Evaluating the effectiveness and cost effectiveness of **D**ementia **C**are **M**apping™ (DCM™) to **e**nable **p**erson-centred care for people with dementia and their carers: A cluster randomised controlled trial **i**n **c**are homes (**DCM EPIC trial**).

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NOTE: Together, the key contacts form the Trial Management Group

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2 TRIAL SUMMARY

AIM: To evaluate the clinical and cost-effectiveness of Dementia Care Mapping™ (DCM™) in addition to Usual Care (UC) versus UC alone for people with dementia living in care homes in England.

DESIGN: Cluster randomised controlled trial (RCT) with follow-up over 16-months, cost-effectiveness analysis and process evaluation.

SETTING: Residential, nursing and dementia care homes in England.

TARGET POPULATION: Care homes, residents with dementia, their relatives/friends and care home staff.

HEALTH TECHNOLOGY: Dementia Care Mapping™ (DCM™) is an established care home intervention used to support the implementation of person-centred care training (PCCT). DCM™ is an observational tool, within a 'practice development cycle'. What this means in practice is that a trained observer (a member of staff in the care home) records the care experience of up to eight people with dementia for up to six consecutive hours. Findings are fed back to staff, who develop individual and group action plans. This is repeated every 4-6 months.

OUTCOMES: The primary endpoint for the efficacy analysis will be based on the Cohen Mansfield Agitation Inventory (CMAI) at 16 months. The primary economic analysis is a cost-utility analysis presenting cost per quality-adjusted life year (QALY) in an incremental cost-effectiveness ratio (ICER). Utility values will be collected using the EQ-5D-5L and the DEMQOL.

SAMPLE SIZE: 50 care homes (750 residents) with 30 (450) and 20 (300) in the intervention and control arms respectively.

Project Time-point (Months)

2.1 TRIAL DESIGN FLOW DIAGRAM

Research Data Timeline per care home (Months)

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UK Care Homes within 3 hubs Screened for Eligibility
Screened for eligibility based upon publicly available information and randomly ordered for invitation to participate.
(West Yorkshire/London/Oxford)

Excluded (care homes) -14
(1) Sufficient number of permanent dementia residents eligible to participate (n=>10 Registered) on.
(2) Unable to sign up to the trial protocol
(3) Unwilling to release staff for DCM training and mapping
(4) Not in catchment area
(5) Non-compliant rating by CQC
(6) Receiving support from local authority / commissioners due to quality / other concerns, -4
(7) Used DCM as practice development tool in last 18 months or planning to implement over the course of the trial.
(8) Taking part in another trial that conflicts with DCM EPIC

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Home Selection, Consent & Training Audit (N=50)
Care homes complete Telephone Eligibility to confirm eligible. Consent for care home participation obtained. Audit undertaken and those requiring dementia awareness training identified.

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Dementia Awareness Training -3
(In approx. 20% homes dependent upon Training Review)

13

Resident Identification
Participants identified from care home records

Excluded (residents)
(1) No diagnosis or assessment of having dementia,
(2) Terminally ill or permanently bed-bound,
(3) Not a permanent resident of a care home
(4) Participating in conflicting trial.

Assessment of Resident Capacity to Consent
Care home staff and Researcher

Resident & Staff/Relative or Friend Consent (Residents: N=15 per care home)
Eligible residents approached by Staff and consented by Researcher
Resident / proxy consent obtained by Researchers

Excluded -2
(1) Unable to obtain consent / unwilling to provide consent
(2) **Staff member** (various exclusions dependent on role)
(3) **Relative / Friend** not a regular visitor

26

Baseline Assessment (Research Visit 1) -1
Care Home Environment, Resident, Staff & organisation measures - undertaken by Researchers as soon as consent obtained from all residents & staff

15

Resident Registration All eligible, consented Residents that have provided data (incl. Proxy) registered

27

Care Home Randomisation (Usual Care (UC) + Dementia Care Mapping (DCM):UC = 3:2) 0

Intervention - UC + DCM (N=30)

Control - UC alone (N=20)

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DCM Training 1-2
2 staff from each Care Home trained within two months of randomisation

Safety Reporting (Monthly post Randomisation)
Adverse Events

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DCM Cycle 1 (3 months post-randomisation) 3

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Outcome Assessment 1 (6 Months Post-Randomisation - Research Visit 2) 6
Resident, Staff & Organisation measures, Medication, Resource Use – undertaken by Researchers

