spent explaining that it wasn't about spying on them, that's how they felt about it." (10181)*

"It was like being spied on." (50010/40010)

These feelings appeared to be more common in staff members who did not fully understand the purposes or processes of DCM™. Such feelings typically, but not always, lessened or went away as the processes involved in implementing DCM™ became more familiar to staff and better understood.

5.3.2.5.3 Inappropriate use of DCM™

Some misunderstandings about the purpose of DCM™ also appeared to lead to it being used in ways that appeared to be inappropriate or not in line with its recommended use. One home reported using evidence from DCM™ to assess potential new members of staff and as part of a fee review to provide evidence that a resident's needs have changed and their fee should be increased:

"We ask all new members of staff to come in for a train where we dementia map them… We also use it [DCM™] for fee review, so if we have someone whose needs have really drastically increased I can go to them and say she needs X amount of day care hours a week and there is the evidence." (Manager 50011)

And in another home DCM™ was perceived as a method for staff to highlight errors in each other's care practices:

"The idea is that if one carer's working with another they can turn to them and say you shouldn't have done that you should do this." (Manager 50018)

It is potentially relevant that both these examples came from managers who had not been trained in DCM™ and appeared, from the content of their interviews, not to fully appreciate the purpose of DCM™. This reconfirms the importance of ensuring that care home staff who hold key leadership roles, such as managers, have a clear understanding of DCM™ in order for it to be implemented appropriately and effectively.

5.3.2.5.4 Summary

In summary, some unexpected and negative consequences of DCM™ implementation were also identified, including conflict between staff over the results of mapping sessions, fear of being scrutinised, and inappropriate uses of DCM™. These undesirable consequences were noted more frequently amongst homes and staff (and particularly managers), where DCM™ was poorly understood. In addition, the impacts of DCM™ were not always easy to identify

or uniformly positive. Some participants struggled to identify any impacts as a result of DCM™ implementation, or to definitively attribute any impacts they did identify to DCM™ implementation. Participants who could not identify or attribute impacts were often, but not always, from homes who had struggled or failed to implement the trial's recommended dose of DCM™.

5.4 What contextual factors shaped if and how the intervention was implemented or worked?

5.4.1 What were the perceived barriers and facilitators to intervention implementation, mechanisms of impact and perceived impact from the perspective of mappers, DCM™ expert mappers, managers, staff, residents and relatives?

The data indicated that implementing DCM™ in care homes is complex, and there are many factors that may facilitate or prevent successful implementation. Barriers and facilitators were identified by managers, mappers, expert mappers and staff members and related to three main themes; care home level barriers and facilitators, intervention barriers and facilitators, and trial barriers and facilitators. [158]

5.4.1.1 Care home level barriers and facilitators

5.4.1.1.1 Care Home Context

Contextual features of care homes affected the degree to which DCM™ was implemented within each care home. This included broad issues, such as the type of setting and staffing levels or losses, and more specific issues such as the availability of computers in the home and funds to support implementation.

The type of care home may have influenced implementation, with additional complications present in nursing homes. However, the value of DCM™ in more complex settings was acknowledged.

> *"I think it's just the work load, really. The amount of work there is sometimes, and with it being a nursing home - the intensity of the workload. Obviously, we have a lot of very poorly people sometimes." (58930 Mapper)*

Managers of residential homes felt they were disadvantaged by a lack of qualified staff members, who might hold expertise that would help to facilitate implementation.

"Because we are only a residential home, erm, y'know, we haven't got nurses and stuff so my staff aren't that confident anyway… I'm glad we got involved because we got a lot out of it, I'm just disappointed that we weren't able to continue." (10666 Manager)

Larger care homes that were well staffed were able to build time for DCM™ into their rotas, whereas smaller care homes with less staff could struggle to accommodate the cover required to facilitate DCM™.

"That's the reason we pulled out, is because they [mappers] couldn't carry on doing their deputy manager role, or senior care role, and be a mapper with the amount of reports ... So I think it's just a bit unrealistic." (50011 Manager)

Across all care home settings, high levels of staff turnover were an issue. Consistency of staff involvement is needed to understand change over time for residents and also to implement changes as a result of DCM™.

"Care homes are really, really busy. Turnover of staff in care homes can be quite dramatic at times, and the realities are there's other pressures on them isn't there. But that's, that's it though isn't it. That's the reality of anywhere though I suppose." (DCM™ expert 70005)

Particularly important in relation to staffing of care homes, was the turnover of mappers. Not only did this lead to delays in implementing DCM™ whilst additional mappers were recruited and trained, but this also impacted on the confidence of remaining mappers, leaving some feeling overwhelmed by what was required of them.

"I think where I struggled and like with the report and things was because I was the only mapper, they were like "I need you to map three people". And it was like 'ahh… my first map'. And I'm mapping three people whereas if there was somebody with me, then we could've both done that together." (50028 Mapper)

Care homes with limited access to computers experienced difficulties with completing the computer-based elements of DCM™.

"We're not always the most IT literate in care homes. Having access to computers and time to analyse can be quite difficult." (50018 Manager)

Some care homes also had high demand or competing priorities at the time, such as CQC reports or problems with staffing levels.

"It was mainly the home, the crisis that the home was in … Knowing the staff we had at the time and the difficulties we had… I struggled just to get them to do the health and safety training, the basics." (50009 Manager)

These findings suggest that DCM™ implementation may be easier in larger nursing or dementia-specific care homes with greater numbers of qualified staff, where there may be greater access to computers and to funds and larger staffing pools to provide cover for mappers to undertake DCM™.

5.4.1.1.2 Manager

The care home manager was a key individual in the success of DCM™. Whilst managers were not always involved in the implementation of DCM™, as they generally had responsibility for rotas, allocation of staff workload and supervision of the mappers, their engagement either ensured it ran efficiently or placed barriers for the mappers.

"I think management support, you know, it can either be amazing when it's amazing or it can be a real difficulty if the manger isn't supportive." (DCM™ expert 70006)

Generally, there was thought to be a lack of support from managers. Managers needed to have awareness of the time required for their mappers to be involved and willing to support this process.

"The managers delegated all aspects – all of it – to the mappers, and didn't take any responsibility for ensuring the process. I think the odd manager was supportive, again from the office, but not really understanding about making time." (DCM™ expert 70004)

Where there were difficulties in the relationship between managers and mappers, issues arose for mappers, particularly at the feedback stage. The hierarchical nature of care homes sometimes acted as a barrier in the process, meaning that mappers were unwilling or felt unable to challenge the care home manager.

"It's mainly from a confidence perspective, [they] were clearly not confident to challenge a manager who was not supporting." (DCM™ expert 70003)

Conversely, where managers were engaged with DCM™, this facilitated the process and helped mappers to make changes based on what was observed during the cycles. Furthermore, where managers valued DCM™, they could see clear benefits from implementing it. For example, one manager believed that it was a key tool to help the CQC rating of the care home improve.

"They were very clear that they thought DCM™ was fantastic, because they saw it as a way of improving the quality of their care to take their home CQC rating from good to outstanding." (DCM™ expert 70004)

Managers referred to adaptations required to make DCM™ fit in their home. This included suggested or actual adaptations to the process of DCM™ itself, such as shorter maps, and hypothetical or actual adaptations to the work of staff, such as changes to rotas and over time.

"We're going to be having to change shifts so they can be on shift at the same time every month because we can do some mapping." (Manager 50010)

These findings suggest that managers are key in the implementation of DCM™, and can act as either a barrier or facilitator. A good relationship between the manager and mappers is crucial to successful implementation.

5.4.1.1.3 Motivation and enthusiasm for DCM™

Motivation and enthusiasm was a key factor when implementing DCM™. Expert mappers emphasised that when managers and staff teams were motivated to be involved in the DCM™ process, mappers were more likely to implement DCM™ within the home.

"The manager would come in and you know be really enthusiastic. They came to the briefing, everybody was at the briefing, the whole home, the manager of the home, do you know what I mean. The company really bought, really bought in to DCM™. And the two girls, the two mappers were just really enthusiastic about it, … and really, really tried their hardest." (DCM™ expert 70005)

Capitalising on this motivation and confidence by undertaking the first cycle of DCM™ soon after the training appeared to have benefits, with greater difficulties experienced if mapping was undertaken or attempted a while after attendance at the training session.

"They went for that training down in London then there was a gap and I kind of think if they had just gone straight in and done the mapping, they might have done it. But I feel that when a few weeks passed, they were struggling to say how we do this… maybe they didn't have the confidence, you know what, to roll it out." (10666 Manager)

The motivations of mappers were sometimes overshadowed by the time constraints within care homes, meaning that the mappers were able to complete the mapping hours, but often struggled to find the time to sit and discuss what had been observed.

> *"When I was actually there we had lots of you know creative really, very inspiring conversations about care practice. But it's trying to nab them, it's almost like it's impossible to nab, sit the person down and really discuss what's going on." (DCM™ expert 70002)*

In summary, having motivation and enthusiasm for making changes to practice was key in the success of DCM™. However, the challenges faced, such as time constraints, sometimes overshadowed the motivation of individuals.

5.4.1.1.4 Staff engagement

As DCM™ is a home level intervention, effective engagement with care home staff influenced the extent to which DCM™ was implemented. Particularly important was having staff who were open to feedback based on the observations, and willing to contribute towards formulating action plans. In some care homes, the mappers were able to engage a large proportion of staff in feedback sessions, which was seen as a positive by the DCM™ experts. Mappers who were in more senior roles may have found it easier to encourage staff to attend feedback sessions, due to their status within the home.

> *"I was so impressed how they just gathered people up, at busy times as well. And they really saw the worth of that, and great discussion. I was, and that was the first home, so I thought wow this really works." (DCM™ expert 70002)*

In order to implement a care home level intervention, the involvement of all staff roles was crucial. The importance of staff members in a range of roles attending feedback sessions was highlighted.

> *"There was a really big crowd actually, and it did include lots of different disciplines of staff, including the painter and decorator and maintenance man, which was great." (DCM™ expert 70002)*

The degree of engagement of the wider care home staff with DCM™ influenced the implementation of DCM™. High levels of engagement with staff led to more of a 'whole home' approach to considering DCM™ feedback and agreeing action plans.

"You really have to get quite a few people across the organisation thinking in the same way to sort of drive that change." (50018 Manager)

Staff engagement was achieved through multiple strategies. These included providing feedback in staff meetings to ensure good coverage, a focus on ensuring staff understood DCM™, its purpose and the outputs of the mapping, a focus on providing positive as well as negative feedback helped to ensure staff were engaged with, and demonstration of the benefits of DCM™.

"We sort of ended up picking two or three very small examples of people who were very happy or very sad and just focusing on those, describing in laymen's terms... They did take it in a positive way because they'd been, initially we said it's for all our residents' well-being." (50018 Mapper)

The selection of mappers influenced how engaged the staff team were. Where mappers were not seen to be popular staff members or people to be respected, it was difficult for them to engage with the staff team to implement change.

"The second time around we held a meeting and nobody came … We did try like you know individual, a few minutes at a time, but I don't think they took it seriously enough, do you know what I mean?" (50010 Mapper)

However, where mappers were respected, engagement was facilitated by implementation and feedback being peer led as opposed to being conducted by an external person.

"It's people that you know and peer-led, it's, you know, it's not like somebody from outside coming and talking with them, it engages the staff." (58930 Manager)

In one home, there was a division in the work environment between staff who did and did not support the mapper, which made feedback sessions particularly difficult. This led to further difficulties in implementing DCM™, as staff were not willing to make changes to practice. This may have been reflective of the culture in the care home, highlighting underlying issues that existed prior to involvement in the trial.

"I would say in that home there's two very definite groups of staff, the ones who want to see progress, who would support the mapper, who would want to encourage her and make it work, and there was also a very strong group of people who say you know 'what she thinks she's telling us'." (DCM™ expert 70001)

Negative attitudes towards DCM™ from both staff and managers also acted a barrier in the engagement with DCM™. If DCM™ was not perceived to be a priority, staff often did not take time to learn about and understand the process.

> *"I felt that the ways that people had been working prior to that, the culture of the place, whilst there was a lot about it which I would really commend it for, there were definitely some things that needed to be looked at. And I felt that there was a reluctance to look at that. And there was quite a lot of defensive response." (DCM™ expert 70001)*

Some staff questioned the validity of DCM™ when the presentation of residents was changeable or they considered that DCM™ did not suit the residents they provided care for.

> *"…some of our residents are quite, quite poorly so it doesn't work for them, it just depends how well they are." (58747 Staff)*

However, gathering together to collectively reflect on DCM™ feedback sometimes made staff feel a part of the process and helped to break down potential barriers and mistrust, for example in relation to being observed and receiving feedback, which staff could have past negative experiences of.

> *"In most cases when it happens, it's a negative experience because there's inspectors from various organisations, so I think it wasn't until we started giving feedback and there was quite a bit of positives in there that the staff really got engaged with the process." (50018 Manager)*

In summary, staff engagement was crucial to the implementation of DCM™. Without the support of the staff team, mappers struggled to make practice changes. The mappers needed to be respected by the staff team for DCM™ to have any influence in the care home. The importance of receiving feedback from peers rather than external individuals was highlighted.

5.4.1.1.5 Mapper qualities

Choice of mappers, including whether they had required qualities, were a key indicator of implementation success. The qualities valued in mappers, that were considered by Managers to facilitate DCM™ implementation, included confidence to undertake the mapping and feedback sessions, leadership skills to motivate and influence action planning in the home, pragmatism, dedication, an interest and enthusiasm for DCM™ and for

improving the care of people with dementia, and a keenness to learn. Managers were asked to select mappers and those recruited were based on the skills required to become a mapper, but also the staff members that were available to choose from in each home, who were deemed likely to remain working at the home for the duration of the trial.

> *"Two team leaders stuck out a being really passionate about people living with dementia." (50019 Manager)*

Attending the training and implementing DCM™ improved the confidence of some mappers.

> *"I never thought I'd be able to do it, but when we got back here, and after the training we actually put it into practice ... It all made sense." (50031 Mapper)*

Mappers having motivation to improve the quality of care for people with dementia helped facilitate the implementation of DCM™. However, for one mapper, the challenges of implementing DCM™ overruled her motivation and she became disengaged with process.

> *"I think it impacted on how they felt about it. It became a chore and one lady I can think of in particular was very excited and motivated about it, and became less so because of the challenges. And that's really sad to see. Someone who had that real passion to just go "do you know it's just too hard and", and, but initially is like "I'm happy to come in on my day off because I think it's marvellous", but when you're not then getting that support it you know wears you out really. Wears you down." (DCM™ expert 70003)*

Certain skills and abilities were also perceived to be central to enabling mappers to undertake the various processes involved in implementing DCM™. These skills and abilities included computer literacy, writing high quality reports, fluency in English, and sufficient academic ability to undertake the more complex components. Conversely, mappers who did not possess some of the aforementioned qualities or skills, despite the trial processes used to identify and recruit mappers with the required skills, could struggle to implement DCM™. In particular, the lack of IT skills, confidence and insufficient fluency in English were cited as barriers to DCM™ implementation.

> *"For me it was quite difficult because English is not my native language." (58930 Mapper)*

The utility of mappers in senior roles was perceived to have positive and negative impacts on DCM™ implementation. Whilst senior staff could possess academic, writing and leadership skills which facilitated DCM™ implementation, it was more difficult to free up staff

in these roles to undertake mapping and they could be subject to multiple competing demands on their time which challenged their ability to implement DCM™.

> *"[I chose] two quite strong team leaders that I knew would be able to get staff on their side and would be able to manage the feedback, because they can be quite difficult sometimes." (50019-Manager)*

> *"I was disappointed that my staff couldn't continue with the mapping, but I think I made the error in the staff I chose… their level of responsibility in the home was too high, so it didn't enable them to have enough time." (50167-Manager)*

Whilst the above qualities and skills were identified as important, in reality it could be difficult for Managers to identify staff members who possessed many or all of the skills required to implement DCM™ in a care home context.

> *"If I look at the whole team there are few other people who would have been possible, academically capable of completing that project. And that's a difficulty." (50167-Manager)*

An important component of mapper choice was commitment from the potential mapper. Agreement was not, however, always forthcoming given the length of the DCM™ course and the often distant geographical locations in which the courses were held. These were logistical issues which were especially problematic for staff with caring or other commitments.

> *"We need someone who would agree to do it, and promise that when they come back they're going to get the job done." (50021-11082-Manager)*

Furthermore, whilst managers recognised the qualities that were important for mappers to possess, in reality the choice of mapper often came down to who was willing and available to undertake the four-day course, particularly if this would involve staying in another area.

> *"When we found out they would have to do four days training in London, [mapper initially chosen] wasn't able to do that. And because we found out almost at the last minute, we just had to grab somebody else that was free really". (10666 Manager)*

A further example of availability being prioritised above ability was seen in in another care home where, following a mapper leaving, the manager did not pick a staff member to attend DCM™ training based on their abilities. Instead, the new mapper was selected based on their availability to attend the course.

"I think when in one case where a manager … didn't have a clue about who to nominate, she was just, she was looking at the off-duty and sort of picking names off the off-duty." (DCM™ expert 70005)

Mappers who were less qualified or experienced found it harder to implement DCM™. The DCM™ process asked mappers who were care assistants to develop and utilise skills that they were not familiar with using. Having the skills to ask questions as part of feedback sessions that allowed staff members to give opinions rather than yes or no responses was particularly challenging for some mappers.

"It was about time, it was about access, it was about computer literacy. And the, for some of the care workers writing anything was a real challenge. You know they just not, not used to putting descriptions down, let alone sort of feedback type questions to ask." (DCM™ expert 70002)

There were many conflicting priorities placed on mappers, particularly if they were staff with additional responsibilities, such as completing the medication rounds or conducing assessments for potential new residents. This impacted on the time available to complete the stages of DCM™.

"Well it was all just such a squeeze in the day, you know, and I remember being at one home where one of the mappers was late, one of the other mappers was busy doing the drugs, you know, and that was quite a familiar scenario". (DCM™ expert 70004)

In summary, selection of mappers had a significant impact on delivery of DCM™ as an intervention. Recruiting mappers with the appropriate skills facilitates the delivery of DCM™, as difficulties with stages of the mapping process such as analysis, and report writing, can result in much more time than anticipated needing to be dedicated to the completion of cycles. For mappers to undertake the DCM™ cycles a degree of effort, commitment and time was necessitated that some mappers had not anticipated or appreciated when agreeing to take on the role. The amount of time required to be away from their usual roles to undertake DCM™ meant that it was not viewed by some, in its current form, as a tenable intervention in a care home setting. Ensuring that Managers understood what skills are particularly important for mappers helps to reduce the likelihood of these acting as a barrier in the delivery of DCM™.

5.4.1.2 Intervention barriers and facilitators

A number of barriers and facilitators related to the DCM™ intervention itself were identified.

5.4.1.2.1 Understanding of DCM™

The extent to which mappers, managers and staff valued and understood the benefits of DCM™ influenced whether it was successfully implemented or facilitated. Where DCM™ was perceived as a tool and process that could improve the quality of care being delivered, managers and mappers were more engaged. In care homes where DCM™ was not understood, particularly in terms of the time commitments required, there were issues with completion of cycles.

> *"The manager that clearly didn't get it, I think was just so busy with everything else. absolutely, you know, I did see her running around like this, yeah." (DCM™ expert 70003)*

An understanding of the DCM™ process and its potential for changing the care delivered in care homes is crucial to successful implementation. Where some of the trained mappers did not fully understand the process, they struggled to explain it to others.

> *"The trouble is, when they came back [from the training], they weren't able to explain properly what they had to do. So, you know, they were trying to explain it to us and we were finding difficulty understanding what was actually involved." (10666 Staff).*

As a result of a lack of understanding of DCM™, managers and staff did not always engage with the process.

> *"I still don't understand it … no one has been able to understand it to me fully… Every time I asked them [the mappers] to explain they were struggling. So I never got a full grasp of what it was all about." (10666 Manager)*

Where managers did not understand the process or value of DCM™, it was perceived as a distraction and it became particularly difficult for mappers to be released from their duties.

> *"I would say the challenges outweigh everything else really." (50009 Manager)*

However, for the majority of mappers, the value of DCM™ was clear and easily understood, even where this was not clear to the managers.

> *"You can see a big difference. You can actually see what goes on through their [the residents] eyes. When you sit there and watch them for about three hours." (10180 Mapper)*

These findings indicate the importance of mappers, managers and staff having a clear understanding of the DCM™ process before attempting to implement it. Without this

understanding, mappers are unable to be released from their duties to complete mapping tasks, as it is not seen as a priority or a valuable tool within the care home.

5.4.1.2.2 Complexity and time demands of DCM™

DCM™ was felt to be complex and time consuming by some participants, with the nature of DCM™ felt by these participants to be a barrier to its implementation in a care home context. Various aspects of DCM™ were felt to be too complex, including the observation phase and associated coding, the report writing, and the language used.

> *"So the report writing, yeah, was horrific to be honest. Very time consuming. Obviously we both had different roles at that point so quite demanding, so getting time, and it's not a very quick process. Like I say it took quite a lengthy period of time. So that were quite bad to be honest, it was very demanding." (50069 Mapper)*

Particular components of the process were identified as time consuming or overly onerous, including the length of the training course, and the paperwork and report writing requirements.

> *"Some of the things that certainly I picked up on, some of the things they found more difficult was around the kind of data analysis and report writing. That was the area that people seemed to find most difficult." (DCM™ expert 70006)*

For some mappers, there were delays between them attending the training course and completing their first cycle of DCM™, which might have led to them forgetting some of the more detailed parts of the process, such as the observational coding framework. The DCM™ experts had to give additional time that was not expected to help mappers 'revise' some parts of their training before starting the mapping cycle.

> *"I mean one person I worked with we did our first IRR, our first kind of check of her accuracy and I think we got, our agreement was kind of in the forties. Like it was very, very low. And that was mapping one person for an hour." (DCM™ expert 70006)*

The time required to undertake DCM™ meant that mappers had to be taken away from their usual roles and defined as 'off the floor', therefore removed from the core business of care delivery in the case of direct care staff.

"The mappers were also carers and nurses and had, you know, activities and tasks and jobs to do as well as the mapping. Yeah, I think they found it quite overwhelming." (58930 Manager)

In addition, some managers felt that once the training course was completed they were then left to implement DCM™ on their own, although in reality every home had access to a DCM™ expert for 5 days to support implementation of their first cycle. Such views raise questions about the fit of DCM™ for care homes and suggest the need to consider adapting standard DCM™ processes for care home staff in the future development of the tool.

5.4.1.3 Trial barriers and facilitators

5.4.1.3.1 Expectations of DCM™ and the trial

Expectations of the trial and what was required to support the implementation of DCM™ did not meet the realities experienced by participants. In particular, the time and costs exceeded those expected by the managers and mappers. This impacted on the schedules in place for each care home and led to the expert mappers having to consistently renegotiate schedules.

"But from start to finish, although we renegotiated kind of schedules for me going down there it was difficult, I think they would say that they weren't aware of the time commitments to it." (DCM™ expert 70005)

Some managers were not aware that the mappers could not be included as members in the staff team and thus could not provide direct care on the days they were mapping. These managers did not appreciate that the mappers were unable to stop mapping to assist residents with any care needs they had during the mapping process. This led to tensions between some managers, mappers and expert mappers.

"They were definitely not aware of that because they were not normally on the part of the numbers, so they didn't realise that they would have to be off the numbers to do the you know, preparing the map, for the mapping, for the map itself and to do the rest of their work." (DCM™ expert 70005)

The range of processes and tasks involved in participation in the trial, as well as those involved in implementing DCM™, such as the completion of trial and DCM™ paperwork, seeking consents, undertaking interviews and identification of staff participants, were not anticipated by managers or mappers prior to taking part.

"They struggled with the copious amounts of paperwork, they told me that if they knew what was involved that wouldn't have gone for it." (50019 Manager)

In summary, conduct of the trial may have negatively influenced perceptions of the tenability of implementing DCM™ in care home settings, with the combined burden of trial and DCM™ participation proving difficult for some care homes to manage. Mismatches occurred between expectations of what the DCM™ intervention entailed and the additional work that was required by managers and staff during the trial, despite having been provided with detailed written and verbal explanations of the processes and time involved by the research team. Care home managers and mappers were not fully aware of the expectations of them during the trial, particularly in relation to the time involved in each stage and component of the trial, and the requirement of mappers to focus on all aspects of the DCM™ intervention while in the mapper role, with the consequence of being unable to attend to usual care work at these times. This had a negative impact on the ability of mappers to implement DCM™, as they were frequently not released from the staff roster to complete the DCM™ procedures.

5.4.1.3.2 DCM™ expert mapper support

DCM™ expert mappers viewed themselves as incredibly valuable to the implementation of DCM™, suggesting that without their input and support, DCM™ would not have not been successfully implemented in the majority of care homes.

"If the expectations had remained the same, I don't think it would have worked without the expert mappers." (DCM™ expert 70006)

However, two DCM™ experts felt that the mappers would have completed the cycles regardless of whether they supported the mappers or not. They thought instead that the observation data or implementation process would have been of a lower quality without their support to the mappers.

"I think some of the classic mistakes that can be made in DCM™ would've been made … and if they hadn't been picked up and supported or changed, it can have a really devastating effect on DCM™." (DCM™ expert 70002)

Support provided by the expert mappers helped to clarify any uncertainties and alleviate mapper doubts.

"It is nice to have somebody sat with you whilst you're actually doing it practically, to be able to say 'Am I using this code or that code?' 'Am I observing this right?'" (58930 Mapper)

When DCM™ expert mapper support was delivered flexibly and with a friendly manner, it was valued by care homes. There were, however, also times when support was perceived as problematic.

"The expert mapper was a little full on. Knew her subject, very passionate, but very, erm, timescale orientated. Which kind of pushed, I think, added to the stress." (58930 Manager)

The DCM™ expert mappers believed they went above on beyond their expected roles to provide support within care homes. They were allocated five days of time to support each care home, however they felt that much more time than this was required. Certain situations led to increased need for DCM™ expert mapper support, such as a care home having only one mapper, or tensions in the relationship between mappers.

"I've tried to support her individually because the other mapper hasn't supported her in the individual care summaries. So I've tried to support her extra by phone and do that, but I don't think she was, she had the skills to do that by herself." (DCM™ expert 70005)

Despite support from the DCM™ expert mapper being provided to all homes during the first cycle of DCM™, not all homes felt supported.

"I feel as if we were, had the training and then left to our own devices really." (50024 Manager)

Conversely, some mappers felt that they did not need the support and that as they know the residents well, they had a better insight into the residents than the DCM™ expert.

"When you learn anything really you just want to go and do it on your own don't you. You don't want someone looking over your shoulder going: yeah, yeah you've not done that right, or I didn't get that or why did you put that … well I know that resident and I know." (50069 Mapper)

For other homes, the mappers benefitted from DCM™ expert mapper support during the first cycle but felt that they required more than was provided, to continue to undertake DCM™ cycles.

"When she'd gone the support had gone" (50010 Mapper)

One DCM™ expert mapper suggested that for future DCM™ research, research assistants should support mappers to complete DCM™ paperwork. However, this does not represent the standard use of DCM™ within care homes and thus the pragmatic trial design employed in the present trial.