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DCM Cycle 2 (8 months post-randomisation) 8

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DCM Cycle 3 (13 months post-randomisation) 13

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Outcome Assessment 2 (16 Months Post-Randomisation - Research Visit 3) 16
Resident and Staff & Organisation measures, Medication, Resource Use - undertaken by Researchers
Qualitative interviews undertaken with a sub-set of residents / carers

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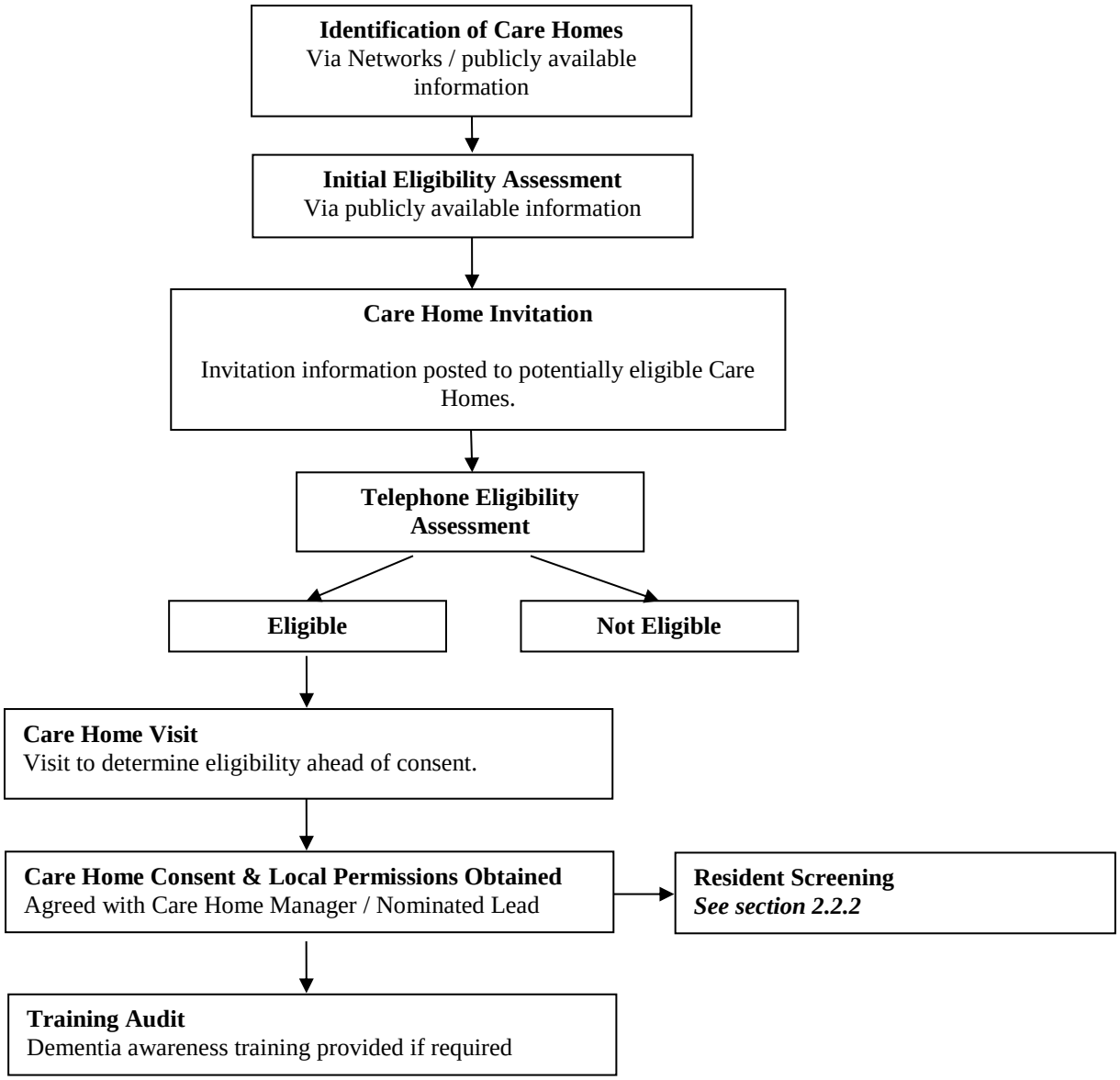
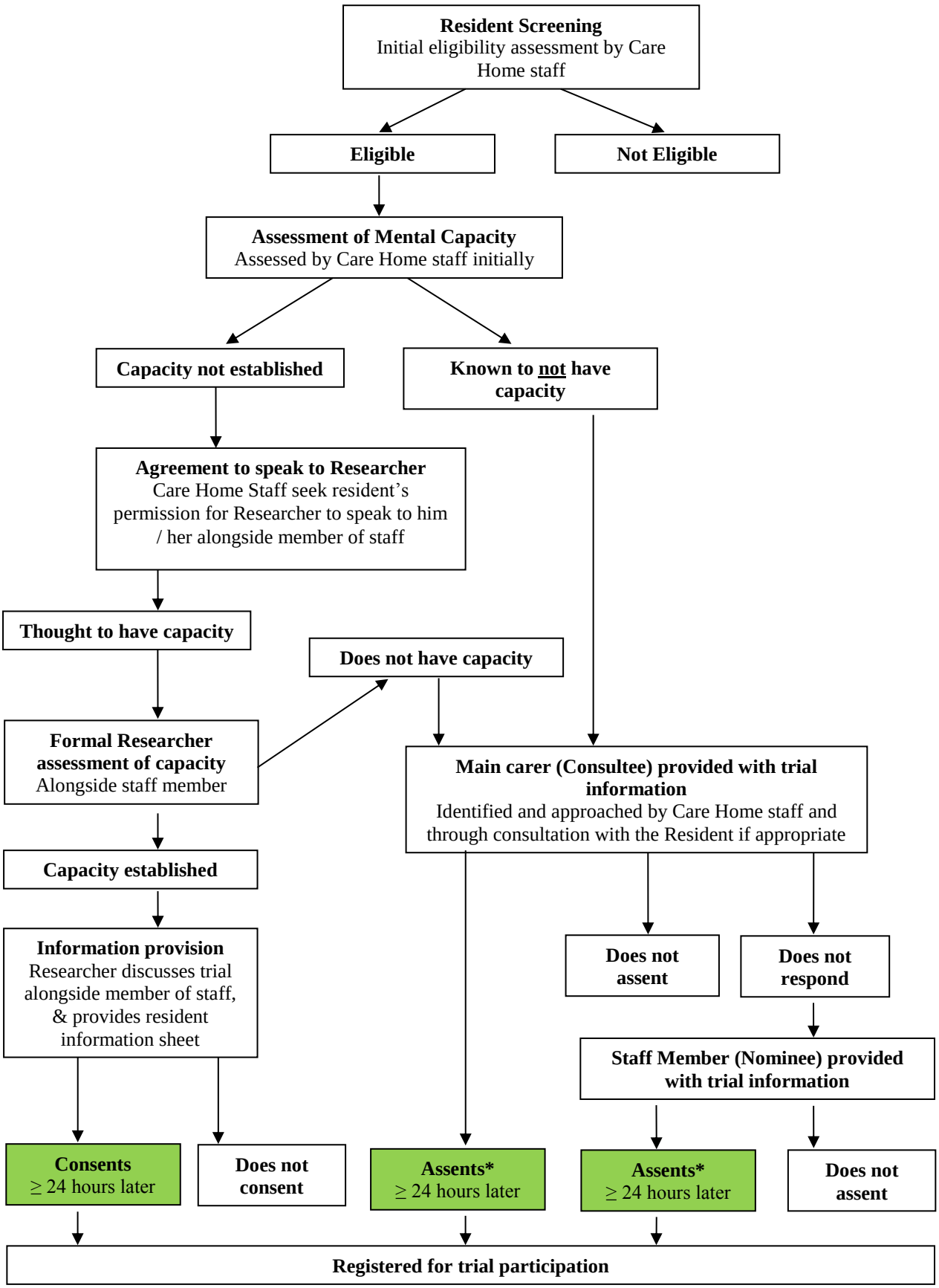
Principal Analyses
Primary outcome: Agitation, Secondary outcomes: BSC, QoL, care quality / Hospital admissions, use of healthcare services.

2.2 PATHWAYS FOR IDENTIFICATION AND CONSENT

2.2.1 Care Home Identification



2.2.2 Resident screening and consent



* This includes resident consultation

3 GLOSSARY OF TERMS

AE	Adverse Event
BCC	Behaviour Category Code
BPSD	Behavioural and psychological symptoms of dementia
BSC	Behaviours staff find challenging
CACE	Complier Average Causal Effect
CDR	Clinical Dementia Rating Scale
CI	Chief Investigator
CMAI	Cohen Mansfield Agitation Inventory
CQC	Care Quality Commission
CRF	Case Report Form
CTRU	Clinical Trials Research Unit
DCM™	Dementia Care Mapping™
DCM EPIC	Evaluating the effectiveness and cost effectiveness of Dementia Care Mapping™ (DCM™) to enable person-centred care for people with dementia and their carers: A cluster randomised controlled trial in care homes
DEMQOL	Dementia Quality of Life measure
DeNDRoN	Dementia and Neurodegenerative Diseases Research Network
DMEC	Data Monitoring Ethics Committee
DPA	Data Protection Act
EAT	Environmental Audit Tool
ENRICH	Enabling Research in Care Homes (A Research Network Initiative)
FAST	Functional Assessment Staging of Alzheimer's Disease
FITS	Focussed Intervention for Training Staff
GCP	Good Clinical Practice
GHQ-12	General Health Questionnaire
GLHC	Group Living Home Characteristics
HSCIC	Health and Social Care Information Centre
HTA	Health Technology Assessment Programme
ICC	Intracluster Correlation Coefficient
ICER	Incremental cost-effectiveness ratio
ISRCTN	International Standard Randomised Controlled Trial Number
MAGDR	Ministerial Advisory Group on Dementia Research
MAR	Missing at Random
ME	Mood/Engagement Value
MNAR	Missing Not at Random
MRC	Medical Research Council
NICE	National Institute for health and Care Excellence
NIHR	National Institute for Health Research
NMB	Net monetary benefit
NPI	Neuropsychiatric Inventory
NRES	National Research Ethics Service
PAS	Pittsburgh Agitation Scale
PCCT	Person-centred care training
PD	Personal Detractions
PI	Principle Investigator
PIS	Patient Information Sheet
PPI	Patient and Public Involvement
QALY	Quality-adjusted life year
QOL	Quality of Life
QUALID	Quality of Life in Late-Stage Dementia
QUIS	Quality of Interactions Schedule
RCT	Randomised controlled trial
REC	Research Ethics Committee
RGF	NHS Research Governance Framework
RUSAE	Related Unexpected Serious Adverse Event
SAE	Serious Adverse Event

SAP	Statistical Analysis Plan
SCIE	Social Care Institute for Excellence
SMART	Specific, Measurable, Achievable, Realistic, Time limited
SOP	Standard Operating Procedure
TMG	Trial Management Group
TSC	Trial Steering Committee
UC	Usual Care

4 BACKGROUND

4.1 INTRODUCTION

A third of people who have dementia reside in a care home [1] and at least two-thirds of people living in care homes have dementia [2]. In July 2011 there were over 4,600 nursing homes and over 13,400 care homes in England, the majority of which provide care for older people [3]. Concerns have consistently been raised about care home quality [4, 5]. Improvement in care quality and staff knowledge and skills is identified within the National Dementia Strategy for England [6] and constitutes a Ministerial Advisory Group on Dementia Research (MAGDR) priority [7]. Poor quality care is associated with poor outcomes for people with dementia including an increase in behaviours staff find challenging (BSC) [8, 9]. Developing an informed and effective care homes workforce is a strategic component of improving care quality [6, 10], however, there remains limited robust evidence regarding effective evidence-based staff training interventions for care homes providing care for people with dementia [11]. Furthermore, to date it has not been possible to achieve the widespread implementation into real-world practice, of evidence-based training interventions developed in the context of research. Dementia Care Mapping™ (DCM™) [12, 13] has the benefit of being an existing practice development intervention, that has been widely used in health and social care settings nationally [14] and internationally [15] for over 15 years, 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 [16-25]. The proposed trial will provide robust evidence, through a formal cluster randomised controlled trial, on the effectiveness and cost effectiveness of DCM™ as an intervention to support care homes to sustainably enable the transfer of learning from person-centred care training (PCCT) into care practice. The outcomes of the trial will evaluate 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.