> *"I think you would've really struggled if they hadn't had someone going in. Be that an expert mapper or be that a research assistant, to go in and support them with doing the paperwork and completing that, which obviously would un-blind the researchers. But they would need some kind of support to be able to engage with the research." (DCM™ expert 70006)*

These findings suggest that DCM™ expert mappers felt that their influence had a positive impact on DCM™ delivery and resulted in substantially more cycles being completed than would have been without their input. However, this support was not always appreciated by the mappers. The implementation data, which shows only 26% of intervention homes completed further, acceptable DCM™ cycles after the expert supported first cycle, suggests the value of expert mapper input for supporting DCM™ implementation in care home settings.

5.4.1.4 Summary

There were many barriers and facilitators to implementing DCM™, due to the complex nature of both the intervention and care home settings. Selection of appropriate staff as mappers was key, ensuring that they had the necessary skills to implement all aspects of DCM™, including suitable language skills, the time to undertake all aspects of DCM™ within their day to day role, were well respected by the staff team, and had leadership capabilities and influence among staff. It was crucial that the expectations of DCM™ were understood by both care home managers and mappers before training was completed. Implementation was easier in larger care homes, where there was a larger staff budget to allow mappers to be released from their usual roles. The support of expert mappers was felt to be particularly important in the beginning to implement DCM™. While this is not a standard component of DCM™ unless purchased as an addition to standard training, it was a necessary feature of mapper support during the trial. These findings have implications for considering the way that mappers are currently trained and the support that may be required to implement DCM™ in practice (fully engage in the 4 phases of a DCM™ practice development cycle).

5.4.1.5 Specific barriers and facilitators to identifying, achieving or maintaining impact

Alongside the barriers to intervention implementation (and so to impact) identified above, there were some specific barriers and facilitators to identifying, achieving or maintaining impacts from DCM™.

5.4.1.5.1 Barriers to identifying impact

Challenges to *identifying* impact arose primarily from perceived difficulties in accurately identifying the impacts of any care improvements on people with dementia. For example, some staff and relatives felt that people with dementia would not be able to recognise the impact of any changes made, and some relatives (who may have been involved in completing outcome measures) felt it was difficult for them to identify changes in their family member due to the infrequency of their contact with the resident:

> *"They [people with dementia] will not acknowledge it [DCM™] as having an impact on them." (50011/10160)*

> *"I think their life has perhaps been improved by it, but I don't know whether they would be able to express that or realise that." (Manager, 58930)*

> *"I think it's amazing and probably essential, and you know, it's hard to get data because… the residents themselves aren't particularly reliable." (Relative, 50016)*

5.4.1.5.2 Barriers to achieving positive impacts

Interviewees spoke of multiple challenges to *achieving* positive impacts from DCM™. Some of the more predictable barriers included staffing, the costs of making changes, and competing priorities for staff such as high workloads or emergencies. For example, if competing priorities meant that action plans were not always carried out then potential impacts from DCM™ were not always realised:

> *"You are trying to carry action plans out, but the day to day everything means that you can't carry them out as much as you'd like to because, like I say, you end up with short staff, you end up with emergencies." (59830/40002)*

Understanding and perceptions of DCM™ (e.g. of its purpose, quality and reliability) and perceptions of the current quality of care in the home appeared to shape the degree to which the outputs of mapping sessions were attended to or seen as indicating a need for change:

"They [staff] don't understand what it is." (50010/10095)

"The main issues [with DCM™] are, some of the things we got on the feedback were well you were looking at so and so, they hadn't slept last night so that's why they've been nodding off the whole time. So even for that resident it sometimes doesn't give you an accurate picture." (50018/10268/10277)

[Answering a question about whether changes to care have occurred] "No I don't think so, because they're all pretty good anyway. The staff here are pretty good. So we do sort of pride ourselves on person-centred care." (50031/10456)

Additional barriers to achieving positive impacts included staff who were not open to change, and a lack of managerial or financial support for changes proposed as a result of DCM™ cycles:

"Obviously you always get a few who don't want to take on board anything." (59830/40002)

"When we do the briefing we, let's say, decided to do some things a different way, and they agree. But later on they found some difficulties, like I said, to change the chairs or something. And then maybe that's cost then." (58757/10446)

5.4.1.5.3 Barriers to maintaining positive impacts

Some care homes experienced challenges in maintaining positive impacts from DCM™ over time. These challenges included difficulties in maintaining staff engagement with the DCM™ process, in particular with the feedback and action planning sessions, and difficulties maintaining momentum as staffing teams changed over time:

"People stopped turning up… The first time around… we had maybe eight or something in here, and they did, you know, we had a good meeting. But then the second time around we held a meeting and no one came… we put posters up all over and we let everyone know that we were doing these feedback sessions… and nobody turned up." (50010/10095 & 10096)

"I think sustained changes certainly from the staff who were here then, but the staff who haven't actually had that form of training, the momentum has waned actually." (Manager 50024)

Of note in relation to achieving *and* maintaining positive impacts for care home residents generally, many examples of impacts for residents were specific to individuals who had been

mapped. These findings suggest that the impacts of DCM™ may be greater for mapped individuals, rather than residents who were not involved in mapping:

> *"The ones that we mapped, I'd like to think are more gainfully employed with their time." (50069/10475)*

> *"We have observed a resident then we have made a care plan specific to that resident's needs." (50011/10160)*

As mapped individuals were a small minority of the trial sample, producing and maintaining a positive effect on residents more generally may have been a difficulty for homes which focused predominantly on action planning for mapped individuals and focussed less on development of home level action plans. Given mappers could select any care home residents to be observed during DCM™ cycles, those mapped were not necessarily trial participants. In addition, a focus in some homes on addressing the needs of mapped individuals may have reduced the longer-term impact of DCM™ as the high rates of death and transfer to other care settings made it likely that many mapped individuals were no longer residing in the homes at follow up:

> *"Even to be observed, for them [mapped individuals], was kind of benefitting… but unfortunately most of them are not here anymore… so we can't say 'oh it's brilliant, working…' (58787/10446)*

Action plans and impacts for mapped residents were not necessarily transferrable to other residents, or were not viewed as such by staff, which may have affected the degree to which positive impacts from DCM™ were able to be maintained over time.

5.4.1.5.4 Facilitators to achieving and maintaining impact

As well as identifying challenges to achieving positive outcomes from DCM™, interviewees also reported a number of factors that facilitated the achievement or maintenance of impacts. Changing staff perceptions of the quality of care they were providing, and/or their perceptions of people with dementia and their needs, was a key impact facilitator:

> *"You don't realise, when you're walking through the room, that you've passed ten people and you haven't even spoke to them." (10095)*

> *"It encourages the staff to think more of them as people… because obviously they [people with more advanced dementia] don't respond as much… so it has helped in*

that way, to make them more aware that they still have to have the same contact, the same explanations for them." (59830/40002)

As creating change in care practices was dependant on staff recognising the need for change, mappers needed to understandably demonstrate the issues with current care in order for these to be recognised and addressed by staff:

"It's really tempting to go in gung-ho and start talking about PEs and the different codes, and it's like trying to sit the staff down and talk about trigonometry. It's not something interesting that makes much sense to them… We sort of ended up picking two or three very small examples of people who were very happy or very sad and just focusing on those, describing it in layman's terms." (50018/10268/10277)

"It was good and clear to see, you know, which areas we really needed to improve on." (Manager 50069)

Making DCM™ feedback accessible helped staff to understand the need for changes in their care practices, and the purpose and value of DCM™ - a lack of understanding of which was an identified a barrier to impact. Creating a shared understanding of the need for improvements was felt to be an important driver for change:

"You really have to get quite a few people across the organisation thinking in the same way to sort of drive that change." (50018/10268)

"One thing I am more aware of is how staff, certain staff, sometimes talk to residents... in the inductions now that we do, we make it really clear about what we want a new member of staff, how we want them to interact, how we want them to speak… I go through how I would like people to speak to residents." (50069/10475)

Embedding DCM™ data, feedback and action plans into the work of the care home, through their inclusion in care plans, handovers and staff meetings, and engaging staff across the home in identifying care improvements, were strategies through which mappers tried to ensure a home-level approach to care improvement:

"We implemented it in our handovers as well as through all the team leaders". (10181)

"Putting together a dementia group which has carers, cleaners, people across the organisation, and you talk to them and try and actually get them on board. You try and sort of instil in them what person-centred care looks like." (50018/10268)

"So then I could …say to the chef 'This gentleman plays with food, what can we do?" 50028/10394)

Some of these actions to embed DCM™ into usual care practice also helped to ensure changes were maintained. In addition, the identification of achievable changes, such as where staff were encouraged to interact more with residents on a routine basis, were considered by participants as a good strategy for facilitating impact.

Summary

Multiple barriers and facilitators to identifying, achieving and maintaining impact were identified by participants. These included difficulties in measuring impacts for people with dementia, competing care priorities, levels of managerial, financial and home-level support for change, and staff understanding and perceptions of DCM™, of current care quality and the need for change, and of people with dementia. A focus on care improvements for mapped individuals can limit impacts for other residents and the maintenance of impact over time.

5.5 Mechanisms of action

In this section we have drawn on the available evidence to assess if the anticipated mechanisms of action or logic model through which we expected DCM™ to have an impact on outcomes, were present.

5.5.1 Ancillary analyses (moderator/mediator analyses)

Complete cases of the cross-sectional sample were included in the analysis of care home level moderators identified *a priori*, see Table 24. Moderators were measured at baseline and assessed by including an interaction between treatment arm and the moderator variable in the primary analysis of CMAI one at a time. There was no evidence of moderation of any pre-specified baseline characteristics on CMAI at 16-months. The results are exploratory and should be treated with caution.

Table 24 Assessment of moderators of treatment effect at 16-months – cross-sectional sample, complete cases – adjusted estimates

Moderator	Unadjusted CMAI score at 16-months (95% CI) Control	Intervention	p-value for interaction[a]
1. Care home size			0.7672
<40 residents	45.1 (42.54, 47.63)	42.8 (40.71, 44.98)	
>= 40 residents	47.0 (44.06, 50.03)	42.9 (40.45, 45.26)	
2. Care home type			0.8713
Independent	46.9 (42.68, 51.20)	40.9 (38.67, 43.12)	
Chain	45.8 (43.58, 48.01)	44.4 (42.16, 46.61)	
3. Agency staff use			0.1815
Below or equal to median	45.5 (42.15, 48.94)	42.2 (40.19, 44.16)	
Above median	46.3 (43.89, 48.69)	43.7 (41.13, 46.34)	
4. Bank staff use			0.2249
Below or equal to median	48.3 (45.19, 51.38)	42.0 (40.01, 43.96)	
Above median	44.3 (41.81, 46.83)	43.8 (41.25, 46.33)	
5. Self-funding (proportion of self-funded places) (continuous)			0.8230
Below or equal to mean	46.1 (43.52, 48.68)	42.6 (40.68, 44.51)	
Above mean	46.1 (43.04, 49.05)	43.3 (40.42, 46.11)	
6. Care home facilities (EAT) (continuous)			0.4339
Below or equal to mean	45.0 (42.11, 47.92)	41.9 (39.80. 43.98)	
Above mean	47.0 (44.29, 49.64)	44.0 (41.58, 46.47)	
7. Group living Home Characteristics (continuous)			0.9756
Below or equal to mean	45.3 (42.67, 47.87)	42.4 (40.38, 44.43)	
Above mean	47.1 (44.09, 50.12)	43.4 (40.85, 45.93)	
8. Care home manager experience (length of time in care home) (continuous)			0.9961
Below or equal to mean	45.9 (43.79, 48.06)	44.2 (42.21, 46.18)	
Above mean	46.8 (41.72, 51.78)	39.8 (37.22, 42.30)	
9. The Quality of Interactions Schedule (QUIS) (proportion positive)			0.0737
Below or equal to mean	46.8 (43.85, 49.81)	44.4 (41.67, 47.11)	
Above mean	45.4 (42.79, 48.02)	41.7 (39.83, 43.65)	
10. Staff-resident ratio (continuous)			0.3592
Below or equal to mean	48.0 (45.03, 50.90)	44.5 (42.41, 46.48)	
Above mean	44.2 (41.64, 46.85)	39.4 (37.07, 41.82)	
11. Average baseline CDR (continuous)			0.3601
Below or equal to mean	44.3 (41.58, 46.95)	39.9 (37.71, 42.12)	
Above mean	47.8 (44.99, 50.69)	44.9 (42.69, 47.06)	
12. Average baseline CMAI (continuous)			0.7150
Below or equal to mean	42.8 (40.43, 45.07)	40.3 (38.21, 42.32)	
Above mean	49.5 (46.40, 52.61)	45.8 (43.37, 48.19)	

[a]the same variables in the model as in the primary analysis with added moderator and interaction term moderator*treatment

All 675 residents in the cross-sectional sample were included in the exploratory analyses of care-home level mediators of the randomised effect of intervention versus control on CMAI at 16-months. The 'natural indirect' or mediated effects of each potential mediator (and their 95% confidence intervals) are given in Table 25 adjusted for all the covariates included in the primary analysis of CMAI. It can be seen that no potential mediator was found to dominate the mediation of the effect of randomised treatment on the primary outcome, and none of the mediated effects were statistically significant at the 5% level. Further analyses are planned (outside the scope of the final analyses reported) to explore whether our *a priori* potential mediators have a clearer role in mediating treatment received on the primary outcome.

Unadjusted scores of predictive and process measures are in Appendix 1, Tables 62 to 64.

Table 25 Causal Mediators Analyses based on Multiple Imputations

	Adjusted Natural Indirect Effect (Standard Error)	95% Confidence Interval
Potential Care Home-Level Mediators (at 6-months):		
Change in care home manager (yes/no)	0.27 (0.22)	-0.16 to 0.70
QUIS (proportion of positive interactions)	0.18 (0.34)	-0.48 to 0.84
EAT improvement in privacy and community (yes/no)	0.21 (0.39)	-0.56 to 0.98
EAT improvement in community links (yes/no)	0.00 (0.37)	-0.72 to 0.73
EAT improvement in domestic activity (yes/no)	0.39 (0.27)	-0.13 to 0.91
Improved Group Living Home Characteristics (yes/no)	-0.67 (0.55)	-1.75 to 0.41
Potential Care-Home Level Mediators (at 16-months):		
Change in care home manager (yes/no)	-0.00 (0.11)	-0.23 to 0.22
QUIS (proportion of positive interactions)	0.00 (0.06)	-0.11 to 0.11
EAT improvement in privacy and community (yes/no)	0.12 (0.23)	-0.34 to 0.58
EAT improvement in community links (yes/no)	-	-
EAT improvement in domestic activity (yes/no)	0.15 (0.17)	-0.18 to 0.47
Improved Group Living Home Characteristics (yes/no)	-0.67 (0.42)	-1.49 to 0.16

Mediator analysis did not account for clustering

5.5.2 Interview data

Drawing on interviewees' perceptions of the DCM™ implementation process and its impacts, alongside the quantitative trial data, we had intended to propose a model for the intervention's mechanisms of impact. This model was intended to set out the processes through which the implementation of DCM™ may lead to change, and the barriers and facilitators which may enable or inhibit the achievement and maintenance of those changes. Whilst the above results set out some of the contextual features required to facilitate DCM™ implementation, and the challenges which need to be overcome in order to implement DCM™ effectively, given the negative trial result and the great variability in DCM™ implementation observed, we have been unable to come to any conclusions about potential mechanisms of action. Specific potential barriers to mechanisms of action were poor implementation of DCM™, particularly beyond the first supported mapping cycle, meaning exposure to DCM™ over the trial period was limited to one or fewer cycles over the 15-month period for three-quarters of the intervention homes.

6. Discussion

6.1 Key findings

The DCM™ EPIC trial was a pragmatic, multi-centre cluster RCT of DCM™'s effectiveness and cost effectiveness compared to usual care control in UK care home settings. The trial evaluated whether DCM™ led to reductions in agitation, other BSC, PRN anti-psychotic and other tranquillizer use and improved quality of life for care home residents with dementia and improved quality of staff interactions with residents. It also sought to determine whether DCM™ was cost-effective. Thirty-one care homes were randomised to implement the DCM™ intervention and 19 to control. A total of 987 residents were recruited and registered; 726 at baseline (308 in the control arm and 418 in intervention) and a further 261 at 16-month follow-up (99 in the control arm and 162 intervention). A total of 675 residents were included in the final cross-sectional sample (287 in the control arm and 388 in intervention) used for the primary analysis; 414 from the original sample and 261 recruited at the 16-month time-point.

6.2 Primary outcomes

Care home residents in intervention arm care homes did not demonstrate any clinically meaningful or statistically significant reduction in agitation compared to control arm residents.

6.3 Secondary outcomes

There were no clinically meaningful or statistically significant differences in BSC, quality of life, PRN use of prescription medications for care home residents with dementia at 6- or 16-month follow-up. However, trends for BSC and mood (depression/apathy) were found in favour of the intervention at 16-months in the closed cohort. The prescription rates of PRN medications were low across both arms at all time-points and this alongside the wide confidence intervals within the secondary analyses makes the results difficult to interpret. The quality of staff interactions did not differ between arms at either time-point.

Given the poor return rates for staff outcome measures we were unable to evaluate any potential impact of DCM™ on staff health related QoL (GHQ-12) or feelings of confidence in caring for people with dementia (SCIDS).

6.4 Economic evaluation

We conducted an economic evaluation alongside a clinical trial adhering where possible to the NICE reference case for technology appraisals. The primary analysis was a cost-utility (cost per QALY) evaluation, and a cost-effectiveness (cost per unit improvement in CMAI) evaluation was conducted as a secondary analysis.

Costs for the intervention per person were £421.07. This depended on a number of assumptions including the number of staff involved, number of cycles implemented and the number of residents who might benefit. In general, our assumptions regarding these costs were conservative. We also conducted a sensitivity analysis which accounted for different costs incurred by care homes dependent on their compliance with the intervention.

Costs of resource use were substantially higher in the intervention arm and this was driven by higher secondary (hospital) care costs. This resulted from the presence of several high cost individuals in the intervention arm (n=6 in the intervention arm had higher costs than the highest cost individual in the control arm). We conducted sensitivity analyses where we removed these six individuals (in a complete case analysis and prior to conducting MI for an analysis using MI data) in order to examine the impact of these outliers on our cost-utility estimates.

Regardless of the utility measure used and the analytical approach adopted, QoL appeared to be higher in the intervention than control arm at 16-months. Although QoL declined over 16-months, in general this decline was lower in the active treatment arm.

The base case ICER was £60,627 and, being substantially over the NICE threshold of £20,000, suggests DCM™ would not be an efficient use of health/social service resources. The sensitivity analyses were consistent in finding the intervention to be more costly but more effective than control. With the exception of analyses which excluded the high cost individuals, ICERs from the sensitivity analyses ranged from £24,139 to £57,509.

Analyses which excluded high cost individuals in the intervention arm yielded ICERs that were below (£10,975/QALY for the CCA) or closer to (£36,371/QALY for the MI analysis) the NICE threshold. When we examined data on comorbidities and the reason for hospital admission for the six high cost individuals, it was not possible to conclude that these higher secondary care costs could have been the result of chance rather than attributable to the intervention. Hence there was no reasonable justification for removing these individuals from the main analyses. ICERs from analyses adjusting for baseline costs or including more compliant care homes only also approached cost-effectiveness. However, these estimates were based on reduced samples and are considered less robust.

Consistent with the main cost-effectiveness analysis, the net benefit regression analyses indicated that DCM™ did not represent value for money when compared to usual care. Furthermore, the net benefit regression and CACE analyses also showed no indication that intervention compliance may have had a mediating effect. This was despite the likelihood that these analyses were biased by the failure to control for (unobserved) factors related to potential differences in care home quality (which might be positively related to the likelihood of compliance as well as resident quality of life).

We found the cost per unit improvement in CMAI to be between £67 and £289 depending on the analysis. This lower figure, although not our base case, is roughly in line with previously generated estimates of comparable interventions. [159, 160]

6.5 Safety

Undertaking DCM™ was not detrimental to care home residents. No unexpected SAEs occurred in the trial and the majority of residents did not have any hospital admissions over the trial period, with admissions figures and length of stay similar across intervention and control arms.

6.6 Comparison to other trials of DCM™ in care home settings

The efficacy of DCM™ has been evaluated in three previous exploratory cluster RCTs [63, 93, 94] and one quasi-experimental trial. [92] The RCT conducted by Chenoweth et al [63] found that researcher led cycles of DCM™ led to significant reductions in agitation and falls for care home residents with dementia compared to those in the usual care control. Likewise, the Norwegian study carried out by Rokstad et al [93] found a significant reduction in overall BSC, agitation and psychosis and a significant improvement in quality of life for care home residents with dementia in the DCM™ intervention arm, compared to usual care control. This study also used researcher-led cycles of DCM™ implementation. Conversely the cluster RCT conducted by van de Ven et al, [94] using care home staff led cycles of DCM™, found no significant difference in agitation between the DCM™ intervention arm and usual care control. This trial did find a significant improvement in staff emotional reactions towards people with dementia in the DCM™ intervention arm compared to control. The quasi-experimental trial conducted by Dichter et al, [92] adopted care home staff led cycles of DCM™ and also found no significant benefits of the DCM™ intervention over control for resident QoL or BSC.

The DCM™ EPIC trial is the only pragmatic, explanatory trial conducted on the effectiveness and cost effectiveness of DCM™ to date. It did not replicate the findings of the exploratory trials conducted by Chenoweth et al [63] or Rokstad et al [93], where significant benefits of DCM™ over usual care control for resident agitation, falls and QoL were indicated. It did support the findings of the exploratory trial by van de Ven [94] and the quasi-experimental trial of Dichter et al [92] where no significant benefits of DCM™ were found for agitation, BSC or QoL over control. Unlike the economic evaluation of DCM™ conducted by van de Ven et al, [161] which found DCM™ to be cost neutral, the DCM™ EPIC trial found DCM™ not to be cost-effective. The costliness of DCM™ as an intervention was also identified by Chenoweth et al, [63] who found the costs of DCM™ per CMAI point averted over usual care, were markedly higher compared to person-centred care training. Due to poor return rates on staff measures, we were unable to assess any potential effects of DCM™ on staff outcomes in the DCM™ EPC trial.

Comparison between the outcomes of the DCM™ EPIC trial and previous trials requires caution given the pragmatic, explanatory design of this trial compared to the exploratory designs of the previous studies. Likewise, this is the only trial to have been conducted in the UK and thus the care home resident population, care systems and costs differ from those of previous trials. Nevertheless, a common feature emerges in that all trials adopting care home staff led cycles of DCM™, even with support from a DCM™ expert or lead, recorded implementation challenges and no significant benefits of DCM™ over usual care control. In the two trials where significant benefits of DCM™ were reported over control, DCM™ was led by researchers and few implementation challenges were identified. This indicates that consideration needs to be given to the model of DCM™ implementation and leadership, with all trials to date adopting care home staff led cycles, failing to find effectiveness over control, in contrast to the trials where efficacy was found through external/research led cycles.

The potential benefits of externally supported interventions is confirmed by other intervention trials in care home settings. The WHELD trial, [76] which combined staff training with support from a WHELD therapist who provided coaching, supervision and regular review over a 9-month period, found statistically significant benefits for quality of life, agitation and neuropsychiatric symptoms and positive care interactions compared to treatment as usual. The benefits being greater for those with moderately severe dementia.

This trial is the first randomised, controlled study of DCM™ in the UK and reflects the largely practice-led development and evolution of the method in the UK. While the current 8th edition of DCM™ was produced following a thorough review process, only the revised observational tool was evaluated using formal research methods, with the additional guidance on DCM™

implementation developed through a series of working groups involving practitioners. [109] A recent systematic review [96] of the published research evidence on the process of DCM™ implementation, when used as a practice development methodology, found only twelve papers representing nine research studies that reported on this area. Only six papers used formal research methods to gather data and all were published from 2014 onwards, indicating the limited published research in this area to date, despite DCM™'s use in practice for over 20 years. The review concluded that more research is required.

The formal process evaluation reported as part of this trial is the largest study of DCM™ implementation to be conducted to date internationally. Therefore, in addition to the process evaluation results reported above, a number of in-depth papers discussing DCM™ implementation from the perspective of mappers, care home staff, care home managers and expert mappers are being prepared in order to contribute to this body of evidence.

6.7 Strengths and limitations of the study

The DCM™ EPIC trial is the largest and only definitive trial of the effectiveness and cost effectiveness of DCM™ to date (worldwide). It successfully recruited on time and to target adding to the relatively limited body of research on conduct of pragmatic, cluster RCT studies in care home settings. Our use of random sampling to approach care homes within specific geographical regions permitted recruitment of a number of care homes who had not participated in research previously. This has increased the pool of care homes who have been exposed to research and in particular to clinical trials and thus the numbers of homes who may be considered 'research ready'. The EPIC trial gave care home staff and managers an opportunity to participate in research and a number of staff trained as mappers discussed the value they placed on being able to access this training for their own professional development. Some of the care homes have expressed a desire to be involved in future research projects with the local recruitment hubs.

The DCM™ EPIC trial has also provided a valuable opportunity to increase the number of researchers with expertise in conducting dementia research within care home settings, across a range of trial roles. Some research assistants employed on the trial have taken up permanent PhD or post-doctoral positions in dementia research or are commencing Clinical Psychology training, ensuring their expertise is retained within the field.

6.7.1 Study design

The EPIC trial followed the Medical Research Council guidance on evaluation of a complex intervention. A cluster RCT design was utilised, appropriate outcome measures were selected, a full economic evaluation was conducted as well as a full, integrated process evaluation.

However, loss to follow-up was larger than had been anticipated (close to 50% vs estimated 25-30%) due mainly to resident deaths because of the frailty of this population and this resulted in the necessity to implement a design change and to adopt an open-cohort design mid-trial. This is not an established design for cluster RCT studies and three of the co-applicants (Walwyn, Farrin and Surr) have been successful in gaining additional funding to conduct methodological research on the use of open-cohort designs.

Cluster blinding to allocation was not feasible within the trial since care home staff were responsible for intervention delivery. Therefore, this could have led to reporting bias. Independent observational measures of agitation (PAS, CMAI-O) were therefore collected by an independent, blinded researcher to permit analysis of potential reporting bias by arm. However, observational measures do not capture agitation that may occur outside of public areas, for example during personal care and the set observation days and time meant agitation could not be assessed that occurred outside of the observational hours, for example evening and night-time and over more than two half- days during a week. Therefore, the comparison between observational and proxy reported measures must be considered with some caution.

Researchers were all blinded to cluster allocation and were not permitted to collect data in homes to which they became unblinded. This required flexibility within the research teams and some cross working between research hubs to provide cover when researchers became unblinded. The independent researcher who collected observational PAS, CMAI-O and QUIS data was both blinded and independent and so had collected no other data in the care home apart from these observational measures. The maintenance of the independent researcher and researcher blinding to cluster allocation of homes in which they collected data was able to be maintained throughout the trial.

Due to the variability in the ability of care home residents with dementia to self-report on measures of BSC and quality of life, the primary and secondary analyses were conducted using staff proxy completed measures. It was not possible to use relative/supporter proxy measures as many residents did not have a proxy informant recruited either due to visiting less frequently than was required for the measures used (at least once a fortnight) or because relatives/supporters did not wish to take part. Proxy completed measures are reported to have some but not full correlation with self-report [162] and therefore, it is a

limitation of this study that outcomes are reliant upon proxy views. Whilst we attempted to use the same staff proxy respondent at each time point, this was not always feasible due to staff turnover, sickness and annual leave. There is no reason, to conclude that these issues affected one arm of the trial more or differently to the other. However, the issues associated with use of staff proxy informants in both arms of the trial must be considered when interpreting the results.

Poor intervention adherence beyond the first expert supported cycle of DCM™ is a further limitation. Given the pragmatic trial design, aiming to implement DCM™ in 'real world' conditions, the findings are important for highlighting implementation challenges and for informing future use in such settings.

6.7.2 Health economic analysis

The health economic analysis has a number of limitations. The level of missing data was high and evaluation heavily reliant on imputation. Given the difficulties in incorporating the cross-sectional cohort approach in the economic evaluation framework, in particular the requirement to have baseline data to calculate change in costs and QALYs, it was not possible to fully capitalise on the increased sample size in a robust way.

The adoption of a health and social care perspective meant that some societal costs were not accounted for in the analysis (e.g. informal care), however it is highly unlikely these would have had a substantial impact on total costs and collecting such data would have presented significant challenges.

Additional consideration is needed of how to deal with high cost outliers [163] and when it may be appropriate to exclude them from analyses. Research should identify the most appropriate way to measure and combine QoL estimates in this group.

Finally, future research should explore the maintenance of the health benefits of the DCM™ intervention identified here.

6.8 Generalisability and sources of bias

Random selection of care homes from the large pool of eligible homes from three geographically wide recruitment hub areas ensured a good representation of different care home settings and thus generalisability of the trial across care home settings in England. This aided minimisation of selection bias. Our exclusion of care homes that were subject to

admissions bans, supportive input or other improvement measures, due issues or concerns around care quality, means a small proportion (c.3%) [164] of the care home sector were not represented in the trial. Following randomisation, the characteristics of the clusters were found to be balanced. No clusters were lost during the trial. There was a higher variation in cluster sizes in control compared to intervention, however the median cluster size was similar in both arms and in both cohorts.

Recruitment of residents was carefully designed to minimise selection bias at various levels. Resident recruitment commenced following the recruitment of care homes but prior to their randomisation. All residents who were identified as eligible and who consented to take part in the trial were recruited. Following the change in design, recruitment at 16-months of all eligible residents with dementia who were not already participating in the trial or who had previously declined to take part, contributed to minimisation of selection bias. Researchers independent of the care home were involved in resident recruitment. Screened and registered residents' characteristics were well balanced across arms and cohorts, demonstrating a lack of selection bias in resident recruitment.

Allocation concealment during the researchers' visits to care homes was not always successful, however every effort was made that researchers collected no further data in care homes to whose allocation they were unblinded. Research blinding to allocation of care homes in which they collected data, was able to be maintained throughout the trial.

6.9 Implementation of a complex intervention

As a pragmatic trial, the DCM™ intervention was implemented as it would usually be in UK care home settings, with some components enhanced from standard practice, but still within the scope of what would be feasible in usual practice. This included (1) selection of care homes on the basis of criteria that would ensure there were no setting conditions likely to reduce ability to engage with the trial e.g. quality concerns, competing research studies; (2) selection of mappers using criteria of required qualities and skills; (3) provision of a standard 4-day DCM™ training course with assessment; (4) provision of support for the first cycle of DCM™ from an expert mapper; (5) provision of standardised documentation for DCM™ implementation e.g. report template, action plan template (6) ongoing telephone and e-mail support from the DCM™ intervention lead; (7) prompts to conduct mapping cycles at the required intervals sent to mappers by SMS and through the post.

DCM™ training was provided at standard training locations (Bradford and London) for 'open' DCM™ courses (those open to any trainees and not purchased by a single provider

organisation for their own staff). However, evidence gathered during the mapper recruitment phase, subsequent efforts to recruit further mappers to replace those who had withdrawn and the process evaluation all indicated that this was difficult for many care home staff and thus restricted who could be recruited as a mapper. For the majority of those recruited as mappers, the four-day training course had to be completed on a residential basis, or required significant daily travel. Some of those identified as potential mappers indicated they would be unable to attend the training because of childcare or other responsibilities, whilst others did not wish to or were concerned about travelling and/or attending the training on a residential basis.

While overall commencement of DCM™ training within the planned two-months of randomisation was adequate, 29% of homes (n=9) experienced delays in training mappers, and one home failed to train any mappers during the trial period. Mapper withdrawal was also high with over half of homes having one or more mappers withdraw during the trial period and a third of homes having no trained mappers in post by 16-month follow up. Reasons for withdrawal were mainly personal (leaving the organisation, ill-health, maternity leave, change of role within the home). Finding suitable replacement mappers who could be trained during the trial period was not possible in the majority of homes. These issues impacted on the ability to implement DCM™ over the trial period and raise questions regarding the long term sustainability of DCM™ as an intervention within care home settings.

Given DCM™ is an established intervention, piloting of its implementation was not considered as a requirement within this trial. However, given the lack of robust evidence on implementation of DCM™ available at the time of trail design and the subsequent implementation challenges identified, undertaking some feasibility work to assess intervention adherence in care home settings and potential barriers and facilitators to this may have been beneficial. Published and practitioner evidence regarding best practice in DCM™ implementation was consulted in designing the study, and experts in use of DCM™ were involved in the trial design and delivery. DCM™ implementation within the trial included the range of supports and prompts for mapping described above, which are over and above what would normally be received by a mapper following completion of DCM™ training. Nevertheless, considerable DCM™ implementation difficulties and problems with compliance were still encountered.

6.9.1 Intervention compliance

DCM™ implementation was poorer than expected and even with DCM™ expert mapper support, 10% of intervention care homes failed to undertake any DCM™ activity and 23%

did not complete one full cycle. A further 52% of homes completed only their first expert mapper supported cycle, leaving just over a quarter (26%) who completed more than one cycle with only 13% (n=4) completing the three full, per protocol cycles to an acceptable level. This was despite a range of methods for tracking and supporting intervention compliance were implemented during the trial. Tracking intervention compliance was challenging and required considerable effort. Despite this there was missing documentation, particularly that associated with briefing and feedback sessions and assumptions had to be made that previous components of the cycle had been completed if documented evidence for later components was submitted e.g. assumption that a briefing session had occurred if there was documented evidence of mapping observations having taken place.

Two homes withdrew from the DCM™ intervention during the trial period, one because they felt DCM™ was not of value and the other because they were unable to identify any suitable mappers following withdrawal of the trained mappers due to personal reasons. The poor intervention compliance was disappointing given our adoption of established DCM™ training and implementation processes and the introduction of enhanced support for the trained care home mappers above that which might be expected in usual DCM™ practice. This has implications for considering implementation of DCM™ in the future, in particular consideration of models of implementation that are not reliant on care home staff.

6.9.2 Integral process evaluation (separate papers in preparation)

An integral process evaluation was conducted within the DCM™ EPIC trial. It investigated the perceptions of DCM™ implementation and impact from the perspective of mappers, care home managers and staff, care home residents with dementia, their relatives/friends and the DCM™ expert mappers. The process evaluation results have provided a valuable context within which to understand and interpret the DCM™ EPIC trial findings and will be presented in detail in additional papers that are currently in preparation.

6.10 Interpretation of results

The results of this trial may potentially be attributed to poor intervention compliance. While DCM™ implementation was successful in a number of sites and the process evaluation was able to identify factors associated with successful implementation as well as barriers to this, the proportion of intervention homes who failed to complete any, or more than the initial expert supported cycle, was disappointing. This indicates that although DCM™ was a well-used intervention within care homes prior to this trial and was assumed therefore, to be

acceptable and feasible to use in these settings, this may not be the case. While the exploratory CACE analyses indicated that the treatment effect may increase if care homes complete at least two DCM™ cycles to an acceptable level compared to completing only one cycle and are thus suggestive of a dose-response relationship, further research would need to be undertaken to explore this potential relationship.

6.10.1 Economic evaluation

We estimated the mean resident cost of DCM™ to be £421.07 and the most costly components of this attendance at DCM™ training and DCM™ expert mapper support. While there appeared to be incremental health (QALY) benefits for the intervention over control, these were relatively modest and out-weighed by the additional costs. As such, DCM™ did not appear to represent value for money in the cost-utility framework. Cost per reduction in CMAI cost-effectiveness values were generated and these should be interpreted alongside previous studies reporting the same metric.

The results were largely driven by a small number of high cost outliers in the intervention arm and sensitivity analyses removing these reduced the ICER substantively. Since we cannot definitively state that these cost outliers were random and not associated with the intervention, they are retained in the main analysis. The conclusions were robust to sensitivity analyses. However, efforts to reduce the cost of the intervention and improve compliance may improve value for money estimates. However, given the DCM™ implementation challenges identified in this study it seems unlikely greater adherence would be feasible to achieve with DCM™ cycles led solely by care home staff. Therefore, the costs of potential alternative models of delivery would need to be considered carefully in future research.

6.10.2 Overall evidence

Systematic reviews have identified DCM™ as effective for reducing agitation immediately and at 6-months post-randomisation in care home residents with dementia [62] and in presenting benefits for care home staff. [165] However, the number of published studies is low, their outcomes varied and robust evidence to guide effective DCM™ implementation is extremely limited. [96] Trials demonstrating efficacy of DCM™ have to date included researcher led cycles of DCM™. The DCM™ EPIC trial sought to examine whether DCM™ implemented within care homes settings, following usual UK models of care home staff led cycles, was effective and cost effective. It is the largest and only explanatory trial of DCM™

conducted internationally and the only UK-based trial. Recruiting 978 residents across 50 care homes, and randomising 31 clusters to DCM™ intervention, DCM™ EPIC is the largest trial of DCM™ conducted to date (the previous largest trial [94] recruited 268 residents in 33 units across 14 care home locations and randomised 13 units in 7 care homes to DCM™). The DCM™ EPIC trial has provided conclusive evidence that implementation of care home staff led cycles of DCM™ is not effective in reducing agitation, BSC, use of PRN anti-psychotic or other tranquillising medications or improving QoL for care homes residents with dementia compared to control. Neither is it cost effective.

The findings of the process evaluation indicate that despite a range of methods to support DCM™ implementation within the trial, care home staff led cycles of DCM™ result in poor intervention compliance, with the vast majority of care homes (74%) failing to complete more than the first DCM™ expert supported cycle. Barriers to DCM™ implementation were found at the individual mapper level, the DCM™ intervention level and the care home level. Further barriers caused by the burdens of trial participation were also identified. Considering these results alongside the findings from previous exploratory trials of DCM™, indicates that externally led or supported implementation of DCM™ may provide a more beneficial and sustainable format for DCM™ delivery. This aligns with the broader contextual challenges faced by care homes in implementing complex interventions that are staff led, these include but are not limited to high staff turnover rates; low staff literacy, numeracy, IT skills and confidence; and lack of time and resources. Future research will need to consider mechanisms for addressing these wider contextual issues within the context of intervention design and delivery. Utilising ‘bottom up’ approaches to intervention design, that involve care home staff, managers and providers may provide a mechanism to identify and address potential challenges within the development process.

7. Conclusions

This trial indicates that as a care home staff led intervention DCM™ is not effective or cost effective at reducing agitation or improving quality of life and care outcomes for residents with dementia living in care home settings. This outcome may be associated with the poor DCM™ implementation we experienced during the trial, despite efforts to support care home mappers to implement the intervention. Providing support for the first DCM™ cycle, in the form of an external expert mapper, enabled 77.4% of intervention homes to complete that cycle, however, DCM™ implementation reduced greatly after the first cycle when this support ended. Given the picture emerging from trials of DCM™ internationally, where care

home staff led cycles of DCM™ have consistently led to negative trials results and researcher led cycles have produced significant outcomes this indicates models of DCM™ implementation that do not rely solely on care home staff to implement them warrant further investigation. The process evaluation revealed the challenges care home staff faced when trying to implement DCM™ including: mappers not having the required skills and qualities to lead change, or feeling unconfident to do so; lack of time, resources and management support; and difficulties in engaging colleagues in supporting the change process. Staff turnover, sickness and other personal issues that impacted on mappers' ability to continue in the role, were also challenging, with over half the homes having at least one mapper withdraw during the study period. Nevertheless, a quarter of intervention care homes did complete two or more DCM™ cycles and staff within the process evaluation reported a range of benefits they felt using the tool had for residents, staff and care practices more broadly. This trial suggests that the majority of care home settings may not provide the right setting conditions for a costly intervention like DCM™ and that externally led models may provide a more practical and resource effective method of implementation. However, further research is needed to evaluate this. Our findings have implications for future complex intervention trials in care home settings. Future research should more carefully consider the setting conditions needed for effective intervention implementation and thus the most appropriate models for delivering these interventions given the available resources and cultural and organisational contexts of care home settings.

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Contribution of authors

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Publications

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10. Appendices

Appendix 1: Supporting tables

Screening

Table 26 Resident original cohort CONSORT by hub

Residents	Hub			Total
	Yorkshire 21 CHs	London 15 CHs	Oxford 14 CHs	50 CHs
Screened	**656**	**419**	**489**	**1564**
Eligible	**451 (68.8%)**	**297 (70.9%)**	**321 (65.6%)**	**1069 (68.4%)**
Not eligible	205 (31.2%)	122 (29.0%)	168 (34.4%)	495 (31.6%)
Does not have formal diagnosis of dementia	133 (64.9%)	67 (54.9%)	98 (58.3%)	298 (60.2%)
Permanently bed-bound	27 (13.2%)	32 (26.2%)	30 (17.9%)	89 (18.0%)
Terminally ill	22 (10.7%)	18 (14.8%)	18 (10.7%)	58 (11.7%)
Not a permanent resident	38 (18.5%)	2 (1.6%)	21 (12.5%)	61 (12.3%)
Insufficient proficiency in English	2 (1.0%)	6 (4.9%)	4 (2.4%)	12 (2.4%)
Consented (out of eligible)	**366 (81.2%)**	**199 (67.0%)**	**216 (67.3%)**	**781 (73.1%)**
Not consented (out of eligible)	85 (18.8%)	98 (33.0%)	105 (32.7%)	288 (26.9%)
Consent refused	69 (81.2%)	87 (88.8%)	82 (78.1%)	238 (82.6%)
By: Resident	24 (66.7%)	4 (11.1%)	8 (22.2%)	36 (15.1%)
Personal consultee	33 (24.8%)	37 (27.8%)	63 (47.4%)	133 (55.9%)
Nominated consultee	12 (17.4%)	46 (66.7%)	11 (15.9%)	69 (29.0%)
Resident died	5 (5.9%)	5 (5.1%)	8 (7.6%)	18 (6.3%)
Unwilling to engage with researcher	4 (4.7%)	2 (2.0%)	5 (4.8%)	11 (3.8%)
Resident transferred elsewhere	7 (8.2%)	2 (2.0%)	7 (6.7%)	16 (5.6%)
No consultee available to consent	0 (0.0%)	0 (0.0%)	2 (1.9%)	2 (0.7%)
Other	1 (1.2%)	2 (2.0%)	2 (1.9%)	5 (1.7%)
Registered (out of consented)	**339 (92.6%)**	**191 (96.0%)**	**213 (98.6%)**	**743 (95.1%)**
Not registered (out of consented)	27 (7.4%)	8 (4.0%)	3 (1.4%)	38 (4.9%)
Died	16 (59.3%)	7 (87.5%)	3 (100.0%)	26 (68.4%)
Withdrawn	1 (3.7%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
No longer eligible	3 (11.1%)	0 (0.0%)	0 (0.0%)	3 (7.9%)
Moved out of care home	7 (25.9%)	0 (0.0%)	0 (0.0%)	7 (18.4%)
Other	1 (3.7%)	1 (12.5%)	0 (0.0%)	2 (5.3%)
Registered at randomisation (out of registered)	**330 (97.3%)**	**185 (96.9%)**	**211 (99.1%)**	**726 (97.7%)**
Died between registration and CH randomisation (out of registered)	9 (2.7%)	6 (3.1%)	2 (0.9%)	17 (2.3%)

Percentages of reasons “Not eligible”, “Not consented” and “Not registered” are calculated out of number of “Not eligible”, “Not consented” and “Not registered” respectively.

Reasons “Not eligible”, “Not consented” and “Not registered” are not mutually exclusive.

Table 27 Additional resident cohort screening by hub

Residents	Hub			Total CHs
	Yorkshire CHs	London CHs	Oxford CHs	
Screened	**569**	**396**	**479**	**1444**
Currently participating in EPIC (out of screened)	185 (32.5%)	109 (27.5%)	131 (27.3%)	425 (29.4%)
Screened and not participating in EPIC (out of screened)	384 (67.5%)	287 (72.5%)	348 (72.7%)	1019 (70.6%)
Screened at baseline but consent refused (out of screened and not participating in EPIC)	43 (11.2%)	57 (19.9%)	42 (12.1%)	142 (13.9%)
Eligible (out of screened)	**189 (33.2%)**	**90 (22.7%)**	**142 (29.6%)**	**421 (29.2%)**
Not eligible (out of screened)*	152 (26.7%)	140 (35.4%)	164 (34.2%)	456 (31.6%)
Does not have formal diagnosis of dementia	93 (61.2%)	57 (40.7%)	103 (62.8%)	253 (55.5%)
Permanently bed-bound	9 (5.9%)	38 (27.1%)	7 (4.3%)	54 (11.8%)
Terminally ill	6 (3.9%)	13 (9.3%)	2 (1.2%)	21 (4.6%)
Not a permanent resident	19 (12.5%)	1 (0.7%)	8 (4.9%)	28 (6.1%)
Insufficient proficiency in English	1 (0.7%)	4 (2.9%)	2 (1.2%)	7 (1.5%)
Moved to the unit <3-months ago	44 (28.9%)	42 (30.0%)	48 (29.3%)	134 (29.4%)
Missing information	1 (0.7%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
Consented (out of eligible)	**120 (63.5%)**	**47 (52.2%)**	**99 (69.7%)**	**266 (63.2%)**
Not consented (out of eligible)*, Missing	68 (36.0%), 1	42 (46.7%), 1	43 (30.3%),0	153 (36.3%), 2
Consent refused by who	65 (95.6%)	36 (85.7%)	39 (90.7%)	140 (91.5%)
Resident	14 (21.5%)	1 (2.8%)	13 (33.3%)	28 (20.0%)
Personal consultee	19 (29.2%)	10 (27.8%)	14 (35.9%)	43 (30.7%)
Nominated consultee	32 (49.2%)	25 (69.4%)	12 (30.8%)	69 (49.3%)
Resident died	1 (1.5%)	2 (4.8%)	2 (4.7%)	5 (3.3%)
Unwilling to engage with researcher	1 (1.5%)	1 (2.4%)	1 (2.3%)	3 (2.0%)
No response from personal consultee	0 (0.0%)	2 (4.8%)	0 (0.0%)	2 (1.3%)
Transferred elsewhere	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
Other	1 (1.5%)	1 (2.4%)	1 (2.3%)	3 (2.0%)
Registered (out of consented)	**119 (99.2%)**	**45 (95.7%)**	**97 (98.0%)**	**261 (98.1%)**
Not registered (out of consented), Missing	1 (0.8%)	2 (4.3%)	1 (1.0%), 1	4 (1.5%), 1
Does not have formal diagnosis of dementia	0 (0.0%)	1 (2.1%)	0 (0.0%)	1 (0.4%)
Moved out of care home	1 (0.8%)	0 (0.0%)	0 (0.0%)	1 (0.4%)
Died	0 (0.0%)	0 (0.0%)	1 (0.8%)	1 (0.4%)
In hospital	0 (0.0%)	1 (2.1%)	0 (0.0%)	1 (0.4%)

*Categories are not mutually exclusive

Table 28 Residents screened in additional cohort by treatment arm

	Control (CHs=19)	Intervention (CHs=31)	Total (CHs=48)
Screened	**494**	**950**	**1444**
Currently participating in EPIC (out of screened)	185 (37.4%)	240 (25.3%)	425 (29.4%)
Screened and not participating in EPIC (out of screened)	309 (62.6%)	710 (74.7%)	1019 (70.6%)
Screened at baseline but consent refused (out of screened and not participating in EPIC)	34 (11.0%)	108 (15.2%)	142 (13.9%)
Eligible	**147 (29.8%)**	**274 (28.8%)**	**421 (29.2%)**
Not eligible*	128 (25.9%)	328 (34.5%)	456 (31.6%)
Does not have formal diagnosis of dementia	61 (47.7%)	192 (58.5%)	253 (55.5%)
Moved to the unit <3-months ago	15 (11.7%)	39 (11.9%)	54 (11.8%)
Permanently bed-bound	6 (4.7%)	15 (4.6%)	21 (4.6%)
Terminally ill	3 (2.3%)	25 (7.6%)	28 (6.1%)
Not a permanent resident	3 (2.3%)	4 (1.2%)	7 (1.5%)
Insufficient proficiency in English	51 (39.8%)	83 (25.3%)	134 (29.4%)
Missing information	1 (0.8%)	0 (0.0%)	1 (0.2%)
Consented (out of eligible)	**100 (68.0%)**	**166 (60.6%)**	**266 (63.2%)**
Not consented (out of eligible)*, Missing	46 (31.3%), 1	107 (39.1%), 1	153 (36.3%), 2
Consent refused by who:	40 (87.0%)	100 (93.5%)	140 (91.5%)
Resident (% out of who)	9 (22.5%)	19 (19.0%)	28 (20.0%)
Personal consultee	10 (25.0%)	33 (33.0%)	43 (30.7%)
Nominated consultee	21 (52.5%)	48 (48.0%)	69 (49.3%)
Resident died	2 (4.3%)	3 (2.8%)	5 (3.3%)
Unwilling to engage with researcher	1 (2.2%)	2 (1.9%)	3 (2.0%)
No response from personal consultee	2 (4.3%)	0 (0.0%)	2 (1.3%)
Transferred elsewhere	1 (2.2%)	0 (0.0%)	1 (0.7%)
Other	1 (2.2%)	2 (1.9%)	3 (2.0%)
Registered (out of consented)	**99 (99.0%)**	**162 (97.6%)**	**261 (98.1%)**
Not registered (out of consented), Missing	1 (1.0%)	3 (1.8%), 1	4 (1.5%), 1
Does not have formal diagnosis of dementia	1 (1.0%)	0 (0.0%)	1 (0.4%)
Moved out of care home	0 (0.0%)	1 (0.6%)	1 (0.4%)
Died	0 (0.0%)	1 (0.6%)	1 (0.4%)
In hospital	0 (0.0%)	1 (0.6%)	1 (0.4%)

*Categories are not mutually exclusive. Percentages of reasons “Not eligible”, “Not consented” and “Not registered” are calculated out of number of “Not eligible”, “Not consented” and “Not registered” respectively. Percentages of who refused the consent are calculated out of “Consent refused”. Those categories are not mutually exclusive.

Table 29 Screening data – original and additional cohort by hub

Screening data – recruited residents by cohorts								
	Original (n=1564)				Additional (n=877)*			
	Yorkshire (n=656)	**London (n=419)**	**Oxford (n=489)**	**Total (n=1564)**	**Yorkshire (n=341)**	**London (n=230)**	**Oxford (n=306)**	**Total (n=877)**
Age at registration (years) Mean (SD)	85.3 (8.00)	84.7 (8.43)	85.1 (8.20)	85.1 (8.18)	85.0 (7.64)	84.2 (8.65)	86.0 (8.11)	85.1 (8.10)
Length of stay (years) Mean (SD)	2.1 (2.29)	2.4 (2.44)	2.5 (2.70)	2.3 (2.48)	1.4 (1.79)	1.7 (2.63)	1.7 (2.17)	1.6 (2.17)
Sex Female N (%)	483 (73.6%)	301 (71.8%)	356 (72.8%)	1140 (72.9%)	248 (72.7%)	164 (71.3%)	213 (69.6%)	625 (71.3%)
Ethnicity N (%)								
White	642 (97.9%)	367 (87.6%)	474 (96.9%)	1483 (94.8%)	338 (99.1%)	208 (90.4%)	300 (98.0%)	846 (96.5%)
Other	7 (1.1%)	40 (9.5%)	8 (1.6%)	55 (3.5%)	0 (0.0%)	20 (8.7%)	5 (1.6%)	25 (2.9%)
Missing	7 (1.1%)	12 (2.9%)	7 (1.4%)	26 (1.7%)	3 (0.9%)	2 (0.9%)	1 (0.3%)	6 (0.7%)
Funding type								
Local Authority	297 (45.3%)	179 (42.7%)	265 (54.2%)	741 (47.4%)	145 (42.5%)	92 (40.0%)	167 (54.6%)	404 (46.1%)
Continuing Healthcare	58 (8.8%)	35 (8.4%)	22 (4.5%)	115 (7.4%)	4 (1.2%)	16 (7.0%)	1 (0.3%)	21 (2.4%)
Self-funded	226 (34.5%)	141 (33.7%)	188 (38.4%)	555 (35.5%)	116 (34.0%)	80 (34.8%)	122 (39.9%)	318 (36.3%)
Local Authority and self-funded	59 (9.0%)	1 (0.2%)	9 (1.8%)	69 (4.4%)	57 (16.7%)	7 (3.0%)	4 (1.3%)	68 (7.8%)
Missing	16 (2.4%)	63 (15.0%)	5 (1.0%)	84 (5.4%)	19 (5.6%)	35 (15.2%)	12 (3.9%)	66 (7.5%)

*Excluding those already participating in the trial and those that were screened at baseline but refused consent.

Table 30 Type of consent of registered residents

Type of consent of registered residents – original and additional cohort				
Original		**Additional**		
	Total (n=726)	**Control (n=99)**	**Intervention (n=162)**	**Total (n=261)**
Consent by:				
Resident	145 (20.0%)	22 (22.2%)	36 (22.2%)	58 (22.2%)
Personal consultee	263 (36.2%)	34 (34.3%)	39 (24.1%)	73 (28.0%)
Nominated consultee	318 (43.8%)	43 (43.4%)	87 (53.7%)	130 (49.8%)

Staff and relative/ friend

Table 31 Staff measures – SCIDS (total number of staff that completed at least one SCIDS item)

	SCIDS summaries								
	Baseline			6-months			16-months		
Mean (SD) missing	**Control (n = 86)**	**Intervention (n = 260)**	**Total (n = 346)**	**Control (n = 84)**	**Intervention (n = 112)**	**Total (n = 196)**	**Control (n = 50)**	**Intervention (n = 132)**	**Total (n = 182)**
Total SCIDS score	**53.2 (8.96) 1**	**53.7 (9.24) 5**	**53.6 (9.16) 6**	**55 (8.64) 1**	**53.5 (8.56) 2**	**54.1 (8.6) 3**	**58.4 (7.97) 1**	**56.8 (8.3) 1**	**57.2 (8.22) 2**
Professionalism	16.7 (2.61) 0	17 (2.75) 4	16.9 (2.72) 4	17.2 (2.72) 3	16.8 (2.52) 2	17 (2.6) 5	18 (2.17) 1	17.6 (2.4) 2	17.7 (2.34) 3
Building relationships	11.7 (2.37) 0	11.8 (2.36) 4	11.8 (2.36) 4	12.3 (2.24) 0	11.9 (2.18) 1	12.1 (2.21) 1	13 (2.39) 1	12.6 (2.24) 1	12.7 (2.28) 2
Core challenges	11.9 (2.84) 1	11.9 (2.9) 6	11.9 (2.88) 7	12.2 (2.71) 1	12 (2.63) 3	12.1 (2.66) 4	13.6 (2.51) 1	12.9 (2.61) 1	13.1 (2.59) 2
Sustaining personhood	12.9 (2.31) 0	13 (2.43) 5	13 (2.39) 5	13.4 (2.27) 2	12.8 (2.47) 1	13.1 (2.4) 3	13.8 (1.96) 1	13.6 (2.11) 2	13.6 (2.07) 3
Booklets circulated to staff	525	1143	1668	546	848	1394	526	1108	1634
Overall score ranging from 17-68 with higher scores indicative of more confidence in delivering care to those with dementia.									