4.2 BEHAVIOURS STAFF FIND CHALLENGING (BSC)

BSC also known as ‘neuropsychiatric’ or ‘behavioural and psychological symptoms of dementia (BPSD)’ are a significant therapeutic challenge [26]. We have chosen to use the term BSC within this trial rather than BPSD as it reflects a more person-centred terminology that better emphasises the bio-psycho-social causes of such behaviours and represents the terminology used by relatives and staff in care home settings. BSC include behaviours such as agitation, aggression, restlessness, hallucinations, delusions, depression, anxiety and apathy [26]. Up to 90% of people living with dementia experience one or more of these behaviours during the course of their condition [26] and BSC are reported in up to 79% of care home residents at any one time [27]. BSC also cause distress to the people with dementia experiencing them [28], are associated with reduced quality of life [29, 30] and have a negative impact on the well-being of other residents [31]. BSC also have significant associated costs [32, 33] including increased risk of hospitalisation [34, 35], Accident and Emergency use [33] and production of excess disability; meaning functional abilities of people decline more quickly than is otherwise expected [33]. 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 [27, 36], distressing to the person with dementia [28], and the most difficult to manage [37] BSC in care home settings. Agitation includes a cluster of extremely problematic behaviours such as aggressive behaviours, physically non-aggressive behaviours and verbal agitation [38]. These include 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 [39]. The presence of these behaviours puts the person who is agitated at risk of triggering aggressive responses from other residents [40]. The presence of agitation therefore causes potential serious risk of harm to the person who is agitated, other residents and staff. Rates of over 60% of nursing home residents with dementia displaying agitation are reported [41, 42], 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 (such as delusions, depression, apathy or dis-inhibition), in terms of clinical management [37] . Agitation places increased burden on care staff [43, 44] who feel less confident in dealing with situations where residents are agitated than in their management of other BSC [45]. The presence of agitation in a person with dementia is also associated with fewer visits from relatives, poorer quality of life [29] and as it is detrimental to relationships with others, social isolation [44]. 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 are prescribed as a first line management approach. However, links of antipsychotics to stroke and excess deaths [46] mean their reduced use is a high government [4] and MAGDR priority [7]. 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 [47, 48] despite lack of evidence of their efficacy. Researching psychosocial approaches to support staff with BSC is therefore a MAGDR (7) research priority.

Agitation and other BSC are not an inevitable consequence of dementia. Agitation is often caused by the care practices and environment surrounding the person with dementia [49] as well as by poorly managed physical health and pain [37, 50]. They reflect an expression of unmet needs by a person with dementia in response to poor quality care [4, 50, 51]. This is often caused by lack of stimulation and engagement for the person with dementia [52]. For example, Brodaty et al [53] 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. Likewise, Weber et al [54] report a significant reduction in BSC when people with dementia attended a therapeutic day hospital programme compared to when these same people with dementia were at home, again indicating the impact of the psychosocial environment. Thus, it is now recognised that the presence of agitation within individuals with dementia in care home settings is associated with organisational aspects of care and the care culture within a care home [50]. It is, hence, recommended that agitation is treated through the use of psychosocial interventions that address the quality of care practice [4, 55-57]. Therefore, agitation is a key treatment target area for people with dementia in care homes and treatment approaches need to take a psychosocial, non-drug based approach.

4.3 PERSON CENTRED CARE

Person-centred care is an effective psychosocial approach in dementia care [58] and is considered a best practice approach to reducing agitation and other BSC [55]. 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 the person's perspective [55, 59]. Person-centred care, therefore, involves evaluating and responding to the unique needs of each person with dementia and offering an individualised approach to care. NICE/SCIE [55] recommend 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 [60] and BSC more generally [57] and reduced use of anti-psychotics [58, 61, 62]. Bird et al [63] found that multifaceted, individualised interventions lead to significant mean improvements in BSC. Therefore an ability to identify individual causes of BSC and suggest appropriate person-centred solutions is required to effect change [63-65]. This, however, 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 [66] for all social care workers in England. Therefore, provision of at least basic training to staff on person-centred care is expected within all care homes in England [55] and is a regulatory requirement [67]. However, there are no widely accepted, standardised person-centred care training (PCCT) materials available and therefore, content, approaches, quality and efficacy of PCCT vary considerably across the sector [68]. Effective PCCT can produce immediate practice benefits [60, 62], 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 generally low [45, 69]. Raising staff knowledge, skills and confidence levels around person-centred ways to work with BSC is therefore a national priority area [6, 7, 10].