Table 32 QUALID – completed by relative/ friend (out of relatives that were registered at each timepoint)

	QUALID summaries – completed by relative/ friend											
	Baseline			6-months			16-months original cohort			16-months cross-sectional cohort		
Mean (SD) missing Median (IQR)	Control (n = 96)	Intervention (n = 101)	Total (n = 197)	Control (n = 85)	Intervention (n = 85)	Total (n = 170)	Control (n = 63)	Intervention (n = 55)	Total (n = 118)	Control (n = 64)	Intervention (n = 55)	Total (n = 119)
QUALID relative/ proxy	22.5 (7.49) 14	21.6 (6.86) 20	22 (7.18) 34	21.6 (7.18) 23	22.1 (8.89) 20	21.8 (8.07) 43	23 (6.24) 25	23.1 (8.41) 24	23 (7.24) 49	23 (6.15) 25	23.1 (8.41) 24	23 (7.18) 49
	21 (17, 28)	21 (17, 25)	21 (17, 26)	20.9 (15, 25)	20 (14.3, 30)	20.9 (15, 27)	23 (18, 26)	22 (16.5, 29)	22 (18, 28)	23 (18, 26)	22 (16.5, 29)	22.5 (18, 28)

Intervention

Table 33 Compliance with intervention by care home

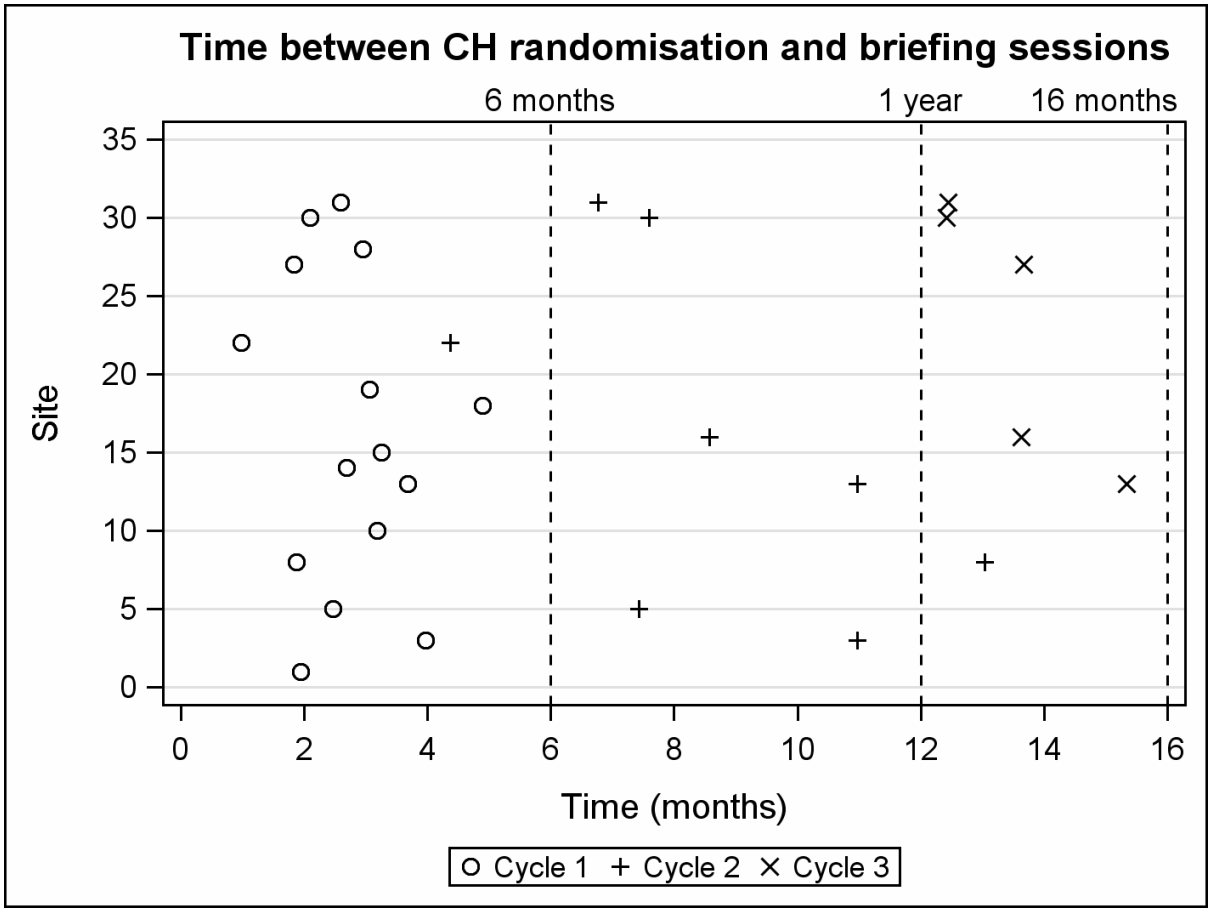
Compliance with intervention by CH (using documented evidence and expert opinion for cycle 1)						
CH hub	**CH**	**CYCLE 1**	**CYCLE 2**	**CYCLE 3**	**No of cycles to at least acceptable level**	**No of cycles to at least partial level**
Yorkshire	1	Acceptable	None	None	One cycle	One cycle
	2	None	None	None	No cycles	No cycles
	3	Acceptable	Acceptable	None	Two cycles	Two cycles
	8	None	None	None	No cycles	No cycles
	9	Acceptable	Partial	None	One cycle	Two cycles
	17	Acceptable	Partial	Partial	One cycle	Three cycles
	24	Acceptable	None	None	One cycle	One cycle
	32	Acceptable	Acceptable	None	Two cycles	Two cycles
	33	Partial	None	None	No cycles	One cycle
	34	None	None	None	No cycles	No cycles
	38	Partial	None	None	No cycles	One cycle
	44	Acceptable	None	None	One cycle	One cycle
	48	Acceptable	Acceptable	Acceptable	Three cycles	Three cycles
Oxford	4	Acceptable	None	None	One cycle	One cycle
	5	Acceptable	Partial	None	One cycle	Two cycles
	6	Acceptable	None	None	One cycle	One cycle
	11	Acceptable	None	None	One cycle	One cycle
	12	Partial	None	None	No cycles	One cycle
	14	Partial	None	None	No cycles	One cycle
	16	Acceptable	Acceptable	Acceptable	Three cycles	Three cycles
	23	Acceptable	Partial	Partial	One cycle	One cycle
	25	Acceptable	Acceptable	None	Two cycles	Two cycles
London	10	Acceptable	None	None	One cycle	One cycle
	19	Acceptable	None	None	One cycle	One cycle
	20	Acceptable	Partial	Partial	One cycle	Three cycles
	26	Acceptable	None	None	One cycle	One cycle
	31	Acceptable	Acceptable	None	Two cycles	Two cycles
	39	Acceptable	None	None	One cycle	One cycle
	40	Acceptable	Acceptable	Acceptable	Three cycles	Three cycles
	42	Acceptable	None	None	One cycle	One cycle
	47	Acceptable	Acceptable	Acceptable	Three cycles	Three cycles

Briefing

Table 34 Summary of briefing sessions as documented

Summary of briefing sessions by cycle - by hub and overall			
	Cycle 1 (n=31)	**Cycle 2 (n=31)**	**Cycle 3 (n=31)**
Number of formal sessions			
1	9 (29.0%)	7 (22.6%)	3 (9.7%)
2	4 (12.9%)	1 (3.2%)	1 (3.2%)
3	2 (6.5%)	1 (3.2%)	1 (3.2%)
Missing	16 (51.6%)	22 (71.0%)	26 (83.9%)
Length of formal sessions (mins)			
Mean (SD) Missing	71.7 (61.72) 16	66.9 (34.94) 23	93.8 (41.31) 27
Median (Range)	40 (20, 240)	60 (30, 140)	97.5 (45, 135)
Total number of staff attended			
Mean (SD) Missing	10.1 (4.52) 18	15.8 (7.44) 23	18.0 (8.19) 28
Median (Range)	10 (3, 20)	14.5 (8, 28)	20 (9, 25)
Number of direct staff attended			
Mean (SD) Missing	11.4 (6.23) 26	15.3 (6.08) 27	14.0 (5.29) 28
Median (Range)	13.0 (3.0, 17.0)	13.5 (10.0, 24.0)	16.0 (8.0, 18.0)
Timing of formal session from randomisation (months)			
Mean (SD) Missing	2.8 (0.98) 16	8.7 (2.79) 23	13.5 (1.19) 26
Median (Range)	2.7 (1.0, 4.9)	8.1 (4.4, 13.0)	13.6 (12.4, 15.3)
Informal briefing sessions held			
Yes N (%) Missing	15 (48.4%) 15	10 (32.3%) 20	3 (9.7%) 26
No	1 (3.2%)	1 (3.2%)	2 (6.5%)
Number of staff informally briefed			
Mean (SD) Missing	10.5 (7.51) 17	13.1 (10.89) 23	19.3 (1.15) 28
Median (Range)	8.5 (2.0, 30.0)	7.0 (4.0, 31.0)	20.0 (18.0, 20.0)

Figure 7 Time between CH randomisation and briefing sessions



Observation

Table 35 Summary of observation as documented

Observations adherence by cycle			
	Cycle 1 (n=31)	**Cycle 2 (n=31)**	**Cycle 3 (n=31)**
Number of mappers observed			
1	1 (3.2%)	1 (3.2%)	1 (3.2%)
2	18 (58.1%)	10 (32.3%)	4 (12.9%)
Missing	12 (38.7%)	20 (64.5%)	26 (83.9%)
N of observation periods			
Mean (SD) Missing	4.3 (2.05) 16	3.9 (1.89) 23	2.0 (0.00) 28
Median (Range)	4 (2, 8)	4 (2, 8)	2 (2, 2)
N of days between first and last observation			
Mean (SD) Missing	3.0 (7.05) 13	4.5 (14.75) 20	0.0 (0.00) 26
Median (Range)	0 (0, 29)	0 (0, 49)	0 (0, 0)
Total mapping time (hours)			
Mean (SD) Missing	8.9 (2.76) 16	9.4 (2.30) 23	7.8 (0.43) 28
Median (Range)	9.2 (4.0, 12.4)	9.9 (6.5, 12.3)	8.0 (7.3, 8.0)
Using all codes Yes N (%) Missing	10 (32.3%) 13	7 (22.6%) 20	2 (6.5%) 26
Total residents observed			
Mean (SD) Missing	5.4 (1.79) 13	5.7 (2.41) 20	5.2 (1.79) 26
Median (Range)	5 (2, 8)	6 (2, 10)	4 (4, 8)
Out of observed:			
N of residents with less than 3 hours of observation			
Mean (SD) Missing	2.2 (1.72) 13	1.1 (2.39) 20	1.0 (1.41) 26
Median (Range)	2 (0, 5)	0 (0, 8)	0 (0, 3)
N of residents with at least 3 hours of observation			
Mean (SD) Missing	3.3 (1.81) 13	4.6 (2.06) 20	4.2 (1.48) 26
Median (Range)	3 (0, 6)	5 (2, 8)	4 (2, 6)
% of observed residents with at least 3 hours of observation			
Mean (SD) Missing	58.7 (33.75) 13	86.0 (25.13) 20	82.5 (24.37) 26
Median (Range)	60 (0, 100)	100 (20, 100)	100 (50, 100)

Table 36 Observation quality by cycle

Observation quality by cycle			
	Cycle 1 (n=31)	**Cycle 2 (n=31)**	**Cycle 3 (n=31)**
Two mappers completed at least 4 hours of observations over a 1 week period			
Yes, completed fully	13 (41.9%)	7 (22.6%)	3 (9.7%)
Completed partially	6 (19.4%)	4 (12.9%)	2 (6.5%)
Not completed	12 (38.7%)	20 (64.5%)	26 (83.9%)
At least 5 residents observed in total with at least 3 hours of available data on each resident			
Yes, completed fully	2 (6.5%)	4 (12.9%)	1 (3.2%)
Completed partially	16 (51.6%)	7 (22.6%)	4 (12.9%)
Not completed	13 (41.9%)	20 (64.5%)	26 (83.9%)
Mappers using all 4 of the coding frames and making at least minimal qualitative notes			
Yes, completed fully	9 (29.0%)	5 (16.1%)	2 (6.5%)
Completed partially	9 (29.0%)	6 (19.4%)	3 (9.7%)
Not completed	13 (41.9%)	20 (64.5%)	26 (83.9%)

Feedback

Table 37 Summary of feedback sessions as documented

Summary of feedback sessions by cycle			
	Cycle 1 (n=31)	**Cycle 2 (n=31)**	**Cycle 3 (n=31)**
Number of mappers participating in the feedback process			
1	1 (3.2%)	2 (6.5%)	
2	13 (41.9%)	7 (22.6%)	3 (9.7%)
Missing	17 (54.8%)	22 (71.0%)	28 (90.3%)
Formal feedback sessions held N (%) Missing			
Yes	12 (38.7%) 17	8 (25.8%) 21	3 (9.7%) 27
No	2 (6.5%)	2 (6.5%)	1 (3.2%)
Total number of formal feedback sessions			
Mean (SD) Missing	1.8 (0.83) 19	1.4 (0.79) 24	1.0 (0.00) 28
Median (Range)	2 (1, 3)	1 (1, 3)	1 (1, 1)
Total length of formal feedback sessions (hours)			
Mean (SD) Missing	2.0 (2.26) 20	1.2 (0.67) 25	0.8 (0.29) 28
Median (Range)	1.2 (0.5, 8.4)	1.0 (0.5, 2.3)	1.0 (0.5, 1.0)
N days between first and last feedback session (days)			
Mean (SD) Missing	2.8 (5.75) 19	1.3 (2.98) 24	0.0 (0.00) 28
Median (Range)	0 (0, 20)	0 (0, 8)	0 (0, 0)
Total number of staff attended formal feedback sessions			
Mean (SD) Missing	9.6 (4.56) 19	12.3 (4.46) 25	12.3 (4.51) 28
Median (Range)	9.0 (2, 17)	11.5 (7, 18)	12.0 (8, 17)
Total number of direct care staff attended formal feedback sessions			
Mean (SD) Missing	8.0 (2.65) 28	8.5 (2.12) 29	12.0 (.) 30
Median (Range)	9 (5, 10)	8.5 (7, 10)	12 (12, 12)

Table 38 Care home and residents feedback points

CH and residents feedback points by cycle			
	Cycle 1 (n=31)	**Cycle 2 (n=31)**	**Cycle 3 (n=31)**
N of care home feedback points			
Mean (SD) Missing	5.0 (3.06) 21	3.7 (1.21) 25	6.0 (5.72) 27
Median (Range)	4.5 (2, 13)	3 (3, 6)	5.5 (0, 13)
Total number of residents with feedback points			
Mean (SD) Missing	4.4 (1.78) 19	4.2 (2.23) 25	3.5 (1.73) 27
Median (Range)	4.5 (1, 7)	5 (1, 6)	4 (1, 5)
Mean number of resident feedback points			
Mean (SD) Missing	3.2 (2.12) 20	2.5 (0.93) 25	2.3 (0.96) 27
Median (Range)	2.8 (0.8, 7.8)	2.9 (1.0, 3.3)	2.4 (1.3, 3.3)
% of achieved resident action plans set in previous cycle		**Cycle 1 to cycle 2**	**Cycle 2 to cycle 3**
Mean (SD) Missing		51.6 (41.75) 22	73.8 (43.38) 26
Median (Range)		64.7 (0, 100)	100.0 (0, 100)
% of achieved CH action plans set in previous cycle			
Mean (SD) Missing		54.8 (44.72) 22	79.2 (25.00) 27
Median (Range)		60.0 (0, 100)	83.3 (50, 100)

Action planning

Table 39 Summary of action planning as documented

Action planning by cycle	Cycle 1 (n=31)	Cycle 2 (n=31)	Cycle 3 (n=31)
Care home action plan received N (%) Missing			
Yes	13 (41.9%) 12	6 (19.4%) 20	4 (12.9%) 26
No	6 (19.4%)	5 (16.1%)	1 (3.2%)
Number of care home action points			
Mean (SD)	4.9 (3.20) 18	5.2 (4.83) 25	5.0 (2.16) 27
Median (Range)	4 (2, 14)	3 (3, 15)	4.5 (3, 8)
Resident action plans received N (%) Missing			
Yes	13 (41.9%) 12	6 (19.4%) 20	3 (9.7%) 26
No	6 (19.4%)	5 (16.1%)	2 (6.5%)
Total number of residents with action points			
Mean (SD)	5.5 (1.85) 18	5.8 (2.86) 25	4.7 (1.15)
Median (Range)	5 (3, 8)	5.5 (2, 10)	4 (4, 6)
Mean number of resident action points			
Mean (SD)	2.0 (1.95) 18	2.0 (1.24) 25	1.8 (1.77) 28
Median (Range)	1.6 (0.1, 7.8)	2.2 (0.1, 3.3)	1.3 (0.3, 3.8)

Table 40 Action planning quality

Action planning quality by cycle N (%) Missing	Cycle 1 (n=31)	Cycle 2 (n=31)	Cycle 3 (n=31)
Standard care home template used			
Yes	13 (41.9%) 18	6 (19.4%) 25	3 (9.7%) 27
No			1 (3.2%)
Standard resident template used			
Yes	12 (38.7%) 18	6 (19.4%) 25	2 (6.5%) 28
No	1 (3.2%)		1 (3.2%)
At least one action point per observed resident			
Yes	5 (16.1%) 18	4 (12.9%) 25	1 (3.2%) 28
No	8 (25.8%)	2 (6.5%)	2 (6.5%)

Resident deaths

Table 41 Residents deaths by treatment arm

Residents deaths by treatment arm			
	Control (n=308)	**Intervention (n=418)**	**Total (n=726)**
Died	111 (36.0%)	161 (38.5%)	272 (37.5%)
Place of death			
Care home	89 (80.2%)	135 (83.9%)	224 (82.4%)
Hospital	22 (19.8%)	26 (16.1%)	48 (17.6%)
Average proportion of deaths per CH at 16-months			
Mean (SD)	0.36 (0.123)	0.39 (0.140)	0.37 (0.134)
Median (Range)	0.41 (0.07, 0.60)	0.36 (0.10, 0.75)	0.36 (0.07, 0.75)

Outcomes

Residents

Table 42 Unadjusted observational CMAI and PAS summaries by time-point – closed cohort

Unadjusted CMAI-O[1] and PAS[2] scores by time-point – closed cohort						
	AM			PM		
	Closed-cohort					
	Control	**Intervention**	**Total**	**Control**	**Intervention**	**Total**
Mean (SD) N completed	**(n = 308)**	**(n = 418)**	**(n = 726)**	**(n = 308)**	**(n = 418)**	**(n = 726)**
Baseline CMAI-O Total Score	**31.1 (3.1) 184**	**30.5 (2.7) 266**	**30.8 (2.9) 450**	**32.0 (3.7) 198**	**31.5 (3.8) 272**	**31.7 (3.8) 470**
Subscales: Aggressive behaviour	9.2 (0.6) 185	9.1 (0.5) 266	9.1 (0.6) 451	9.4 (1.1) 198	9.3 (1.0) 272	9.3 (1.1) 470
Physically non-aggressive	7.2 (1.8) 184	6.9 (1.7) 265	7.0 (1.8) 449	7.6 (2.1) 198	7.3 (2.0) 272	7.4 (2.0) 470
Verbally agitated	5.5 (1.3) 184	5.3 (0.9) 266	5.4 (1.1) 450	5.6 (1.4) 198	5.6 (1.6) 272	5.6 (1.6) 470
Other	9.3 (0.9) 184	9.2 (0.7) 266	9.2 (0.8) 450	9.4 (1.1) 198	9.3 (0.8) 272	9.3 (0.9) 470
6-months CMAI-O Total Score	**31.1 (4) 159**	**31.3 (3.6) 209**	**31.2 (3.8) 368**	**31.6 (3.6) 151**	**32.0 (3.9) 206**	**31.8 (3.8) 357**
Subscales: Aggressive behaviour	9.3 (1.0) 159	9.2 (0.6) 209	9.2 (0.8) 368	9.3 (0.9) 151	9.3 (0.8) 206	9.3 (0.9) 357
Physically non-aggressive	6.8 (1.8) 159	6.9 (1.8) 209	6.9 (1.8) 368	7.1 (2.0) 151	7.4 (2.0) 206	7.3 (2.0) 357
Verbally agitated	5.7 (1.7) 159	5.6 (1.7) 209	5.6 (1.7) 368	5.8 (1.7) 151	5.8 (1.9) 206	5.8 (1.8) 357
Other	9.4 (1.0) 159	9.6 (1.2) 209	9.5 (1.1) 368	9.4 (1.0) 151	9.5 (1.1) 206	9.5 (1.1) 357
16-months CMAI-O Total Score	**31.2 (3.8) 102**	**30.4 (3.2) 129**	**30.7 (3.5) 231**	**31.3 (4.1) 97**	**31 (3.9) 124**	**31.1 (4.0) 221**
Subscales: Aggressive behaviour	9.3 (1.1) 102	9.3 (1.0) 129	9.3 (1.0) 231	9.3 (1.2) 97	9.4 (1.3) 124	9.4 (1.3) 221
Physically non-aggressive	6.7 (1.5) 102	6.5 (1.5) 129	6.6 (1.5) 231	6.8 (1.5) 97	6.7 (1.9) 124	6.8 (1.8) 221
Verbally agitated	5.8 (2.2) 102	5.4 (1.4) 129	5.6 (1.8) 231	5.8 (2.0) 97	5.5 (1.5) 124	5.6 (1.7) 221
Other	9.4 (1.0) 102	9.2 (0.7) 129	9.3 (0.8) 231	9.4 (1.0) 97	9.3 (1.0) 124	9.4 (1.0) 221
Baseline PAS score	1.0 (1.5) 185	0.8 (1.5) 266	0.8 (1.5) 451	1.3 (1.6) 197	1.3 (2.2) 271	1.3 (2.0) 468
6-months PAS score	0.9 (1.9) 159	0.9 (1.4) 209	0.9 (1.7) 368	1.1 (1.9) 151	1.2 (1.8) 204	1.2 (1.8) 355
16-months PAS score	1.0 (1.8) 102	0.7 (1.6) 129	0.9 (1.7) 231	1.2 (2.1) 97	0.9 (1.9) 123	1.0 (2.0) 220

[1]CMAI-O: scores 29-116, higher score indicates more frequent agitated behaviour, [2]PAS: range of 0-16, with higher scores representing higher levels of agitation

Figure 8 Graphical depiction of change in average CMAI scores in care homes (cross-sectional) by treatment arms (16 months-baseline)

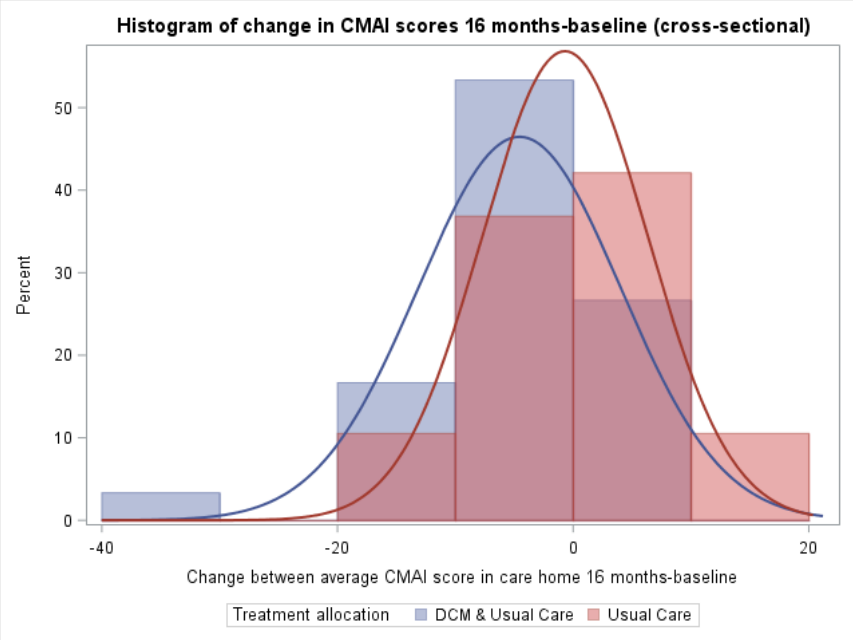
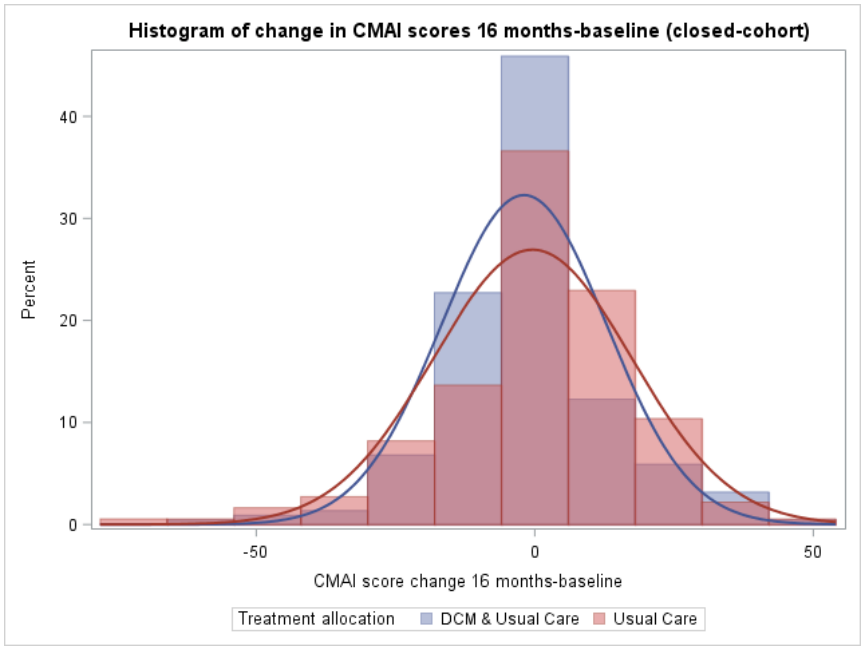


Figure 9 Graphical depiction of change in CMAI scores (closed-cohort) by treatment arms (16 months-baseline and 6 months-baseline)



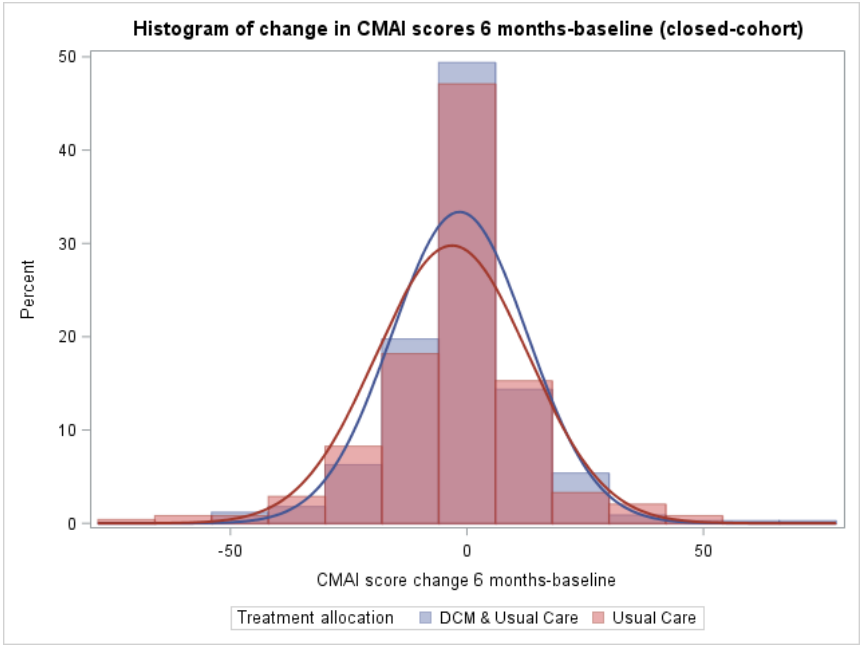


Table 43 Observational CMAI (CMAI-O) and PAS summaries – unadjusted scores

	CMAI-O and PAS summaries											
								16-months original cohort			16-months cross-sectional cohort	
		Baseline			6-months							
		Intervention			Intervention			Intervention			Intervention	
Mean (SD) N	Control (n = 308)	(n = 418)	Total (n = 726)	Control (n = 308)	(n = 418)	Total (n = 726)	Control (n = 308)	(n = 418)	Total (n = 726)	Control (n = 287)	(n = 388)	Total (n = 675)
Total CMAI-O (10:00-12:00)	31.1 (3.1) 184	30.5 (2.7) 266	30.8 (2.9) 450	31.1 (4) 159	31.3 (3.6) 209	31.2 (3.8) 368	31.2 (3.8) 102	30.4 (3.2) 129	30.7 (3.5) 231	31.1 (3.8) 156	30.5 (3.3) 209	30.8 (3.5) 365
CMAI-O subscales (10:00-12:00):												
Verbally agitated	5.5 (1.3) 184	5.3 (0.9) 266	5.4 (1.1) 450	5.7 (1.7) 159	5.6 (1.7) 209	5.6 (1.7) 368	5.8 (2.2) 102	5.4 (1.4) 129	5.6 (1.8) 231	5.8 (2.2) 156	5.5 (1.5) 209	5.6 (1.8) 365
Physically non-aggressive	7.2 (1.8) 184	6.9 (1.7) 265	7 (1.8) 449	6.8 (1.8) 159	6.9 (1.8) 209	6.9 (1.8) 368	6.7 (1.5) 102	6.5 (1.5) 129	6.6 (1.5) 231	6.7 (1.4) 156	6.5 (1.5) 209	6.6 (1.4) 365
Other	9.3 (0.9) 184	9.2 (0.7) 266	9.2 (0.8) 450	9.4 (1) 159	9.6 (1.2) 209	9.5 (1.1) 368	9.4 (1) 102	9.2 (0.7) 129	9.3 (0.8) 231	9.3 (1) 156	9.2 (0.7) 209	9.2 (0.8) 365
Aggressive behaviour	9.2 (0.6) 185	9.1 (0.5) 266	9.1 (0.6) 451	9.3 (1) 159	9.2 (0.6) 209	9.2 (0.8) 368	9.3 (1.1) 102	9.3 (1) 129	9.3 (1) 231	9.3 (0.9) 156	9.3 (1) 209	9.3 (1) 365
Total CMAI-O (12:00-17:00)	**32 (3.7) 198**	**31.5 (3.8) 272**	**31.7 (3.8) 470**	**31.6 (3.6) 151**	**32 (3.9) 206**	**31.8 (3.8) 357**	**31.3 (4.1) 97**	**31 (3.9) 124**	**31.1 (4) 221**	**31.4 (3.8) 148**	**31.1 (3.9) 206**	**31.2 (3.9) 354**
Median (IQR)	31 (29, 34)	30 (29, 32.6)	30 (29, 33)	30 (29, 33)	30 (29, 34)	30 (29, 33)	29 (29, 32)	29 (29, 32)	29 (29, 32)	29 (29, 32)	29 (29, 32)	29 (29, 32)
CMAI-O subscales (12:00-17:00):												
Verbally agitated	5.6 (1.4) 198	5.6 (1.6) 272	5.6 (1.6) 470	5.8 (1.7) 151	5.8 (1.9) 206	5.8 (1.8) 357	5.8 (2) 97	5.5 (1.5) 124	5.6 (1.7) 221	5.8 (1.9) 148	5.7 (1.7) 206	5.7 (1.8) 354
Physically non-aggressive	7.6 (2.1) 198	7.3 (2) 272	7.4 (2) 470	7.1 (2) 151	7.4 (2) 206	7.3 (2) 357	6.8 (1.5) 97	6.7 (1.9) 124	6.8 (1.8) 221	6.9 (1.5) 148	6.8 (1.9) 206	6.9 (1.8) 354
Other	9.4 (1.1) 198	9.3 (0.8) 272	9.3 (0.9) 470	9.4 (1) 151	9.5 (1.1) 206	9.5 (1.1) 357	9.4 (1) 97	9.3 (1) 124	9.4 (1) 221	9.3 (0.9) 148	9.3 (0.9) 206	9.3 (0.9) 354
Aggressive behaviour	9.4 (1.1) 198	9.3 (1) 272	9.3 (1.1) 470	9.3 (0.9) 151	9.3 (0.8) 206	9.3 (0.9) 357	9.3 (1.2) 97	9.4 (1.3) 124	9.4 (1.3) 221	9.3 (1.1) 148	9.3 (1.2) 206	9.3 (1.1) 354
Total PAS (10:00-12:00):	1 (1.5) 185	0.8 (1.5) 266	0.8 (1.5) 451	0.9 (1.9) 159	0.9 (1.4) 209	0.9 (1.7) 368	1 (1.8) 102	0.7 (1.6) 129	0.9 (1.7) 231	1.1 (1.9) 156	0.8 (1.7) 209	0.9 (1.8) 365
Total PAS (12:00-17:00):	1.3 (1.6) 197	1.3 (2.2) 271	1.3 (2) 468	1.1 (1.9) 151	1.2 (1.8) 204	1.2 (1.8) 355	1.2 (2.1) 97	0.9 (1.9) 123	1 (2) 220	1.2 (1.9) 148	0.9 (1.8) 205	1 (1.8) 353

Sensitivity analyses

Table 44 Supportive analysis assuming missing data are MAR – closed-cohort

Analysis	Adjusted Mean in Control	Adjusted Mean in Intervention	Estimated Mean Difference	Lower 95% Confidence Limit	Upper 95% Confidence Limit	p-value	Adjusted ICC for Intervention	Adjusted ICC for Control	N
Supportive analyses (closed-cohort)									
6-months									
CMAI	43.44	44.04	0.59	-1.98	3.17	0.653	0.049	0.001	726
CMAI-O (AM)	31.40	31.86	0.46	-0.37	1.30	0.276	0.019	0.000	726
CMAI-O (PM)	31.64	32.20	0.57	-0.27	1.40	0.182	0.023	0.001	726
PAS (AM)	1.04	1.18	0.14	-0.24	0.52	0.473	0.022	0.001	726
PAS (PM)	1.05	1.23	0.18	-0.20	0.57	0.350	0.021	0.001	726
16-months									
CMAI-O (AM)	30.90	30.50	-0.40	-1.27	0.46	0.361	0.014	0.001	726
CMAI-O (PM)	31.17	31.05	-0.13	-1.09	0.84	0.795	0.012	0.001	726
PAS (AM)	0.91	0.79	-0.12	-0.52	0.28	0.547	0.008	0.001	726
PAS (PM)	1.08	0.91	-0.17	-0.67	0.33	0.502	0.018	0.001	726

Table 45 Primary and sensitivity analyses – complete cases, cross-section

Analysis	Estimated mean in control	Estimated mean in intervention	Estimated Mean Difference	Lower 95% Confidence Limit	Upper 95% Confidence Limit	p-value	Unadjusted ICC for Intervention Arm	Unadjusted ICC for Control Arm	Adjusted ICC for Intervention Arm	Adjusted ICC for Control Arm	N
Primary analysis	45.52	43.33	-2.19	-4.81	0.43	0.099	0.0546	0.0002	0	0	666
Key sensitivity analysis	46.01	43.73	-2.28	-4.98	0.42	0.095	0.0497		0.007		666
Sensitivity analysis (1) adjusting for before after eligibility change	44.85	42.65	-2.2	-4.82	0.43	0.099	0.0546	0.0002	0	0	666
(2) care home size as a continuous variable	45.48	43.16	-2.32	-5.03	0.38	0.090	0.0546	0.0002	0	0	661
(3) assuming homogeneous clustering across arms	45.45	43.30	-2.16	-4.75	0.43	0.100	0.0497		0		666

Table 46 Sensitivity analyses (4-5) CMAI, PAS and CMAI-O at 16-months – complete cases

Closed-cohort analysis – PAS and CMAI-O at 16-months, complete cases											
Analysis	**Estimated mean in control**	**Estimated mean in intervention**	**Estimated Mean Difference**	**Lower 95% Confidence Limit**	**Upper 95% Confidence Limit**	**p-value**	**Unadjusted ICC for Intervention**	**Unadjusted ICC for Control**	**Adjusted ICC for Intervention**	**Adjusted ICC for Control**	**N**
CMAI	46.00	42.44	-3.57	-6.65	-0.48	0.025	0.0779	0.0003	0.0261	0.002	400
PAS (AM)	1.10	0.66	-0.44	-1.04	0.15	0.140	0.0882	0.0012	0.0031	0.0024	170
PAS (PM)	1.40	0.75	-0.65	-1.4	0.09	0.084	0.2394	0.0108	0.2265	0.0151	174
CMAI-O (AM)	31.08	30.04	-1.04	-2.25	0.17	0.089	0.1189	0.0009	0.0251	0.0079	169
CMAI-O (PM)	31.42	30.71	-0.72	-2.12	0.69	0.310	0.0985	0.0003	0.0272	0.0018	176

Table 47 CMAI, observational CMAI and PAS at 6-months – complete cases

Closed-cohort analysis – CMAI, PAS and CMAI-O at 6-months, complete cases											
Analysis	**Estimated mean in control**	**Estimated mean in intervention**	**Estimated Mean Difference**	**Lower 95% Confidence Limit**	**Upper 95% Confidence Limit**	**p-value**	**Unadjusted ICC for Intervention**	**Unadjusted ICC for Control**	**Adjusted ICC for Intervention**	**Adjusted ICC for Control**	**N**
CMAI	43.32	43.73	0.41	-2.6	3.42	0.784	0.1356	0.011	0.0892	0	572
CMAI-O (AM)	31.41	31.79	0.38	-0.66	1.42	0.468	0.09	0.0001	0.0418	0.0006	270
CMAI-O (PM)	31.79	32.34	0.55	-0.73	1.83	0.393	0.121	0.0127	0.1445	0.0353	278
PAS (AM)	0.90	1.08	0.18	-0.29	0.66	0.446	0.112	0.0018	0.0862	0.0022	268
PAS (PM)	1.09	1.23	0.14	-0.42	0.7	0.621	0.1001	0	0.0779	0.0077	275

Table 48 Sensitivity analysis (5) - CMAI score at 16-months – closed-cohort - deaths and withdrawals assumed MNAR - two-way tipping point analysis

	Deaths shifted by																
Treatment effect p-values	**-40**	**-35**	**-30**	**-25**	**-20**	**-15**	**-10**	**-5**	**0**	**5**	**10**	**15**	**20**	**25**	**30**	**35**	**40**
Withdrawals and moves shifted by																	
-40	0.028	0.025	0.023	0.022	0.02	0.019	0.019	0.018	0.018	0.018	0.018	0.019	0.02	0.021	0.023	0.025	0.028
-35	0.029	0.027	0.025	0.023	0.021	0.02	0.02	0.019	0.019	0.019	0.019	0.02	0.021	0.022	0.024	0.026	0.029
-30	0.03	0.028	0.026	0.024	0.023	0.022	0.021	0.02	0.02	0.02	0.021	0.021	0.022	0.024	0.026	0.028	0.03
-25	0.032	0.03	0.027	0.026	0.024	0.023	0.022	0.022	0.021	0.021	0.022	0.023	0.024	0.025	0.027	0.029	0.032
-20	0.034	0.031	0.029	0.027	0.026	0.024	0.024	0.023	0.023	0.023	0.023	0.024	0.025	0.027	0.029	0.031	0.034
-15	0.036	0.033	0.031	0.029	0.027	0.026	0.025	0.025	0.025	0.025	0.025	0.026	0.027	0.029	0.031	0.033	0.036
-10	0.038	0.036	0.033	0.031	0.03	0.028	0.027	0.027	0.027	0.027	0.027	0.028	0.029	0.031	0.033	0.036	0.039
-5	0.041	0.038	0.036	0.034	0.032	0.031	0.03	0.029	0.029	0.029	0.029	0.03	0.032	0.033	0.036	0.038	0.041
0	0.044	0.041	0.038	0.036	0.034	0.033	0.032	0.032	0.031	0.031	0.032	0.033	0.034	0.036	0.038	0.041	0.044
5	0.047	0.044	0.041	0.039	0.037	0.036	0.035	0.034	0.034	0.034	0.035	0.036	0.037	0.039	0.041	0.044	0.048
10	0.05	0.047	0.045	0.042	0.04	0.039	0.038	0.037	0.037	0.037	0.038	0.039	0.041	0.042	0.045	0.048	0.051
15	0.054	0.051	0.048	0.046	0.044	0.042	0.041	0.041	0.041	0.041	0.041	0.043	0.044	0.046	0.049	0.052	0.055
20	0.058	0.055	0.052	0.05	0.048	0.046	0.045	0.045	0.044	0.045	0.045	0.046	0.048	0.05	0.053	0.056	0.06
25	0.062	0.059	0.056	0.054	0.052	0.05	0.049	0.049	0.048	0.049	0.049	0.051	0.052	0.055	0.057	0.061	0.065
30	0.067	0.064	0.061	0.058	0.056	0.055	0.054	0.053	0.053	0.053	0.054	0.055	0.057	0.059	0.062	0.066	0.07
35	0.072	0.069	0.066	0.063	0.061	0.06	0.058	0.058	0.058	0.058	0.059	0.06	0.062	0.064	0.067	0.071	0.075
40	0.077	0.074	0.071	0.068	0.066	0.065	0.064	0.063	0.063	0.063	0.064	0.065	0.067	0.07	0.073	0.077	0.081

Table 49 NPI-NH at baseline – unadjusted scores

	Baseline														
	Mean (SD) Missing														
	Number experiencing the behaviour N (%) completed			Frequency score			Severity score			Caregiver distress score			Total domain score		
	Control (n = 308)	DCM™ Intervention (n = 418)	Total (n = 726)	Control	DCM™	Total	Control	DCM™	Total	Control	DCM™	Total	Control	DCM™	Total
Total score:	308 (100%)	417 (99.8%)	725 (99.9%)							3.4 (4.72) 0	3.2 (4.37) 0	3.3 (4.52) 0	13 (13.95) 0	11.7 (12.35) 0	12.2 (13.06) 0
Subscales:															
Delusions	59 (19.2%)308	69 (16.5%)417	128 (17.7%)725	2.7 (1.12) 0	2.7 (1.13) 2	2.7 (1.12) 2	1.8 (0.71) 0	1.8 (0.68) 2	1.8 (0.69) 2	1.9 (1.28) 1	1.5 (1.41) 3	1.7 (1.35) 4	5.3 (3.41) 0	4.9 (3.04) 2	5.1 (3.21) 2
Hallucinations	47 (15.3%)307	59 (14.2%)416	106 (14.7%)723	2.6 (1.04) 0	2.6 (1.04) 1	2.6 (1.04) 1	1.4 (0.58) 0	1.5 (0.63) 1	1.5 (0.61) 1	0.8 (0.91) 0	1.2 (1.25) 1	1 (1.13) 1	3.8 (2.46) 0	4.2 (2.83) 1	4 (2.66) 1
Agitation/ Aggression	145 (47.1%)308	192 (46%)417	337 (46.5%)725	3 (0.95) 1	2.9 (0.94) 0	2.9 (0.95) 1	1.6 (0.67) 1	1.6 (0.69) 0	1.6 (0.68) 1	1.7 (1.23) 0	1.8 (1.28) 1	1.7 (1.25) 1	5 (2.85) 2	4.7 (2.86) 0	4.8 (2.85) 2
Depression/ Dysphoria	92 (30%)307	129 (30.9%)418	221 (30.5%)725	2.6 (0.94) 0	2.3 (1.01) 1	2.4 (0.98) 1	1.5 (0.67) 0	1.4 (0.6) 2	1.5 (0.63) 2	1.3 (1.04) 0	1.1 (1.14) 1	1.2 (1.1) 1	4.1 (2.77) 0	3.6 (2.63) 2	3.8 (2.7) 2
Anxiety	80 (26%)308	98 (23.5%)417	178 (24.6%)725	2.8 (0.94) 2	2.6 (0.96) 3	2.7 (0.96) 5	1.7 (0.71) 2	1.5 (0.6) 3	1.6 (0.66) 5	1.6 (1.19) 2	1.5 (1.25) 3	1.6 (1.23) 5	5.2 (3.16) 2	3.9 (2.32) 3	4.5 (2.8) 5
Elation/Euphoria	25 (8.1%)308	34 (8.2%)416	59 (8.1%)724	2.6 (0.96) 0	2.8 (1.07) 0	2.7 (1.02) 0	1.3 (0.44) 1	1.5 (0.62) 0	1.4 (0.56) 1	0.4 (1) 0	0.7 (1.04) 0	0.6 (1.02) 0	3.4 (2.16) 1	4.4 (2.81) 0	4 (2.59) 1
Apathy/Indifference	91 (29.5%)308	130 (31.2%)417	221 (30.5%)725	3.1 (0.89) 1	3.1 (0.9) 1	3.1 (0.89) 2	1.6 (0.69) 1	1.6 (0.67) 1	1.6 (0.67) 2	0.8 (1.03) 1	0.8 (0.99) 1	0.8 (1.01) 2	5.4 (3.3) 1	5.2 (3.07) 1	5.3 (3.16) 2
Disinhibition	51 (16.6%)308	65 (15.6%)416	116 (16%)724	2.8 (1.05) 0	2.6 (0.94) 0	2.7 (0.99) 0	1.7 (0.71) 0	1.4 (0.61) 0	1.5 (0.67) 0	1.5 (1.3) 1	1.2 (1.15) 0	1.3 (1.22) 1	5 (3.29) 0	3.8 (2.62) 0	4.3 (2.97) 0
Irritability/Lability	117 (38%)308	153 (36.7%)417	270 (37.2%)725	2.9 (1.04) 3	2.7 (0.92) 0	2.8 (0.98) 3	1.7 (0.67) 3	1.5 (0.65) 0	1.6 (0.66) 3	1.7 (1.21) 4	1.3 (1.23) 0	1.5 (1.23) 4	5.3 (3.16) 3	4.4 (2.85) 0	4.8 (3.01) 3
Aberrant motor behaviour	94 (30.5%)308	135 (32.5%)416	229 (31.6%)724	3.6 (0.73) 0	3.4 (0.77) 0	3.5 (0.76) 0	1.6 (0.68) 0	1.6 (0.7) 0	1.6 (0.69) 0	1.1 (1.21) 0	1.1 (1.31) 0	1.1 (1.27) 0	5.9 (3) 0	5.7 (3.04) 0	5.8 (3.02) 0
Sleep and night time behaviour disorders	48 (15.6%)307	77 (18.4%)418	125 (17.2%)725	3.1 (0.78) 0	2.9 (0.95) 5	3 (0.89) 5	1.5 (0.65) 0	1.7 (0.74) 5	1.6 (0.71) 5	1.8 (1.39) 0	2 (1.43) 5	1.9 (1.42) 5	4.9 (2.64) 0	5 (2.73) 5	5 (2.68) 5
Appetite and eating changes	57 (18.5%)308	98 (23.6%)415	155 (21.4%)723	3.3 (0.85) 3	3.3 (0.79) 4	3.3 (0.81) 7	1.9 (0.63) 2	1.8 (0.72) 4	1.8 (0.69) 6	1.3 (1.18) 2	1.3 (1.19) 4	1.3 (1.18) 6	6.4 (2.92) 3	6.1 (3.26) 4	6.2 (3.13) 7

Table 50 NPI-NH at 6-months – unadjusted scores

	6-months Mean (SD) Missing														
	Number experiencing the behaviour N (%) completed			Frequency score			Severity score			Caregiver distress score			Total domain score		
	Control (n = 308)	DCM™ Intervention (n = 418)	Total (n = 726)	Control	DCM™	Total	Control	DCM™	Total	Control	DCM™	Total	Control	DCM™	Total
***Total score:**	244 (79.2%)	320 (76.6%)	564 (77.7%)							3 (4.03) 0	2.4 (3.26) 0	2.6 (3.62) 0	11.3 (12.35) 0	9.7 (10.14) 0	10.4 (11.17) 0
Subscales:															
Delusions	33 (13.5%)245	42 (13.2%)319	75 (13.3%)564	2.5 (1) 2	2.4 (1.01) 0	2.4 (1) 2	1.7 (0.68) 2	1.7 (0.67) 0	1.7 (0.67) 2	1.7 (1.19) 2	1.6 (1.19) 0	1.6 (1.19) 2	4.7 (3.07) 2	4.3 (2.99) 0	4.4 (3.01) 2
Hallucinations	26 (10.6%)245	29 (9.1%)319	55 (9.8%)564	2.8 (0.88) 0	2.6 (0.98) 0	2.7 (0.94) 0	1.5 (0.71) 0	1.4 (0.57) 0	1.5 (0.63) 0	1.2 (1.12) 0	0.7 (0.84) 0	0.9 (1) 0	4.5 (2.72) 0	3.7 (1.91) 0	4.1 (2.34) 0
Agitation/Aggression	120 (49%)245	125 (39.2%)319	245 (43.4%)564	2.9 (0.89) 0	2.6 (0.94) 0	2.8 (0.93) 0	1.8 (0.71) 0	1.6 (0.66) 0	1.7 (0.69) 0	1.8 (1.17) 0	1.7 (1.2) 0	1.7 (1.18) 0	5.4 (3.24) 0	4.4 (2.62) 0	4.9 (2.98) 0
Depression/Dysphoria	63 (26%)242	101 (31.6%)320	164 (29.2%)562	2.4 (1.01) 0	2.4 (0.97) 1	2.4 (0.98) 1	1.4 (0.59) 0	1.4 (0.57) 1	1.4 (0.57) 1	1.2 (1.17) 0	0.9 (0.9) 1	1 (1.02) 1	3.7 (2.66) 0	3.5 (2.35) 1	3.6 (2.47) 1
Anxiety	47 (19.3%)244	57 (17.9%)319	104 (18.5%)563	2.7 (0.99) 2	2.5 (0.87) 1	2.6 (0.93) 3	1.6 (0.74) 2	1.5 (0.66) 1	1.6 (0.7) 3	1.6 (1.2) 2	1.2 (1.06) 1	1.4 (1.13) 3	4.6 (2.92) 2	4 (2.71) 1	4.3 (2.81) 3
Elation/Euphoria	15 (6.1%)244	19 (6%)319	34 (6%)563	2.8 (1.01) 0	2.4 (0.9) 0	2.6 (0.96) 0	1.4 (0.63) 0	1.3 (0.67) 0	1.4 (0.65) 0	0.3 (0.8) 0	0.3 (0.58) 0	0.3 (0.68) 0	4.3 (3.27) 0	3.4 (2.81) 0	3.8 (3.01) 0
Apathy/Indifference	73 (29.9%)244	116 (36.3%)320	189 (33.5%)564	3.1 (0.87) 1	2.8 (0.98) 1	2.9 (0.95) 2	1.7 (0.77) 1	1.5 (0.62) 1	1.6 (0.7) 2	0.7 (0.93) 1	0.7 (0.91) 1	0.7 (0.91) 2	5.7 (3.39) 1	4.3 (2.91) 1	4.9 (3.16) 2
Disinhibition	35 (14.3%)244	30 (9.4%)320	65 (11.5%)564	2.7 (1.07) 0	2.9 (0.88) 0	2.8 (0.99) 0	1.7 (0.67) 0	1.7 (0.83) 0	1.7 (0.74) 0	1.7 (1.39) 0	1.6 (1.45) 0	1.6 (1.41) 0	4.9 (3.08) 0	5.3 (3.44) 0	5.1 (3.23) 0
Irritability/Lability	83 (33.9%)245	99 (30.9%)320	182 (32.2%)565	2.6 (0.92) 0	2.7 (0.88) 0	2.7 (0.9) 0	1.6 (0.66) 0	1.6 (0.69) 0	1.6 (0.68) 0	1.5 (1.14) 0	1.3 (1.18) 1	1.4 (1.17) 1	4.5 (3.12) 0	4.4 (2.89) 0	4.5 (2.99) 0
Aberrant motor behaviour	71 (29.1%)244	90 (28.2%)319	161 (28.6%)563	3.4 (0.73) 0	3.4 (0.69) 0	3.4 (0.7) 0	1.6 (0.62) 0	1.7 (0.67) 0	1.7 (0.65) 0	1.1 (0.98) 0	1.1 (1.12) 0	1.1 (1.06) 0	5.6 (2.58) 0	6 (2.98) 0	5.8 (2.81) 0
Sleep and night time behaviour disorders	39 (15.9%)245	51 (16%)319	90 (16%)564	3 (1) 0	2.9 (0.97) 0	3 (0.98) 0	1.5 (0.79) 0	1.6 (0.66) 0	1.6 (0.72) 0	1.7 (1.28) 0	2 (1.26) 0	1.8 (1.27) 0	4.9 (3.55) 0	5 (3.01) 0	5 (3.24) 0
Appetite and eating changes	48 (19.6%)245	46 (14.4%)319	94 (16.7%)564	3.3 (0.7) 1	3.2 (0.88) 1	3.3 (0.79) 2	1.9 (0.62) 1	1.8 (0.63) 1	1.8 (0.62) 2	1.4 (1.21) 1	1.6 (1.3) 1	1.5 (1.25) 2	6.3 (2.87) 1	5.8 (2.71) 1	6 (2.79) 2

Table 51 NPI-NH at 16-months original cohort – unadjusted scores

	16-months original cohort														
	Number experiencing the behaviour N (%) completed			Frequency score			Severity score			Caregiver distress score			Total domain score		
Mean (SD) Missing	Control (n = 308)	DCM™ Intervention (n = 418)	Total (n = 726)	Control	DCM™	Total	Control	DCM™	Total	Control	DCM™	Total	Control	DCM™	Total
Total score:	185 (60.1%)	222 (53.1%)	407 (56.1%)							1.8 (3.12) 0	1.6 (2.79) 0	1.7 (2.94) 0	10.4 (9.25) 0	7.7 (9.36) 0	8.9 (9.4) 0
Subscales:															
Delusions	18 (9.7%)185	20 (9%)222	38 (9.3%)407	2.8 (1.26) 0	2.6 (1.1) 0	2.7 (1.16) 0	1.7 (0.57) 0	1.5 (0.51) 0	1.6 (0.55) 0	0.9 (1.16) 0	1.5 (1.07) 1	1.2 (1.13) 1	5.2 (3.03) 0	3.9 (2.28) 0	4.5 (2.71) 0
Hallucinations	15 (8.1%)185	20 (9%)222	35 (8.6%)407	2.3 (1.18) 0	3 (1.08) 0	2.7 (1.15) 0	1.4 (0.63) 0	1.3 (0.44) 0	1.3 (0.53) 0	0.2 (0.41) 0	0.6 (0.82) 0	0.4 (0.7) 0	3.3 (2.32) 0	3.8 (1.99) 0	3.6 (2.12) 0
Agitation/ Aggression	82 (44.3%)185	76 (34.2%)222	158 (38.8%)407	3 (0.92) 0	2.8 (1.02) 0	2.9 (0.97) 0	1.5 (0.55) 0	1.5 (0.64) 0	1.5 (0.59) 0	1.4 (1.17) 0	1.6 (1.17) 0	1.4 (1.17) 0	4.5 (2.3) 0	4.5 (3) 0	4.5 (2.65) 0
Depression/ Dysphoria	63 (34.1%)185	55 (24.8%)222	118 (29%)407	2.6 (0.9) 1	2.5 (0.95) 1	2.5 (0.92) 2	1.3 (0.49) 1	1.2 (0.49) 1	1.3 (0.49) 2	0.6 (0.94) 1	0.6 (0.77) 1	0.6 (0.86) 2	3.5 (2.09) 1	3.1 (1.87) 1	3.3 (1.99) 2
Anxiety	29 (15.7%)185	34 (15.3%)222	63 (15.5%)407	2.9 (0.84) 0	2.7 (0.94) 1	2.8 (0.9) 1	1.5 (0.51) 0	1.5 (0.67) 1	1.5 (0.59) 1	1 (0.98) 0	1 (1.16) 1	1 (1.07) 1	4.5 (2.28) 0	4.4 (2.83) 1	4.4 (2.56) 1
Elation/Euphoria	7 (3.8%)185	14 (6.3%)222	21 (5.2%)407	3.1 (0.9) 0	2.6 (1.02) 0	2.8 (1) 0	1.3 (0.49) 0	1.2 (0.43) 0	1.2 (0.44) 0	0 (0) 0	0.2 (0.58) 0	0.1 (0.48) 0	4.1 (2.19) 0	3.3 (2.09) 0	3.6 (2.11) 0
Apathy/Indifference	73 (39.5%)185	62 (27.9%)222	135 (33.2%)407	3.3 (1.01) 0	3 (1) 0	3.2 (1.01) 0	1.6 (0.69) 0	1.6 (0.73) 0	1.6 (0.71) 0	0.4 (0.63) 0	0.5 (0.88) 0	0.4 (0.76) 0	5.5 (3.33) 0	5.2 (3.4) 0	5.3 (3.36) 0
Disinhibition	24 (13%)185	24 (10.8%)222	48 (11.8%)407	2.5 (1.04) 1	2.5 (1.14) 0	2.5 (1.08) 1	1.3 (0.47) 1	1.3 (0.56) 0	1.3 (0.52) 1	0.8 (1.03) 1	1.3 (1.3) 0	1.1 (1.19) 1	3.6 (2.43) 1	3.6 (2.59) 0	3.6 (2.48) 1
Irritability/Lability	65 (35.1%)185	66 (29.7%)222	131 (32.2%)407	3 (0.76) 0	2.6 (1.04) 0	2.8 (0.92) 0	1.5 (0.56) 0	1.4 (0.61) 0	1.5 (0.59) 0	1.2 (1.09) 0	1 (1.1) 0	1.1 (1.1) 0	4.5 (2.3) 0	4 (2.83) 0	4.2 (2.58) 0
Aberrant motor behaviour	54 (29.2%)185	38 (17.1%)222	92 (22.6%)407	3.4 (0.74) 0	3.5 (0.73) 1	3.4 (0.73) 1	1.4 (0.56) 0	1.5 (0.56) 2	1.4 (0.56) 2	0.5 (0.84) 0	0.9 (1.15) 2	0.7 (0.98) 2	4.7 (2.41) 0	5.2 (2.35) 2	4.9 (2.38) 2
Sleep and night time behaviour disorders	22 (11.9%)185	27 (12.2%)222	49 (12%)407	2.7 (1.08) 0	2.8 (1.03) 4	2.8 (1.04) 4	1.1 (0.35) 0	1.4 (0.59) 4	1.3 (0.51) 4	0.8 (1.01) 0	1.7 (1.47) 4	1.2 (1.32) 4	3.1 (1.58) 0	4 (2.1) 4	3.6 (1.9) 4
Appetite and eating changes	30 (16.2%)185	25 (11.3%)222	55 (13.5%)407	3 (0.96) 4	3.2 (0.77) 4	3.1 (0.88) 8	1.8 (0.61) 4	1.7 (0.78) 4	1.8 (0.69) 8	1.2 (1.23) 4	1.5 (0.93) 4	1.3 (1.11) 8	5.9 (2.96) 4	5.8 (3.22) 4	5.8 (3.05) 8

Table 52 NPI-NH at 16-months cross-sectional cohort – unadjusted scores

	16-months cross-sectional cohort														
	Number experiencing the behaviour N (%) completed			Frequency score			Severity score			Caregiver distress score			Total domain score		
Mean (SD) Missing	Control (n = 287)	Intervention (n = 388)	Total (n = 675)	Control	Intervention	Total	Control	Intervention	Total	Control	Intervention	Total	Control	Intervention	Total
Total score:	284 (99%)	384 (99%)	668 (99%)							1.6 (2.86) 0	2 (3.77) 0	1.9 (3.41) 0	10 (10.46) 0	8.4 (10.25) 0	9.1 (10.36) 0
Subscales:															
Delusions	24 (8.5%)284	50 (13%)384	74 (11.1%)668	2.9 (1.26) 0	2.6 (1.13) 1	2.7 (1.17) 1	1.7 (0.62) 0	1.5 (0.62) 1	1.6 (0.62) 1	0.8 (1.1) 0	1.5 (1.15) 2	1.3 (1.17) 2	5.3 (3.28) 0	4 (2.66) 1	4.5 (2.92) 1
Hallucinations	29 (10.2%)284	37 (9.6%)384	66 (9.9%)668	2.5 (1.09) 0	2.8 (1.12) 0	2.7 (1.11) 0	1.5 (0.69) 0	1.3 (0.53) 0	1.4 (0.6) 0	0.4 (0.78) 0	0.8 (0.95) 0	0.6 (0.89) 0	3.9 (3) 0	3.8 (2.38) 0	3.8 (2.65) 0
Agitation/ Aggression	116 (40.8%)284	141 (36.7%)384	257 (38.5%)668	3 (0.92) 0	2.9 (0.95) 2	2.9 (0.94) 2	1.5 (0.57) 0	1.5 (0.58) 1	1.5 (0.57) 1	1.3 (1.14) 0	1.6 (1.22) 2	1.4 (1.19) 2	4.7 (2.48) 0	4.7 (2.67) 2	4.7 (2.58) 2
Depression/ Dysphoria	95 (33.5%)284	105 (27.3%)384	200 (29.9%)668	2.5 (0.94) 2	2.4 (0.96) 1	2.5 (0.95) 3	1.3 (0.53) 2	1.3 (0.52) 1	1.3 (0.52) 3	0.6 (0.92) 2	0.8 (1) 1	0.7 (0.96) 3	3.5 (2.35) 2	3.2 (2.03) 1	3.3 (2.19) 3
Anxiety	48 (17%)283	72 (18.8%)384	120 (18%)667	2.6 (0.98) 0	2.6 (0.95) 2	2.6 (0.96) 2	1.5 (0.62) 0	1.5 (0.61) 2	1.5 (0.61) 2	0.7 (0.96) 0	1.1 (1.22) 2	1 (1.14) 2	4 (2.45) 0	4 (2.57) 2	4 (2.51) 2
Elation/Euphoria	13 (4.6%)283	22 (5.7%)384	35 (5.2%)667	2.8 (0.93) 0	2.6 (0.9) 0	2.7 (0.9) 0	1.4 (0.51) 0	1.3 (0.55) 0	1.3 (0.53) 0	0 (0) 0	0.2 (0.5) 0	0.1 (0.4) 0	3.8 (1.88) 0	3.6 (2.61) 0	3.7 (2.34) 0
Apathy/Indifference	95 (33.5%)284	108 (28.1%)384	203 (30.4%)668	3.3 (1) 0	2.9 (1) 0	3.1 (1.01) 0	1.6 (0.71) 0	1.5 (0.65) 0	1.5 (0.68) 0	0.3 (0.63) 0	0.5 (0.85) 0	0.4 (0.76) 0	5.5 (3.41) 0	4.6 (3.06) 0	5 (3.25) 0
Disinhibition	35 (12.3%)284	42 (10.9%)384	77 (11.5%)668	2.7 (1.09) 1	2.6 (1.03) 0	2.6 (1.05) 1	1.3 (0.53) 1	1.5 (0.71) 0	1.4 (0.64) 1	0.7 (0.93) 1	1.5 (1.38) 0	1.2 (1.26) 1	3.8 (2.7) 1	4.4 (3.22) 0	4.1 (2.99) 1
Irritability/Lability	94 (33.1%)284	127 (33.1%)384	221 (33.1%)668	3 (0.84) 0	2.6 (0.96) 1	2.8 (0.93) 1	1.5 (0.58) 0	1.4 (0.57) 1	1.5 (0.58) 1	1.1 (1.05) 0	1.1 (1.13) 1	1.1 (1.09) 1	4.5 (2.44) 0	4 (2.66) 1	4.2 (2.58) 1
Aberrant motor behaviour	83 (29.2%)284	74 (19.3%)384	157 (23.5%)668	3.4 (0.8) 0	3.4 (0.72) 1	3.4 (0.76) 1	1.4 (0.59) 0	1.5 (0.58) 2	1.5 (0.58) 2	0.5 (0.85) 0	0.9 (1.15) 2	0.7 (1.01) 2	4.9 (2.53) 0	5.2 (2.54) 2	5.1 (2.53) 2
Sleep and night time behaviour disorders	28 (9.9%)284	49 (12.8%)384	77 (11.5%)668	2.9 (1.07) 1	2.8 (0.94) 5	2.9 (0.98) 6	1.2 (0.42) 1	1.5 (0.59) 5	1.4 (0.55) 6	0.8 (0.97) 1	1.7 (1.49) 5	1.4 (1.38) 6	3.7 (2.11) 1	4.3 (2.14) 5	4 (2.13) 6
Appetite and eating changes	41 (14.4%)284	44 (11.5%)384	85 (12.7%)668	3.1 (1.01) 7	3.3 (0.74) 4	3.2 (0.88) 11	1.9 (0.69) 7	1.6 (0.67) 4	1.7 (0.69) 11	1.1 (1.23) 7	1.4 (1.03) 4	1.3 (1.12) 11	6.1 (3.39) 7	5.3 (2.75) 4	5.7 (3.07) 11

Table 53 Behaviours staff find challenging, medications and mood (based on NPI domains) at 6-months

Closed-cohort – behaviours staff find challenging, medications, mood at 6-months						
	Logistic regression models	**Treatment odds ratio (treated control)**	**Lower 95% confidence limit**	**Upper 95% confidence limit**	**p-value**	**N**
Behaviours staff find challenging	Complete cases only	0.941	0.598	1.479	0.7921	558
	Missing data imputed assuming MAR	0.95	0.612	1.476	0.8196	726
	Cluster specific - complete cases only	0.939	0.561	1.57	0.8088	558
	Cluster specific - missing data imputed assuming MAR	0.951	0.584	1.547	0.8381	726
PRN antipsychotic medication	Complete cases only	0.454	0.114	1.815	0.2640	581
	Missing data imputed assuming MAR	0.455	0.093	2.236	0.3314	726
	Complete cases only without hub	0.494	0.093	2.629	0.4084	581
	Missing data imputed assuming MAR without hub	0.533	0.095	2.997	0.4743	726
Mood						
Depression/dysphoria	Complete cases only	1.34	0.862	2.082	0.1932	558
	Missing data imputed assuming MAR	1.32	0.872	1.999	0.1895	726
Anxiety	Complete cases only	1.023	0.59	1.774	0.9343	558
	Missing data imputed assuming MAR	1.011	0.617	1.656	0.9668	726
Apathy/indifference	Complete cases only	1.319	0.79	2.2	0.2897	559
	Missing data imputed assuming MAR	1.33	0.853	2.073	0.2075	726

Table 54 Behaviours staff find challenging, medications and mood (based on NPI domains) at 16-months

Closed cohort – behaviours staff find challenging, medications, mood at 16-months						
	Logistic regression models	**Treatment odds ratio (treated control)**	**Lower 95% confidence limit**	**Upper 95% confidence limit**	**p-value**	**N**
Behaviours staff find challenging	Complete cases only	0.605	0.339	1.079	0.0886	403
	Missing data imputed assuming MAR	0.57	0.343	0.948	0.0305	726
	Cluster specific - complete cases only	0.591	0.308	1.133	0.1131	403
	Cluster specific - missing data imputed assuming MAR	0.577	0.334	0.996	0.0484	726
PRN antipsychotic medication	Complete cases only without hub	0.766	0.132	4.457	0.7666	406
	Missing data imputed assuming MAR without hub	0.783	0.114	5.368	0.8019	726
Mood						
Depression/dysphoria	Complete cases only	0.614	0.345	1.094	0.0980	404
	Missing data imputed assuming MAR	0.592	0.369	0.95	0.0298	726
Anxiety	Complete cases only	1.027	0.51	2.069	0.9395	403
	Missing data imputed assuming MAR	1.037	0.588	1.83	0.9004	726
Apathy/indifference	Complete cases only	0.601	0.322	1.124	0.1109	403
	Missing data imputed assuming MAR	0.601	0.38	0.952	0.0302	726

Table 55 Behaviours staff find challenging, medications and mood (based on NPI domains) at 16-months

Cross-sectional sample – behaviours staff find challenging, medications, mood at 16-months						
	Logistic regression models	**Treatment odds ratio (treated control)**	**Lower 95% confidence limit**	**Upper 95% confidence limit**	**p-value**	**N**
Behaviours staff find challenging	Complete cases only	0.723	0.481	1.088	0.1198	668
	Missing data imputed assuming MAR	0.720	0.479	1.083	0.1146	675
	Cluster specific - complete cases only	0.683	0.4	1.166	0.1619	668
	Cluster specific - missing data imputed assuming MAR	0.681	0.4	1.158	0.1561	675
Antipsychotic medication	Complete cases only	1.166	0.127	10.688	0.892	413
	Missing data imputed assuming MAR	1.28	0.153	10.685	0.8189	675
Mood						
Depression/dysphoria	Complete cases only	0.757	0.51	1.123	0.1666	668
	Missing data imputed assuming MAR	0.757	0.511	1.123	0.1672	675
Anxiety	Complete cases only	1.134	0.667	1.928	0.6422	667
	Missing data imputed assuming MAR	1.133	0.67	1.916	0.6423	675
Apathy/indifference	Complete cases only	0.81	0.525	1.249	0.3402	668
	Missing data imputed assuming MAR	0.81	0.525	1.249	0.3403	675

Table 56 Quality of life analysis – QUALID (relative/ friend and staff)

Quality of life analysis – closed-cohort QUALID (relative/ friend and staff)									
Analysis	**Estimated Mean Difference**	**Lower 95% Confidence Limit**	**Upper 95% Confidence Limit**	**p-value**	**Unadjusted ICC for Intervention**	**Unadjusted ICC for Control**	**Adjusted ICC for Intervention**	**Adjusted ICC for Control**	**N**
6-months									
QUALID (staff) - complete cases only	-0.62	-1.91	0.67	0.334	0.1357	0.0173	0.0627	0.0001	560
QUALID (staff) - missing data imputed assuming MAR	-0.74	-1.91	0.43	0.214	0.129	0.005	0.035	0.001	726
16-months									
QUALID (staff) - complete cases only	-0.04	-1.24	1.16	0.948	0.0838	0.0064	0	0	404
QUALID (staff) - missing data imputed assuming MAR	-0.07	-1.26	1.11	0.902	0.07	0.004	0.004	0	726

Table 57 Quality of life analysis – cross-sectional sample QUALID (relative/ friend and staff)

Quality of life analysis – cross-sectional cohort QUALID (relative/ friend and staff)									
Analysis at 16-months	**Estimated Mean Difference**	**Lower 95% Confidence Limit**	**Upper 95% Confidence Limit**	**p-value**	**Unadjusted ICC for Intervention**	**Unadjusted ICC for Control**	**Adjusted ICC for Intervention**	**Adjusted ICC for Control**	**N**
QUALID (staff) - complete cases only	-0.06	-1.14	1.02	0.910	0.0788	0.0089	0.0119	0.0015	668
QUALID (staff) - missing data imputed assuming MAR	-0.05	-1.12	1.02	0.922	0.082	0.01	0.015	0.002	675

Table 58 Prescription of regular medications – closed-cohort at baseline and 6-months

Prescription of regular medications – closed-cohort at baseline and 6-months							
		Baseline			6-months		
N prescribed (% sample)		Control (n = 308)	Intervention (n = 418)	Total (n = 726)	Control (n = 308)	Intervention (n = 418)	Total (n = 726)
Antipsychotic		44 (14.3%)	51 (12.2%)	95 (13.1%)	35 (11.4%)	37 (8.9%)	72 (9.9%)
Benzodiazepine		20 (6.5%)	21 (5.0%)	41 (5.6%)	14 (4.5%)	14 (3.3%)	28 (3.9%)
Non-benzodiazepine anxiolytic		0 (0%)	4 (1.0%)	4 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-benzodiazepine hypnotic		22 (7.1%)	14 (3.3%)	37 (5.1%)	20 (6.5%)	15 (3.6%)	35 (4.8%)
Memantine		26 (8.4%)	28 (6.7%)	54 (7.4%)	21 (6.8%)	27 (6.5%)	48 (6.6%)
Antidepressant		127 (41.2%)	135 (32.3%)	262 (36.1%)	107 (34.7%)	113 (27.0%)	220 (30.3%)
Cholinesterase inhibitor		47 (15.3%)	61 (14.6%)	108 (14.9%)	40 (13.0%)	54 (12.9%)	94 (12.9%)
Anticonvulsant		14 (4.5%)	20 (4.8%)	34 (4.6%)	13 (4.2%)	17 (4.1%)	30 (4.1%)
Mood stabiliser		1 (0.3%)	2 (0.5%)	3 (0.4%)	1 (0.3%)	4 (1.0%)	5 (0.7%)
Pain relief		143 (46.4%)	213 (51.0%)	356 (49.0%)	105 (34.1%)	160 (38.3%)	265 (36.5%)
Total number of medications prescribed on the MAR over the reporting period	**Mean (SD) N taken/ month**	8.7 (4.3) 304	8.7 (4.01) 414	8.7 (4.13) 718	8.5 (3.73) 240	9.2 (4.4) 336	8.9 (4.15) 576
	Median (Q1, Q3)	8 (6, 11)	8 (6, 11)	8 (6, 11)	8.5 (6, 11)	9 (6, 12)	9 (6, 12)

Frequencies are given out of those in the respective samples, assuming the missing data reflects no prescriptions.

Table 59 Number of closed-cohort and cross-sectional cohort residents prescribed regular medications at 16-months

		Prescription of regular medications - 16-months only					
		16-months original cohort			16-months cross-sectional cohort		
N (% sample)		**Control (n = 308)**	**Intervention (n = 418)**	**Total (n = 726)**	**Control (n = 287)**	**Intervention (n = 388)**	**Total (n = 675)**
Antipsychotic		29 (9.4%)	27 (6.5%)	56 (7.7%)	41 (14.3%)	46 (11.9%)	87 (12.9%)
Benzodiazepine		11 (3.6%)	9 (2.2%)	20 (2.8%)	18 (6.3%)	14 (3.6%)	32 (4.7%)
Non-benzodiazepine anxiolytic		0 (0.0%)	1 (0.2%)	1 (0.1%)	0 (0.0%)	1 (0.3%)	1 (0.1%)
Non-benzodiazepine hypnotic		14 (4.5%)	12 (2.9%)	26 (3.6%)	21 (7.3%)	22 (5.7%)	43 (6.4%)
Memantine		17 (5.5%)	21 (5.0%)	38 (5.2%)	31 (10.8%)	44 (11.3%)	75 (11.1%)
Antidepressant		80 (26.0%)	68 (16.3%)	148 (20.4%)	119 (41.5%)	131 (33.8%)	250 (37.0%)
Cholinesterase inhibitor		28 (9.1%)	33 (7.9%)	61 (8.4%)	50 (17.4%)	71 (18.3%)	121 (17.9%)
Anticonvulsant		9 (2.9%)	10 (2.4%)	19 (2.6%)	9 (3.1%)	15 (3.9%)	24 (3.6%)
Mood stabiliser		1 (0.3%)	0 (0.0%)	1 (0.1%)	2 (0.7%)	0 (0.0%)	2 (0.3%)
Pain relief		84 (27.3%)	121 (28.9%)	205 (28.2%)	140 (48.8%)	201 (51.8%)	341 (50.5%)
Total number of medications prescribed	Mean (SD) N taken/ month	8.9 (3.82) 165	8.9 (4.61) 214	8.9 (4.28) 379	8.7 (3.71) 260	8.8 (4.74) 368	8.7 (4.34) 628
on the MAR over the reporting period	Median (Q1, Q3)	9 (6, 11)	8 (6, 12)	9 (6, 12)	9 (6, 11)	8 (5, 11)	8 (6, 11)

Frequencies are given out of those in the respective samples, assuming the missing data reflects no prescriptions.

Table 60 Administration of PRN medications by cohort and time point

	Baseline			6 months			16 months original cohort			16 months cross-sectional cohort		
N (% sample)	**Control (n = 308)**	**Intervention (n = 418)**	**Total (n=726)**	**Control (n = 308)**	**Intervention (n = 418)**	**Total (n=726)**	**Control (n = 308)**	**Intervention (n = 418)**	**Total (n=726)**	**Control (n = 287)**	**Intervention (n = 388)**	**Total (n = 675)**
Antipsychotic medication	1 (0.3%)	1 (0.2%)	2 (0.3%)	2 (0.6%)	1 (0.2%)	3 (0.4%)	1 (0.3%)	0 (0.0%)	1 (0.1%)	1 (0.3%)	1 (0.3%)	2 (0.3%)
Benzodiazepine medication	9 (2.9%)	8 (1.9%)	17 (2.3%)	9 (2.9%)	9 (2.2%)	18 (2.5%)	4 (1.3%)	2 (0.5%)	6 (0.8%)	10 (3.5%)	6 (1.5%)	16 (2.4%)
Non-benzodiazepine anxiolytic medication	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-benzodiazepine hypnotic medication	2 (0.6%)	3 (0.7%)	5 (0.7%)	1 (0.3%)	1 (0.2%)	2 (0.3%)	4 (1.3%)	1 (0.2%)	5 (0.7%)	6 (2.1%)	1 (0.3%)	7 (1.0%)
Anticonvulsant medications	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Mood stabiliser medications	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pain relief medications	67 (21.8%)	69 (16.5%)	136 (18.7%)	74 (24%)	93 (22.2%)	167 (23.0%)	48 (15.6%)	40 (9.6%)	88 (12.1%)	71 (24.7%)	67 (17.3%)	138 (20.4%)

Frequencies are given out of those in the respective samples, assuming the missing data reflects no administrations.

Care homes

Table 61 QUIS summaries - unadjusted

		QUIS summaries								
		Baseline			6-months			16-months		
All interactions (% positive) missing		Control (n = 19)	Intervention (n = 31)	Total (n = 50)	Control (n = 19)	Intervention (n = 31)	Total (n = 50)	Control (n = 19)	Intervention (n = 31)	Total (n = 50)
AM	0-15 min interval	255 (75.3%) 0	297 (83.8%) 2	552 (79.9%) 2	268 (89.2%) 0	283 (91.9%) 0	551 (90.6%) 0	180 (86.7%) 0	376 (83.5%) 0	556 (84.5%) 0
	15-30 min interval	288 (71.9%) 0	334 (88.9%) 2	622 (81%) 2	250 (84%) 0	271 (89.7%) 0	521 (86.9%) 0	165 (86.1%) 0	254 (85.4%) 0	419 (85.7%) 0
	30-45 min interval	213 (68.5%) 0	296 (85.1%) 1	509 (78.2%) 1	224 (88.4%) 0	280 (88.6%) 0	504 (88.5%) 0	204 (86.3%) 0	285 (81.8%) 1	489 (83.6%) 1
	45-60 min interval	264 (83.7%) 0	303 (87.1%) 1	567 (85.5%) 1	258 (85.7%) 0	226 (81.9%) 0	484 (83.9%) 0	231 (84%) 0	276 (81.2%) 1	507 (82.4%) 1
PM	0-15 min interval	298 (81.2%) 0	317 (79.5%) 2	615 (80.3%) 2	217 (78.3%) 0	341 (90%) 0	558 (85.5%) 0	211 (80.6%) 0	324 (83%) 0	535 (82.1%) 0
	15-30 min interval	264 (75.4%) 0	312 (76.9%) 2	576 (76.2%) 2	168 (81.5%) 0	272 (86.8%) 0	440 (84.8%) 0	216 (80.6%) 0	316 (81%) 0	532 (80.8%) 0
	30-45 min interval	246 (72.4%) 0	291 (74.9%) 1	537 (73.7%) 1	188 (69.7%) 0	319 (89.7%) 0	507 (82.2%) 0	200 (83%) 0	256 (86.3%) 0	456 (84.9%) 0
	45-60 min interval	237 (67.9%) 0	255 (76.1%) 1	492 (72.2%) 1	193 (70.5%) 0	299 (88.6%) 0	492 (81.5%) 0	171 (83%) 0	233 (89.3%) 0	404 (86.6%) 0
Both AM/PM	0-15 min interval	553 (78.5%) 0	614 (81.6%) 4	1167 (80.1%) 4	485 (84.3%) 0	624 (90.9%) 0	1109 (88%) 0	391 (83.4%) 0	700 (83.3%) 0	1091 (83.3%) 0
	15-30 min interval	552 (73.6%) 0	646 (83.1%) 4	1198 (78.7%) 4	418 (83%) 0	543 (88.2%) 0	961 (86%) 0	381 (82.9%) 0	570 (83%) 0	951 (83%) 0
	30-45 min interval	459 (70.6%) 0	587 (80.1%) 2	1046 (75.9%) 2	412 (79.9%) 0	599 (89.1%) 0	1011 (85.4%) 0	404 (84.7%) 0	541 (83.9%) 1	945 (84.2%) 1
	45-60 min interval	501 (76.2%) 0	558 (82.1%) 2	1059 (79.3%) 2	451 (79.2%) 0	525 (85.7%) 0	976 (82.7%) 0	402 (83.6%) 0	509 (84.9%) 1	911 (84.3%) 1
All interactions		2065 (74.9%) 0	2405 (81.7%) 1	4470 (78.6%) 1	1766 (81.7%) 0	2291 (88.6%) 0	4057 (85.6%) 0	1578 (83.7%) 0	2320 (83.7%) 0	3898 (83.7%) 0

Table 62 Care home CDR summaries

	CDR summaries											
CDR	**Control (n = 308)**	**Baseline Intervention (n = 418)**	**Total (n = 726)**	**Control (n = 308)**	**6-months Intervention (n = 418)**	**Total (n = 726)**	**Control (n = 308)**	**16-months original Intervention (n = 418)**	**Total (n = 726)**	**Control (n = 287)**	**16-months cross-sectional Intervention (n = 388)**	**Total (n = 675)**
Global CDR as categories N (%)												
0	1 (0.3%)	2 (0.5%)	3 (0.4%)	0 (0.0%)	1 (0.2%)	1 (0.1%)	0 (0.0%)	1 (0.2%)	1 (0.1%)	0 (0.0%)	1 (0.3%)	1 (0.1%)
0.5	17 (5.5%)	23 (5.5%)	40 (5.5%)	6 (1.9%)	7 (1.7%)	13 (1.8%)	5 (1.6%)	0 (0.0%)	5 (0.7%)	11 (3.8%)	6 (1.5%)	17 (2.5%)
1	79 (25.6%)	101 (24.2%)	180 (24.8%)	37 (12.0%)	77 (18.4%)	114 (15.7%)	27 (8.8%)	49 (11.7%)	76 (10.5%)	55 (19.2%)	101 (26.0%)	156 (23.1%)
2	111 (36.0%)	160 (38.3%)	271 (37.3%)	110 (35.7%)	145 (34.7%)	255 (35.1%)	54 (17.5%)	89 (21.3%)	143 (19.7%)	90 (31.4%)	151 (38.9%)	241 (35.7%)
3	98 (31.8%)	130 (31.1%)	228 (31.4%)	92 (29.9%)	92 (22.0%)	184 (25.3%)	99 (32.1%)	83 (19.9%)	182 (25.1%)	128 (44.6%)	125 (32.2%)	253 (37.5%)
Missing	2 (0.6%)	2 (0.5%)	4 (0.6%)	63 (20.5%)	96 (23.0%)	159 (21.9%)	123 (39.9%)	196 (46.9%)	319 (43.9%)	3 (1.0%)	4 (1.0%)	7 (1.0%)
Global CDR score												
Mean (SD) missing	1.97 (0.85) 2	1.98 (0.84) 2	1.98 (0.84) 4	2.19 (0.74) 63	2.01 (0.77) 96	2.09 (0.76) 159	2.35 (0.79) 123	2.14 (0.77) 196	2.24 (0.79) 319	2.2 (0.83) 3	2.03 (0.8) 4	2.1 (0.82) 7
Median (IQR)	2 (1, 3)	2 (1, 3)	2 (1, 3)	2 (2, 3)	2 (1, 3)	2 (2, 3)	3 (2, 3)	2 (2, 3)	2 (2, 3)	2 (2, 3)	2 (1, 3)	2 (1, 3)
Subscales:												
Memory (primary category)	1.95 (0.81) 2	1.91 (0.84) 2	1.93 (0.83) 4	2.23 (0.73) 63	2.03 (0.75) 96	2.12 (0.75) 159	2.34 (0.7) 123	2.14 (0.76) 196	2.23 (0.74) 319	2.21 (0.78) 3	2.04 (0.79) 4	2.11 (0.79) 7
Orientation	1.98 (0.86) 1	1.87 (0.93) 3	1.92 (0.9) 4	2.17 (0.78) 63	1.96 (0.86) 95	2.05 (0.83) 158	2.32 (0.79) 124	2.12 (0.82) 196	2.21 (0.81) 320	2.2 (0.85) 4	2.02 (0.86) 4	2.1 (0.86) 8
Judgement and problem solving	1.85 (0.91) 2	1.89 (0.95) 3	1.88 (0.93) 5	2.12 (0.83) 63	1.95 (0.87) 92	2.03 (0.86) 155	2.29 (0.83) 123	2.12 (0.84) 196	2.2 (0.84) 319	2.14 (0.88) 3	1.98 (0.87) 4	2.05 (0.87) 7
Community affairs	1.86 (0.76) 0	1.9 (0.78) 2	1.88 (0.77) 2	2.04 (0.64) 64	1.95 (0.68) 90	1.99 (0.66) 154	2.17 (0.67) 123	2.09 (0.69) 196	2.13 (0.68) 319	2.07 (0.69) 3	2 (0.72) 4	2.03 (0.71) 7
Home and hobbies	1.79 (0.87) 0	1.86 (0.85) 3	1.83 (0.86) 3	2.09 (0.75) 63	1.94 (0.77) 90	2 (0.77) 153	2.15 (0.82) 123	2.04 (0.76) 196	2.09 (0.79) 319	2.02 (0.84) 3	1.92 (0.79) 4	1.96 (0.81) 7
Personal care	2.29 (0.86) 2	2.3 (0.83) 1	2.3 (0.84) 3	2.36 (0.8) 63	2.45 (0.72) 90	2.41 (0.76) 153	2.59 (0.74) 123	2.55 (0.68) 196	2.57 (0.71) 319	2.41 (0.9) 3	2.39 (0.82) 5	2.4 (0.85) 8

Table 63 Care home EAT summaries

	EAT summaries								
	Baseline			6-months			16-months		
Mean % (SD) missing	**Control (n = 19)**	**Intervention (n = 31)**	**Total (n = 50)**	**Control (n = 19)**	**Intervention (n = 31)**	**Total (n = 50)**	**Control (n = 19)**	**Intervention (n = 31)**	**Total (n = 50)**
Total EAT score (%)	53.5 (9.17) 1	53 (10.26) 2	53.2 (9.76) 3	58.9 (6.04) 4	52.9 (8.57) 3	55 (8.22) 7	54.7 (9.28) 3	55.3 (8.52) 4	55.1 (8.7) 7
Median (IQR)	53.2 (47.2, 62.3)	52.5 (46, 61)	52.9 (46.1, 62.3)	61.5 (56.5, 63.3)	52.1 (46.6, 61)	56.5 (48.2, 62.5)	55.2 (48.4, 62.3)	55.8 (51.3, 60.7)	55.8 (49.8, 60.7)
Subscale scores (%)									
Safety	47.8 (13.83) 0	48.4 (16.08) 1	48.2 (15.1) 1	52.8 (16.68) 0	57.9 (13.56) 0	56 (14.86) 0	59.3 (14.58) 0	56.2 (16.28) 0	57.4 (15.57) 0
Size	30.7 (23.74) 0	23.9 (24.64) 1	26.5 (24.28) 1	29.8 (21.93) 0	19.9 (26.67) 0	23.7 (25.22) 0	33.3 (27.78) 0	22.8 (27.85) 1	26.9 (28.02) 1
Visual access features	23.1 (11.52) 0	25.4 (12.88) 1	24.5 (12.3) 1	19.6 (12.13) 1	21.2 (13.41) 1	20.6 (12.84) 2	17.6 (12.38) 0	24.1 (15.55) 0	21.6 (14.65) 0
Highlighting useful stimuli	91.8 (13.65) 0	86.3 (13.59) 1	88.4 (13.74) 1	89.5 (13.97) 0	89.1 (11.52) 0	89.2 (12.37) 0	91.3 (10.8) 0	93 (9.02) 0	92.4 (9.66) 0
Wandering	48.5 (35.95) 0	45.6 (38.08) 1	46.7 (36.92) 1	66 (32.27) 2	43.1 (38.02) 2	51.6 (37.34) 4	52.3 (33.05) 2	53.9 (30.81) 0	53.4 (31.27) 2
Familiarity	71.1 (16.74) 0	74.4 (24.44) 1	73.2 (21.65) 1	73.5 (16.09) 0	80.2 (12.82) 0	77.7 (14.38) 0	70.4 (18.87) 0	79.6 (16.02) 1	76 (17.58) 1
Privacy and community	76.6 (19.13) 0	81.5 (14.25) 1	79.6 (16.3) 1	77.1 (20) 0	75.8 (18.83) 0	76.3 (19.09) 0	76.8 (23.54) 0	72.2 (18.17) 0	73.9 (20.27) 0
Community links	51.3 (48.93) 0	48.3 (49.97) 1	49.5 (49.08) 1	69.4 (42.49) 1	46.8 (49.89) 0	55.1 (48.14) 1	36.8 (46.67) 0	46.7 (50.74) 1	42.9 (48.95) 1
Domestic activity	35 (9.36) 1	33.2 (11.43) 2	33.9 (10.62) 3	35.9 (11.62) 0	32.5 (11.46) 0	33.8 (11.52) 0	34.9 (10.22) 0	33.1 (10.19) 0	33.8 (10.14) 0

Table 64 Group living home characteristics

	GLHC summaries								
	Baseline			6-months			16-months		
Mean (SD) missing Median (IQR)	**Control (n = 19)**	**Intervention (n = 31)**	**Total (n = 50)**	**Control (n = 19)**	**Intervention (n = 31)**	**Total (n = 50)**	**Control (n = 19)**	**Intervention (n = 31)**	**Total (n = 50)**
Total GLHC score	32.2 (4.09) 0	31.1 (4.19) 2	31.5 (4.14) 2	29.9 (5.13) 0	30.2 (5.25) 0	30.1 (5.15) 0	29.9 (3.91) 0	30.8 (4.29) 0	30.4 (4.13) 0
	31 (28.5, 36)	31 (28, 33)	31 (28, 35.2)	29 (26, 34)	30 (27, 33)	29.5 (26.5, 33)	29 (27, 34)	31 (27, 34)	31 (27, 34)

Health economic analysis

Table 65 Resource Use – complete case sample*

		Intervention					Control				
Health care resource item	**Month**	**N**	**Mean**	**SD**	**Min**	**Max**	**N**	**Mean**	**SD**	**Min**	**Max**
Primary care											
GP face to face visit	0	214	1.61	2.17	0	12	175	1.54	1.63	0	8
	6	214	1.31	2.10	0	13	175	1.46	1.69	0	8
	16	214	0.84	1.43	0	8	175	0.93	1.69	0	9
GP telephone call	0	214	0.72	1.62	0	12	175	0.71	1.24	0	6
	6	214	0.49	0.99	0	5	175	0.39	0.92	0	7
	16	214	0.36	0.89	0	5	175	0.29	0.71	0	4
District nurse visit	0	214	1.22	7.02	0	90	175	1.79	5.29	0	43
	6	214	0.36	1.24	0	13	175	1.53	4.88	0	41
	16	214	0.75	3.44	0	39	175	0.57	2.68	0	27
District nurse telephone call	0	214	0.08	0.44	0	3	175	0.13	0.44	0	2
	6	214	0.03	0.19	0	2	175	0.14	0.53	0	4
	16	214	0.03	0.24	0	2	175	0.13	1.25	0	16
Secondary care											
Nights spent in hospital	0	214	0.72	4.06	0	43	175	0.66	3.81	0	37
	6	214	0.64	3.02	0	28	175	0.29	1.58	0	15
	16	214	0.14	1.14	0	12	175	0.01	0.08	0	1
Hospital day centre visit	0	214	0.01	0.10	0	1	175	0.02	0.13	0	1
	6	214	0.00	0.07	0	1	175	0.00	0.00	0	0
	16	214	0.00	0.07	0	1	175	0.03	0.20	0	2
Hospital outpatient clinic visit	0	214	0.14	0.61	0	7	175	0.14	0.46	0	4
	6	214	0.08	0.27	0	1	175	0.06	0.31	0	3
	16	214	0.07	0.35	0	3	175	0.01	0.15	0	2
Hospital A&E visit	0	214	0.15	0.83	0	11	175	0.10	0.39	0	2
	6	214	0.07	0.27	0	2	175	0.06	0.29	0	2
	16	214	0.01	0.12	0	1	175	0.01	0.08	0	1

*Values represent resource use in the previous month only and are extrapolated for the whole trial period

Table 66: Main* Unit Costs

Resource item	Unit cost	Assumptions and source
Advanced nurse practitioner	£ 77.24	NHS 2015-16 reference costs
Advanced nurse practitioner (phone)	£ 33.08	NHS 2015-16 reference costs
Counsellor	£ 62.03	PSSRU 2011/2
District nurse	£ 37.98	NHS 2015-16 reference costs
DISTRICT NURSE (phone)	£ 16.16	NHS 2015-16 reference costs
GP	£132.69	PSSRU 2009/10
GP phone	£ 28.39	PSSRU2014/5
Health visitor	£ 64.81	NHS 2015-16 reference costs
HEALTH VISITOR (phone)	£ 26.38	NHS 2015-16 reference costs
Hospital A&E	£137.74	NHS 2015-16 reference costs
Hospital outpatient clinic	£136.79	NHS 2015-16 reference costs
Hospital overnight stay	£464.83	NHS 2015-16 reference costs
Member of community health team	£ 43.00	PSSRU 2015/6
Physiotherapist	£ 48.94	NHS 2015-16 reference costs
Psychiatrist or psychologist	£142.98	PSSRU 2011
Social worker	£ 39.50	PSSRU 2015/6
Speech and language therapist	£ 88.02	NHS 2015-16 reference costs

*Main resource use items only. Unit costs for resources used less frequently are available on request.

Appendix 2: Summary of substantial amendments

Summary of EPIC Substantial Amendments

SA1 - Approved 10/01/2014

Collection of data from medical records / Health and Social Care Information Centre (HSCIC)

The proposed plan for collection of resource use data (prescription medication usage, repeat hospital attendances / admissions / safety data) was to obtain all required information from a review of the resident's care home records. Having undertaken some consultation with other researchers doing care home research and collecting similar data, we have been informed that this data is often incomplete / ambiguous and further clarification has needed to be sought from the residents' medical records.

In order to minimise missing data and ensure a meaningful dataset is obtained, we therefore propose to amend section 13.5.5 of the protocol (see enclosed protocol with tracked changes) and the following participant information and consent / declaration forms (see enclosed documents with tracked changes) to include researcher consent to access the residents' medical records (either via direct searching, or remotely via the HSCIC):

- Resident Information Sheet
- Short form of Resident Information Sheet
- Resident Consent Form
- Personal Consultee Declaration Form
- Personal Nominee Declaration Form

Full NHS R&D permissions will be obtained from the relevant trusts and the study researchers will apply for research passports and approval to access these notes.

SA2 - Approved 22/04/2014

Changes to the Care Home Information Sheet

The Care Home Information Sheet has been amended to incorporate comments following PPI review. The content has also been updated to amend inaccuracies and provide additional information and clarification regarding trial processes.

Amendments to the approved document are highlighted using tracked changes. Below provides a brief summary of the key changes:

- Clarification of abbreviated title – The EPIC trial.
- Addition of Trade Mark (DCM^{TM}) throughout.
- Clarification of "What will happen in the study"
    - Care Home Selection
    - Confirming Care Home Eligibility
    - Participant Consent
    - Care Home Allocation
    - DCM Training
    - Data Collection – Researcher Interview / Questionnaires
- Clarification of "What do I do if I am Interested in taking part?"

SA3 – Approved 26/06/2014

Protocol amendments

- **Updated Care Home Selection process**

The proposed plan for care home selection has been revised during consultations with the statistical team and researchers experienced in recruitment in the care home setting to minimise the burden on care home staff. In order to maximise response rates whilst retaining a representative sample of care homes in an attempt to maximise generalisability of trial results we therefore propose to amend section 7.2 of the protocol (see enclosed version with tracked changes) to incorporate the following key changes;

- Care Homes within Hub catchment area screened for eligibility and randomly ordered for subsequent contact.
- Invitation information sent to ordered samples of eligible care homes.
- Researchers contact all invited care homes (via telephone) to determine interest – care home reply slip no longer required.
- If interested care homes will complete eligibility assessments via researcher interview, eligibility screening questionnaire no longer required.

- **Eligibility Criteria**
    - **English Proficiency**

Following discussions with the Trial Management Group (TMG) and Trial Steering Committee (TSC) we intend to update the eligibility criteria for Residents, Staff (completing Staff Measures only), and Resident's Relative / Friend to include the following; "Has sufficient proficiency in English to contribute to the data collection required for the research".

We propose this change for Staff completing Staff Measures as this questionnaire will be self-completed by members of Staff with no assistance from trial researchers. Therefore to ensure that staff comprehend questions asked they would require sufficient proficiency in written English. Validated translations of assessments are also not available, therefore the TMG agreed it was not appropriate to use translated versions due to the potential impact on the validity of data collected. Consultation with care home managers and staff suggested that the majority of staff working within a UK care home should have sufficient English proficiency as required for employment.

The proposed change has been suggested for Residents and their Relative / Friend (if applicable) as assessments are completed via Researcher Interview, therefore sufficient English proficiency is required to develop a meaningful dialog. Availability and accuracy of translated discussions was deemed to be infeasible by the TMG/TSC.

- **Proxy Informant**

As outlined in the protocol the primary outcome for analysis is based upon completion of the CMAI by a Proxy Informant (Staff). Therefore, we propose to update section 8 of the protocol to incorporate the following inclusion criteria for Residents;

- Has an allocated member of staff willing to provide proxy data.

- **Screening Questionnaires**

Proxy Informants (Staff and Relative/Friend) were initially required to demonstrate their willingness to participate by completing and returning a screening questionnaire. However following a review of the process the TMG have confirmed that it would be more appropriate to collect Proxy Informant data via Researcher Interview. It is hoped that this will decrease the burden on Proxy Informants and increase response. We therefore propose to amend the relevant section of the protocol (10.1-10.2).

- **Mutually exclusive roles**

The protocol outlines roles that staff members can undertake within the trial and highlights any that are mutually exclusive (e.g. Mapper cannot act as Proxy Informant). However to clarify further we propose to update exclusion criteria by role to ensure eligibility is assessed ahead of consent. This update will also clarify that a Staff Nominated Consultee cannot actively participate in the trial in any way (e.g. Providing Staff or Proxy Measures).

- **Translation of trial documentation (information sheets/questionnaires)**

Following consultation with the TMG and suggested updates regarding sufficient English Proficiency the TMG agreed that Translation of trial documentation would no longer be required. Discussions regarding the variety of translations required by region (Hub) also suggested that this process would not be feasible. Therefore references to translation of materials have been removed from the protocol (please refer to tracked changes).

- **Data collection / assessments**

    - **Assessments**

We propose to amend data collection assessments used within the trial (please refer to tracked changes) following review with the TMG as summarised below;

- DEMQOL replaced with QOL-AD: TMG agreed more appropriate to trial population.
- CES replaced with SCIDS: TMG agreed more appropriate to trial population.
- BADL removed: TMG agreed not appropriate to collect in trial population.

The overall quantity, and therefore perceived participant burden remains the same.

    - **Completion of Assessments (PAS / QUIS)**

The proposed plan for collection of independent assessments (PAS / QUIS) suggested that the PAS and QUIS would be completed on a random 25% of registered residents. However as these assessments are completed following observations made within communal areas the TMG agreed that it would not be appropriate to restrict observations to a random sample of residents, as if they were not available within communal areas at the time of observation, the data could not be completed, affecting the integrity of data for analysis. Thus it was agreed that PAS / QUIS data would be collected for all registered residents. The protocol has been updated (please refer to tracked changes) to incorporate these changes.

- **Monitoring – Recording Sessions**

    - **DCM^{TM} Intervention – Feedback Sessions**

The protocol outlines planed recording of Dementia Care Mapping Feedback sessions within a sample (minimum of 10 Care Homes) of randomised Care Homes (n=30). Following discussions with DCM^{TM} Experts it was agree that the feasibility and accuracy of standardised review would not be sufficiently robust therefore should not be undertaken. Therefore, we propose to update section 12.7 of the protocol (please see tracked changes) to remove references to audio recording.

- **Withdrawal**

- **Proxy Informant – Relative / Friend**

We propose to amend the planed process for data collection following Relative / Friend withdrawal. The protocol currently suggests that in the event of a Relative / Friend withdrawal Researchers would encourage continuation of completion of a subset of assessments. However, following review with the statistical team, discussions concluded that this process would not be feasible and does not significantly impact upon the validity of data for analysis. Therefore, we propose to amend section 12.12 of the protocol (please refer to tracked changes) to outline that in the event of a Relative / Friend withdrawal a new Proxy Informant will be identified to complete all assessment measures.

- **Resident Safety**

Following consultation with the trial Data Monitoring Ethics Committee (DMEC) we propose changes to the protocol (please refer to tracked changes) to collect sufficient safety data for on-going safety monitoring. Proposed changes include;

  - Proactive (monthly) reporting of Adverse Events that fulfil Serious (SAE) criteria (i.e. Hospitalisation).
  - Annual summary of hospitalisations for registered residents collected from Health and Social Care Information Centre (HSCIC).

Suggested amendments to safety reporting have been reviewed by external experts (DMEC/TSC) to ensure reporting is commensurate with risk for this population in the context of this trial.

- **Data Monitoring Ethics Committee (DMEC)**

In accordance with guidance from the trial funder (NIHR HTA) a trial DMEC has been established and responsibilities agreed. We therefore propose changes to the protocol (please refer to tracked changes) to incorporate the DMEC.

Patient Information Sheets and Informed Consent Document amendments

- **Study Title**

Following consultation with Patient and Public Involvement groups and Experts by Experience, the TMG have agreed to amend the study title in publicly available information to remove the acronym DCM (Dementia Care Mapping). We therefore include amended information sheets and consent documents with the title amended throughout.

- **Participant Consent**

  - **Mapper**

We propose to add an additional statement to the Mapper consent form to reference the DCM™ Training Course schedule to make it clear to Mappers that we are asking them to be available for training; “I agree to attend the next scheduled DCM™ training course if my care home is randomly allocated to DCM™ + UC. <Insert course date>”. As the DCM™ Training Course is a publicly available course, dates are scheduled in advance and cannot be changed, so we need to be sure that mappers are able to attend on specified dates. This will reflect the implementation of the intervention in practice.

- **Staff Proxy**

The proposed plan for Staff Proxy Informant consent was vague in the protocol, with no previous Staff Proxy Informant Consent form being submitted for REC approval. Therefore, in accordance with the proposed protocol update which removes references to the screening questionnaire (implied consent following return of data) a Staff Proxy Informant Consent Form has been produced and is submitted for approval. This document will be version 4.0 (dated 30.05.2014) to match existing documentation following approval of this amendment.

- **Resident (including Nominated and Personal Consultee)**

As Resident and a Resident’s Relative / Friend data is not used as part of the primary analysis, the TMG have agreed that consent to obtain information from Residents and their Relative/Friend can be optional. We therefore propose to update the relevant information sheets to incorporate these optional statements (please refer to tracked changes version attached.

- **Short form of Participant Information**

Following consultation with Patient and Public Involvement groups and Experts by Experience we have developed shortened versions of the information sheets for Staff (Measures), Staff Proxy, Relative / Friend Proxy. These short versions summarise key information from existing information sheets in a simple to understand format. It is intended that these information sheets will be used in addition to existing participant information to ensure informed consent is obtained.

The existing Short form of the Resident Information Sheet has also been amended to reflect the format of the new short form information sheets. Please refer to relevant attachments for additional information. These documents will be versioned 4.0 (dated 30.05.2014) to reflect existing documentation following approval of this amendment.

SA 4 – Approved 10/09/2014

Protocol amendments

- **Submission of a new document for approval (Personal Consultee Introductory Letter)**

The protocol (version 4.0) states in section 8.3.2 – Consent for those (Residents) without capacity, that if an identified potential personal consultee is not present within the Care Home during participant (Resident) recruitment they may be posted information regarding taking part (acting as a personal consultee) by the Care Home. We therefore enclose a proposed introductory letter template to be sent by Care Homes with the relevant (REC approved) Information Sheets. As this letter is designed to be sent by the Care Home it will be used as a template, and added to where appropriate by the Care Home to personalise it for the person in question.

- **Submission of a new document for approval (Personal Consultee Reminder Letter)**

The protocol (version 4.0) states in section 8.3.2 – Consent for those (Residents) without capacity, that a reminder will be sent to a potential personal consultee within one week of being approached to complete the relevant (REC approved) declaration form. We therefore enclose a proposed reminder letter template for Researchers to send within one week of initial approach (if required). As this letter is designed to be sent after initial discussions with the Researcher it this letter will be used as a template and added to by the Researcher where appropriate.

- **Submission of a new document for approval (Relative/Friend Proxy Informant Introductory Letter)**

The protocol (version 4.0) states in section 10.1 – Relative/Friend and Informants, that if an identified potential Relative/Friend is not present within the Care Home during participant recruitment that information regarding taking part can be posted (by the Care Home) to them. We therefore enclose a proposed introductory letter template to be sent by the Care Home with the relevant (REC approved) Information Sheets. As this letter is designed to be sent by the Care Home it will be used as a template, and added to where appropriate by the Care Home to personalise it for the relative.

SA5 – Approved 15/01/2015

Patient Information Sheets and Informed Consent Document amendments

- **Submission of a new document for approval (GP Letter)**

The protocol (version 4.0) states in section 12.1 – Intervention Details – Usual Care, that all GPs that deliver care within a consenting Care Home will be provided with current best practice guidelines for managing BSC (Behaviours Staff find Challenging to support). We therefore enclose a proposed GP Letter template to be sent to GP practices with a copy of current antipsychotic

prescribing guidance (Alzheimer's Society). Please note in accordance with the protocol this information will not detail Residents currently participating in the study.

SA6 – Approved 15/01/2015

Protocol amendments

- **Change of Sponsor**

Following acceptance of a Professorship role at Leeds Beckett University Claire Surr, DCM EPIC Chief Investigator will be transferring from the University of Bradford to Leeds Beckett from February 2015. Therefore, the study Sponsor will be transferred to reflect this move.

The following documents have therefore been updated;

- NHS R&D and REC Form
  - A3-1. Chief Investigator
  - A4. Sponsor contact
  - A64. Details of Research Sponsor
  - A76. Insurance and/or Indemnity
- Protocol (v5.0) section 20.4 – Clinical Governance Issues
- Protocol (v5.0) section 23 – Statement of Indemnity
- Protocol (v5.0) section 24 – Trial Organisational Structure

- **Care Home Eligibility Criteria**

Based upon experience from "pilot" care home recruitment and consultation with the trial oversight committees (TMG/TSC) we propose to amend the Care Home Eligibility criteria to clarify requirements to have a sufficient population of permanent residents living with dementia to recruit (register) a minimum of 10 Residents. This wording will reduce exclusion of Care Homes that would otherwise be eligible but do not achieve the criteria as currently worded.

The protocol has also been updated to clarify minimum and maximum resident recruitment limits. As previously stated a minimum of 10 registered (Eligible, Consented, and completed Data) residents is required per Care Home. Following experiences of Care Home recruitment to date the trial team have also investigated whether a maximum recruitment limit is required. However from review of impact of cluster size variability on the power calculations for analysis with the trial oversight committees (TMG/TSC) have confirmed that no maximum limit for resident recruitment is required.

Therefore, the protocol (v5.0) section 7.1 Care Home Eligibility has been updated to reflect the suggested changes summarised above.

- **Resident Eligibility Criteria**

During Care Home screening it has become apparent that the potential for co-enrolment to other studies is not only relevant to Care Homes, but Residents as well. For example, a trial may be recruiting a large number of homes within the DCM EPIC Hub catchment areas (London, Oxford, and West Yorkshire) but may only be recruiting a small proportion of Residents within the participating Care Home. Therefore it would not be appropriate to exclude the Care Home, due to the associated impact upon Care Home Recruitment, but it would be appropriate to exclude the Resident, due to the potential for confounding factors and associated participant burden and research fatigue.

Therefore the protocol (v5.0 – section 8.1) has been updated to include "involvement in another trial that conflicts with DCM^{TM} or with the data collection during the course of their involvement in the EPIC study".

- **Randomisation**

Following randomisation of the first two "pilot" homes the team have reviewed the stratification factors (external factor (other than intervention) that could impact upon trial outcome) for Care Home Randomisation with the trial oversight committees (TMG/TSC). It was noted that the current 4 stratification factors do not include stratification by Hub (London, Oxford, and West Yorkshire). However, it was noted that "previous use of DCM^{TM}" could depict Hub, with Oxford Care Homes introducing DCM^{TM} at a local level.

Therefore, the team concluded, in consultation with the trial oversight committees that the Care Home Randomisation stratification factors should be updated to replace "previous use of DCM^{TM}" with "Recruiting Hub". Protocol v5.0, section 11.2 has been updated to reflect the suggested changes summarised above.

SA7 – Approved 22/10/2015

<u>Protocol amendments</u>

- **Witnessing Consent**

We have had a few recent instances where we have quite illegible resident signatures – some can pass for a signature; others are more of a mark. We have discussed this with the Chief Investigator who is happy that any form of signature stands as informed consent, and notes that we must

respect residents' dignity by not asking for a witness counter signature just because their handwriting isn't clear. In the current version of the protocol (section 8.3.1) we say:

"Residents who are able to give informed consent will sign the trial consent form. Where a resident is unable to sign his/her name, s/he will be asked to make a mark on a consent form that will be witnessed by an independent observer (staff member, relative or friend)."

However, on checking HRA guidance and the clinical trials toolkit it seems that any form of mark is acceptable and we would only expect a witness where a participant cannot write at all.

Following verbal confirmation from the REC Manager that following the HRA guidance on this issue is acceptable, we have removed this statement from the protocol and clarified that the witness of an independent observer is only required where a resident is unable to make any kind of mark on the form. As such, section 8.3.1 has been updated as follows:

'Residents who are able to give informed consent will sign, or make a mark on the trial consent form. Where a resident is unable to sign, or make a mark, s/he will be asked to indicate his/her consent verbally. This will be witnessed by an independent observer (staff member, relative or friend) and recorded on the trial consent form.'

- **Text messages to mappers**

In order to assist the mappers in planning subsequent cycles, ahead of each of the three DCM™ mapping cycles, we will send a short text messages to each mapper. The standard wording for these text messages can be found in the attached document (Mapper Text Reminders_V1.0_28/09/2015

The following statement has been added to section 12.2.3 to reflect this process:

"Ahead of each mapping cycle the CTRU will contact each mapper via SMS to remind them of the upcoming cycle."

Patient Information Sheets and Informed Consent Document amendments

The table below summarises Substantial amendments made to the Participant Information Sheets, consent forms and covering letters. All amendments can be reviewed in tracked changed versions of the relevant document.

Document	Amendment Details
Relative/Friend Proxy Informant Introductory	• **NEW LETTER**: We have drafted a new letter to be used in instances where the Personal Consultee is also invited to act as the Relative/Friend Proxy Informant for the resident. The current Relative/Friend Proxy Informant covering letters

Letter for Personal Consultees	previously approved by the REC are aimed at Relative/Friends who have no prior knowledge of the EPIC study, so are not appropriate in these circumstances.
Personal Consultee Reminder Letter – POSTAL TEMPLATE (approach by CH Manager)	• **NEW LETTER**: The current Personal Consultee Reminder Letter previously approved by the REC is aimed at Personal Consultees who have previously spoken with the Researcher at the care home regarding the EPIC study. In some instances, the potential Personal Consultee is approached via post as opposed to face to face in the Care Home (ie. in cases where their visits don't coincide with the researcher's time in the care home), and therefore the wording of the current letter isn't appropriate. This new letter is aimed at Personal Consultees who have had no prior contact with the Researcher and therefore the initial approach would be by the Care Home Manager / Research Lead.
Personal Consultee Reminder Letter – POSTAL TEMPLATE (approach by Researcher)	• **NEW LETTER**: This letter will be used for circumstances similar to the one outlined above, however this will be for cases where a potential Personal Consultee has already given consent to be contacted by the Researcher directly and therefore the letter is from the Researcher, rather than the CH Manager / Research Lead.
Relative/Friend Proxy Consent form	• Updated to include date of birth (for identification purposes). • Address and telephone number of relative/friend proxy added in and a sentence regarding why this is collected added to page 2. • Optional consent questions amended from initials to 'Y' or 'N' to aid completion.
Personal Consultee Declaration Form	• There had been some confusion highlighted by the Researchers over question 12 therefore an additional question (Q12) has been added for clarification – The additional question confirms if the Personal Consultee is happy to be asked questions about their relative/friend (i.e. acting as a proxy) • Due to the addition of Q12, Q13 has been reworded to confirm that if the personal consultee is not willing to be a relative/friend proxy they are happy for other relatives/friends to take on this role. • Address and telephone number of personal consultee added in and a sentence regarding why this is collected added to page 2.

SA8 – Approved 04/02/2016

Protocol amendments

- **Process Evaluation**

More detail added to protocol on how the process evaluation associated with the trial will work in practice. The design of the process evaluation remains the same (integrating data from the main trial dataset/documentation with qualitative data from interviews and focus groups) we have simply provided more detail on the patient information leaflets and consent forms, data collection methods, sampling and data analysis that will be used.

Summaries of the extra detail provided are as follows:

- **Data collection**

More detail has been provided on the data that will be extracted from the main trial dataset and trial documentation. Topic guides have been developed to indicate the kinds of questions that will be asked of participants during the qualitative data collection. The topic guides are enclosed with this amendment application.

- **Sampling**

In order to explore implementation of the intervention with sufficient depth, we plan to conduct the qualitative data collection in a subset of homes. Homes will be primarily selected according to degree of intervention implementation so that the factors affecting implementation can be thoroughly explored. More details on the sampling strategy are included in the amended protocol. A more basic evaluation of implementation (utilising data from the main trial dataset and trial documentation) will still take place across all homes.

- **Data Analysis**

More detail is provided on the approach to the qualitative data analysis (Framework Analysis) and how the qualitative and quantitative analysis will be integrated.

- **Staff measure booklet**

There has been a poor return rate for the staff measures booklet, despite multiple efforts to increase compliance. Following consultation and discussion with the DMEC and the TSC it has been agreed that persistence with staff data is important because Dementia Care Mapping (the intervention) is designed to effect a ‘whole home’ change. To try and increase compliance the TSC have suggested reducing the length and identifiable nature of the staff booklet. To this end, we are

proposing to remove the GHQ12 questionnaire and the request for personal data from the booklet. We would also like to improve the aesthetics of the booklet to ensure it is as easy for staff to complete as possible.

- **Relative/Friend Informants**

There has been poor trial participation by relatives/friends despite efforts to encourage uptake. It has been agreed by the oversight committees that the low percentage of data received will not be sufficient for quantitative analyses. Therefore, new relative/friend informants will not be identified at any follow up time points as this would utilise significant researcher resources but be unlikely to result in much additional uptake or data. However, we will continue to request follow up data for relative/friends who provided data at baseline because data from different time points could still be usefully analysed (for example to allow analysis of agreement between staff, resident and relative/friend completed measures and to augment the process evaluation). Relatives/friends who completed these baseline measures also indicated that they valued the opportunity to share their experiences and so would be likely to continue to take part. It seems unethical to exclude their data due to poor participation from other relatives.

Patient Information Sheets and Informed Consent Document amendments

We have developed new participant information leaflets and consent forms for the three groups that will be asked to participate in the process evaluation - staff, residents and relatives. The information leaflets and consent forms have been developed with PPI input.

SA9 – Approved 15/04/2016

Protocol amendments

- **Design Change**

We are proposing a change to the design of the EPIC Trial, such that additional residents will be recruited at the 16-month follow-up time point from each care home to minimise bias (due to higher than anticipated loss to follow-up) and maintain power and validity of the trial. This impacts on the following elements of trial conduct:

  - Additional resident screening, recruitment and registration
  - Identification of new staff proxies
  - Additional data collection from staff proxies
  - Data management

- Statistical analyses

Therefore, the relevant sections of the protocol have been updated and the following new supporting documents have been produced to support the recruitment process;

- 16M Resident Information Sheet_SHORT_v1.0 18 March 2016
- 16M Resident Information Sheet_v1.0 18 March 2016
- 16M Resident Consent Form_v1.0 18 March 2016
- 16M Personal Consultee Introductory Letter_v1.0 18 March 2016
- 16M Personal Consultee Declaration Form_v1.0 18 March 2016

- **Staff Proxy Informant Consent**

We propose an alternative method of documenting staff agreement to provide data about the resident they know well. In a similar trial in care homes run by the CTRU, the REC have agreed that provision of information to staff proxies followed by verbal consent to take on the role is sufficient. Agreement to hold their name for follow-up purposes is documented by the researcher in the data collection booklets. It is felt that this process is fit for purpose given we are not collecting any other personal data relating to the staff member.

We propose adoption of this process for involvement of all staff proxies recruited at 16-months in the EPIC trial, and will adjust the data collection booklets accordingly.

- **Care Home Indemnity**

We propose to remove the statement “Possession of the appropriate insurance will be checked at point of recruitment of the care home to the study.” This is in line with new guidance received following the change of study Sponsor. The Sponsor has advised removal of this statements as EPIC is a trial of a low risk intervention, with care home employees delivering the intervention. Therefore, it is appropriate to assume that standard care home insurance will cover activities of their employees and additional checks are not required.

- **Staff Measures data collection**

Following a review of data collection, we have amended the trial protocol (section 9 – Staff roles, eligibility, recruitment, and consent) to include collection of “current pattern of work”. This information will be used to determine the impact of shift patterns on staff training and exposure to the trial intervention.

- **Process Evaluation – Relative Friend Recruitment**

We are proposing to introduce a new document “RF Introductory Letter – PE” to support postal invitations to Relative/Friends to participate in the Process Evaluation. This document would be sent with a copy of the relevant information sheet and consent form, to RFs currently participating in the main trial that are not available in the care home during researcher visits. EPIC Researchers would confirm that postal contact is appropriate with the Care Home Manager (or delegate) prior to contacting the Relative/Friend.

In addition to the new introductory letter we also propose to amend the RF consent form so that those completing and returning by post can outline their availability for discussions. This information would be useful to help Researchers schedule their time and ensure availability for RF feedback.

Following comments from the trial funder we also propose to amend the number of residents and staff members approached to participate in the PE. We had originally planned to include 2-3 residents and 8 members of staff, however we now propose to recruit up to 5 residents and up to 10 members of staff. This amendment will also allow for flexibility in homes that have limited numbers of residents, or the emergence of key themes from fewer interviews.

- **GP Information for residents recruited at 16M**

We propose to update the Protocol (section 12) to clarify that we will only be sending generic best practice guidance to GPs for residents recruited at BL and not those additional residents recruited at 16M (associated with design change summarised above). This is due to the timelines for circulation of information to GPs and the potential confusion regarding active care home participation in the project, which ceases after 16-month data collection. The guidance information would therefore also have limited impact upon trial outcomes at this stage (i.e. supporting person centred care).

- **Personal Consultee Capacity**

Following a review of trial processes, we are proposing to update the Protocol (section 8.1.2 Consent for those without capacity) to clarify the process for confirming ongoing capacity of Personal Consultees (PC). As a PC is not required to visit a care home with any frequency, and has the ability to provide postal ascent for trial participation, trial Researchers may never have face-to-face contact with a PC. Therefore, it is not feasible to determine any changes in capacity overtime in accordance with the MCA. In these instances, it is essential to obtain input from care home staff that may have more frequent interactions with the PC and be best placed to identify changes in capacity over time.

SA10 – Approved 25/07/2016

Protocol amendments

- **Process Evaluation – participant demographics**

We are proposing additional data collection of participant demographics (Age/Gender) for those consented to participate in the process evaluation to aide with summarising the population sampled at analysis. As participants in the Process Evaluation are not required to have taken part in the main trial (as the intervention impacts the entire Care Home irrespective of individual trial participation) we are not able to summarise demographics as a subset of the main trial population. Therefore, we have amended relevant sections of the EPIC Protocol (section 14 – Process Evaluation).

We have also updated the topic guides to include prompts to confirm participant details (ID, Role) at the start of the interview to assist with identification of recordings as is best practice for qualitative interviews. Any personal identifiers (i.e. Name) will be removed from all transcriptions.

- **Text Messages to Mappers**

We propose to introduce an additional text message to Staff members acting as DCM^{TM} Mappers to highlight the mutually exclusive roles in EPIC ahead of follow-up (6- and 16-months). In EPIC Researchers completing follow-up data collection (6- and 16-months post randomisation) are blinded to Care Home allocation and are therefore not aware of any changes to Staff members delivering the trial intervention (Researchers recruit Staff to act as Mappers at baseline in all home (n=50), however due to high staff turnover these often change during the course of the trial for those homes randomised to deliver the intervention (n=31)). This has therefore led to instances of inappropriate members of staff (i.e. Mappers – those delivering the trial intervention) providing data (Staff Proxy Informant) for participating residents.

We would therefore like to circulate the following text message ahead of follow-up (6- and 16-months) to staff acting currently consented as a Mapper;

“EPIC Researchers will be visiting your home shortly to collect some more data. Please remember not to provide data on behalf of any residents during this visit. Do not tell the Researcher you are acting as a DCM Mapper. Regards, The EPIC team!”

The following statement has been added to the Protocol (section 9 Staff roles, eligibility, recruitment and consent);

“A text message will be sent to trained DCM^{TM} mappers ahead of data collection (6 and 16months post randomisation) to remind mappers not to provide proxy data relating to residents

Appendix 3: Rationale for design change

HTA extension application 11/13/15 The EPIC Trial
(March 2016)

Justification

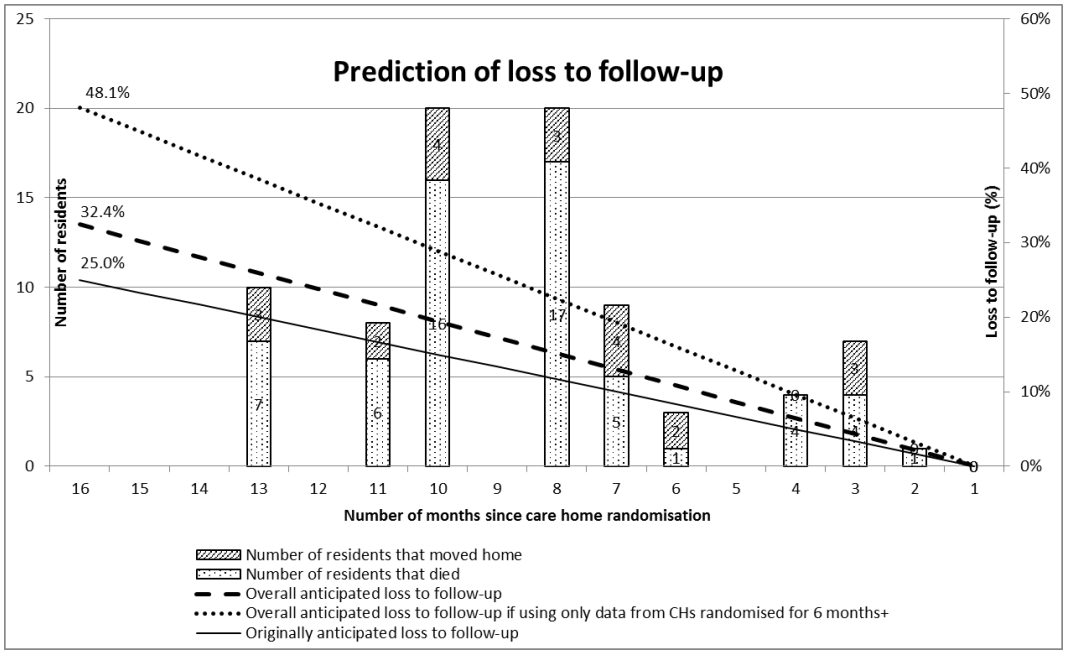
In our original sample size estimation, we anticipated a 25% loss to follow-up rate of residents at 16-months (our primary outcome) following care home randomisation, to detect a clinically important difference of 3 points (SD 7.5) in agitation using the CMAI questionnaire. If loss to follow-up was higher than anticipated (but no greater than 35%), our sample size of 750 residents was still intended to provide more than 85% power at a 2-sided 5% significance level to detect the moderate effect size, equating to 0.4 SDs.

By monitoring loss to follow-up within the trial, we are now confident that the rate will exceed our lower limit of 25%. Using data from care homes randomised into the trial up to the 27th November 2015, we predict that loss to follow-up at 16-months will be in the range of 32.4% to 48.1%. As such, continuation of the trial as currently planned is unlikely to provide sufficient power for statistical analysis of the primary endpoint and so an amendment is required to ensure the results of trial are robust and generalizable. Therefore, based on consideration of all the available options, we propose recruiting more residents at follow-up (i.e. move to an “open cohort” design).

As of 27th November 2015, there were 42 care homes randomised, with 638 registered residents. Residents are registered before care home randomisation. Overall, there were 11 residents lost before the care homes were randomised, so at the point of randomisation 627 residents were included in the trial. None of the care homes had reached the 16-month follow-up time point, and there were two care homes currently at 13-months following randomisation.

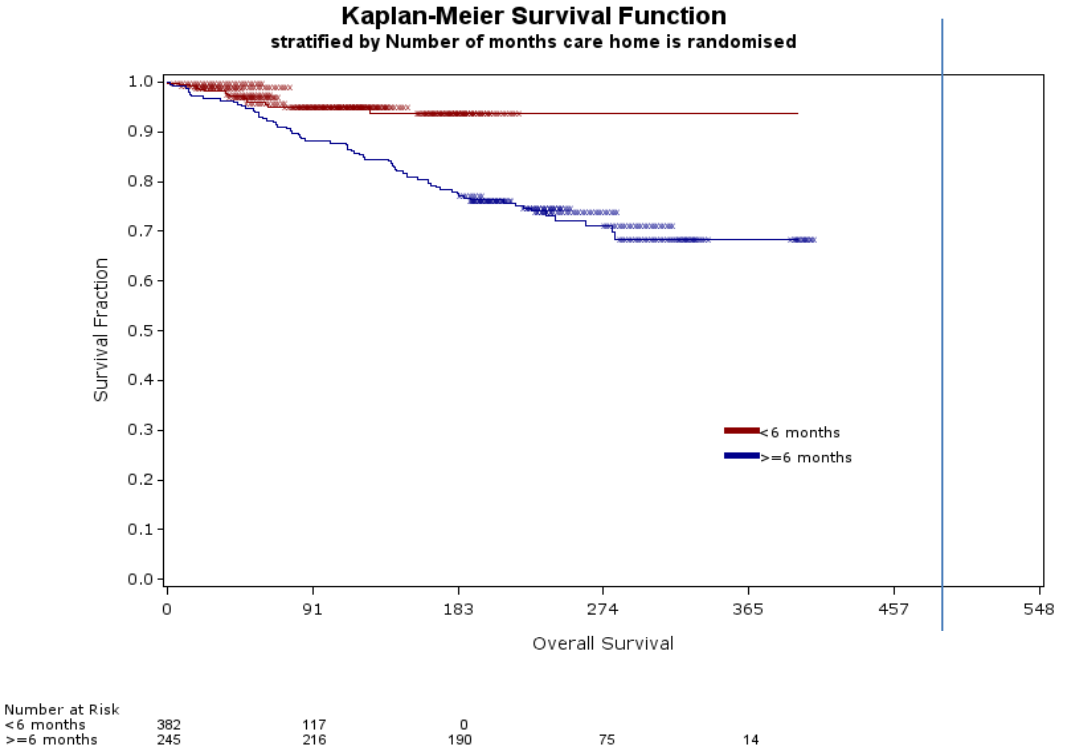
Loss-to-follow-up rates were estimated using the number of residents who died or moved care home between randomisation and 27th November 2015. The rate was then extrapolated to 16-months. Figure 10 summarises the actual and predicted loss-to-follow-up rates by number of months since randomisation. The same is displayed graphically in the Kaplan-Meier curve in Figure .

Figure 10: Predicted loss to follow-up



x-axis represents number of months care homes have been randomised, numbers lost to follow-up are grouped by care home and month

Figure 11: Kaplan-Meier Survival Curve stratified by the length of care home in the trial



Numbers at risk: at care home randomisation, 3, 6, 9 and 12-months. Note that 16-months is 487 days “survival”.

In order to provide a robust evaluation of the trial, we propose to move to An **open cohort design** in which **all eligible residents** (i) residing in the care home for 3-months or more at

16-months after care home randomisation and (ii) who are not already taking part in the trial or who have not already declined to take part, will be approached to provide consent for trial participation at the 16-months follow-up visit. All those consenting to take part (residents already participating in the trial and consented at baseline, as well as additional residents consenting at 16-months), will provide data at 16-months.

The key impact of this option will be an increase to the size of the cohort at follow-up to maintain the power of the trial and its ability to detect the effect size of 0.4 with 90% power.

Sample size calculations

With a current estimated 48.2% loss to follow up, we expect to lose 360 residents before 16-month follow-up meaning we will have data at all three time points from 388 residents. All the other parameters – significance level, 2-sided test, ICC of 0.1 are the same. We have worked out sample size calculations for three different scenarios of additional recruitment and all provide sufficient power to detect the effect size of 0.4.

If we recruit, on average, an additional three residents per care home at 16-month follow-up (from the remaining 48 care homes) the sample size will be 388+48*3=532 residents (that is 10.64 residents/ care home). Design effect will be 1+(10.64-1)*0.1=1.964. We will achieve 89% power to detect the effect size of 0.4.

Replacing residents with 35% recruited residents (columns F and G), overall number of residents available for analysis would be 388+254 (additional recruits)=642. Mean number of residents/ CH (cluster size) would be 12.8. Design effect is now 1+(12.8-1)*0.1=2.18. And the power to detect effect size of 0.4 would be 91% (or with 90% power, we can detect smaller effect size of 0.39).

Replacing residents with 25% recruited residents (columns H and I), overall number of residents available for analysis would be 388+182 (additional recruits)=570. The mean number of CH residents/ CH (cluster size) will be 11.4. Design effect is now 1+(11.4-1)*0.1=2.04. And the power to detect 0.4 effect size would be 90%.

All scenarios will achieve the desired effect size with sufficient power. The message to researchers should still be to recruit as many residents as possible in order to minimise bias. We will need to monitor recruitment to ensure we have at least 3 extra residents from each remaining care home.

Benefits of this design change are:

a) we will be able to detect intervention effects at the care home level (as the intervention is aimed at the whole care home);

b) our conclusions can be generalised to a broader population of residents (i.e. not just to those still residing in the care home 16-months following randomisation);

c) we will be able to analyse based on both a cross-sectional (i.e. open cohort) and closed cohort (longitudinal) design;

d) we will minimise selection bias by providing an objective criterion for inclusion (all eligible consenting residents);

e) our recruitment process will be resource-effective since all eligible residents can be approached to participate at a single time-point;

f) we will be less reliant on assumptions around missing data mechanisms.

Consideration was given to recruiting only a proportion of eligible residents at each home at 16-months (to increase resident numbers to 75% baseline recruits in line with originally predicted loss to follow-up rates). However the team and oversight committees (TSC and DMEC) agreed that such an option would be open to selection bias, that statistical power and the ability to generalise could be limited by including a ceiling of the number of residents recruited at baseline. Recruitment processes could also be protracted by virtue of allowing time for Personal Consultee response – i.e. should this be negative, further resident-consultee dyads would then need to be approached, so considerably lengthening the recruitment process and adding to researcher workload (and thus cost).

As well as maintaining power and increasing generalisability, this design change incurs minimal additional cost (see 'justification of funding requested' section below), compared for example to recruiting additional clusters.

This application for extension and the included options have been discussed in detail at the DMEC and TSC meetings in November and December 2015, respectively, based on the figures presented here. Those committee members supported the open cohort design, with the DMEC recommending it provided we address the risk of selection bias. It should be noted that, as of the beginning of January 2016, we have met our target of randomising 50 care homes but the patterns of loss to follow-up remain unchanged.

We believe approaching <u>all</u> eligible residents best addresses the potential threat of selection bias. With additional recruitment of eligible residents we will be able to achieve power of over

90% even if loss to follow-up in the original sample of residents was 50%. Moving to an open cohort design will require additional funding and time to complete the trial – we are requesting an additional 3-months extension to the trial (to end Dec 2017) to allow for the additional analysis and write-up time that will be needed if the design change is approved. We are not requesting additional funding for all co-applicants and trial staff for this period (see reconciliation spreadsheet for details).

Impact if approved

The design change only involves recruiting additional residents from care homes that are already randomised and aware of the requirements of the trial. We envisage that additional trial processes will result in minimal additional burden on care homes.

Researchers will be able to combine 16-month follow-up visits to existing care homes (to see existing residents) with recruitment and data collection for newly eligible residents. This reduces researcher burden (when compared to recruiting entirely new care homes), although it does involve additional time at each care home which is costed in a later section of this application.

By implementing an open cohort design we will be able to generalise trial results to a broader group of dementia residents and complete the trial robustly with sufficient power.

Impact if not approved

If the request is not approved, high attrition rates may decrease the statistical power, introduce bias in trial reporting and pose a threat to the validity and generalizability of the trial.

If we continue with the trial with its current design, based on current data the anticipated proportion of residents lost to follow-up (died or moved care home) would be at least 32%. However, only 17/42 (40.5%) care homes have been randomised for more than 6-months. If only those randomised for more than 6-months contributed to the estimation of overall loss to follow-up (as this allows more precise estimates), the predicted loss at 16-months would be 48%.

Loss of entire cluster(s) is also a realistic scenario with small clusters being most likely to be lost. Loss of clusters in addition to loss of residents induces further bias, as loss of cluster as a unit of randomisation has greater influence in cluster randomised trial analysis than loss of individual residents.

Table 67: Effect size detected based on the number of residents at the end of recruitment (variable cluster size with incorporated loss to follow up)

Number of registered residents at randomisation	750			
Loss to follow up	32%		48%	
Design effect	1.96		1.72	
Power	90%	80%	90%	80%
Able to detect **the effect size**	**0.41**	**0.36**	**0.45**	**0.39**

The design effect (due to clustering of resident outcomes within care homes) is lower with higher loss to follow-up because the available mean cluster size at follow-up is smaller. However, high losses to follow-up with loss of entire clusters threaten the validity of the trial, introduce bias and affect generalisability.