Whilst effective PCCT can produce immediate practice benefits, evidence suggests, that PCCT alone might not sustain change over time [11, 60, 62, 70]. For this reason in many reported studies, PCCT is often accompanied by an additional intervention to support ongoing change. For example, Fossey et al [61] 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 [58] 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 post-test the benefits were non-significant, while 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 [11], however, Moniz-Cook et al. [62] found the benefits of PCCT with no additional intervention were not sustained at 1-year. The PCCT programmes evaluated so far, therefore, provide evidence that additional support alongside the training intervention is required in order to facilitate sustained benefits [71]. The use of additional interventions to support the sustained implementation and embedding of PCCT in practice is recommended over an extended period of time [72]. 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 [73-75]. Current successful interventions that combine staff training with ongoing support such as the FITS [61] are resource intensive and require regular ongoing input from a specialist practitioner and for these reasons have not yet been possible to implement widely in everyday practice. Therefore, interventions that provide staff with knowledge to support BSC, that are cost-effective and that have already been successfully implemented in real world practice are required. Any such intervention will need to accommodate the varying amounts, content and quality of PCCT that is a feature of the sector.

4.4 DEMENTIA CARE MAPPING™ (DCM™)

DCM™ [12, 13] is an established and National Institute for Clinical Excellence/Social Care Institute for Excellence (NICE/SCIE) [55] recommended, routine care home/NHS practice development intervention, that is regularly used for ensuring a systematic approach to providing individualised person-centred care. It is used to support the sustained implementation of PCCT in dementia care practice [76]. DCM™ is an observational tool, set within a practice development cycle. It includes five phases: briefing, observation, analysis, feedback and action planning. Briefing involves providing information about DCM™ to staff, residents and visitors so they are aware of the process that will take place, their role/involvement in that process, and have an opportunity to ask questions. During the observation period a trained observer (mapper) records the care experience of up to eight people with dementia for a length of time determined by the purpose of the observation (map). This can be short focussed maps (for example over mealtime periods) up to longer maps of six or more hours to gain a broad picture of the residents' day and night time experience. During feedback findings are provided to staff using a structured report format. Action planning is a joint activity between the mapper and the staff team. Both individual and group level action plans are developed. This cycle is repeated every 4-6 months to monitor and revise action plans. Once initial training and skills development in the method is completed mappers are able to conduct cycles of mapping independently of external input, meaning DCM™ requires no external input over the long term and is therefore potentially less resource intensive and more closely aligned with real world dementia practice than other interventions [61]. Whilst DCM™ has been used in dementia care for nearly 20 years including implementation in care home settings [21, 77-80], and has strong face validity within the practice field [81], there is limited robust evidence of its efficacy in relation to clinical outcomes such as reduction of BSC. Practice implementation reports that the benefits of DCM™ include the improvement of patient well-being [18, 23, 82] and helping

staff see care from the point of view of the person with dementia, leading to evidence-based feedback and action planning that motivates staff and helps them to feel more confident to implement person-centred care [80, 81].

At the point of funding there were only five published studies that examine the benefits of using DCM™ for improving clinical outcomes. A Dutch pilot study [83] found DCM™, used alone, reduced verbal agitation and anxiety in people with dementia and improved care staff feelings of connectedness with residents. An Australian pilot study [84] found improvements in the quality of staff interactions and reductions in agitation and depression through use of DCM™. There are three RCT studies of the efficacy of DCM™ published to date. A cluster RCT conducted in care homes in Australia [58], found that at 10-months post randomisation DCM™, when used alone, was associated with significantly reduced agitation and falls among residents with dementia. A Norwegian cluster RCT [85] in care homes found a significant reduction in neuropsychiatric symptoms as measured by the Neuropsychiatric Inventory (NPI) and on the NPI sub-scales of agitation and psychosis. It also found a significant improvement in quality of life, compared to controls after 10 month follow-up. A cluster RCT study in care homes within the Netherlands [86] found no difference between the DCM™ intervention group and control group on agitation and a significant decrease in neuropsychiatric symptoms in the control group compared to the intervention group. Staff in the intervention group reported significantly less negative emotional reactions and significantly more positive reactions over time than the control group. This study also reported potential intervention fidelity issues within the DCM™ intervention care homes, indicating less than desirable implementation of the intervention in some of the clusters.

Limitations of the studies conducted to date include:

- Relatively small number of clusters (Australia) or small numbers of care homes containing multiple clusters (Norway)
- Use of DCM™ alone rather than alongside PCCT in accordance with best practice guidelines (Australia). This reflects the Australian context where PCCT is the exception rather than assumed good practice;
- Only two full cycles of DCM™ before final follow up limiting the potential for impact, given the length of time that changes within practice can take to implement and see potential benefits (Australia, Norway, Netherlands);
- Follow up period of only 10 months post randomisation again 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 compromising staff ownership of the DCM™ process including implementation of any action plans. This also restricts generalisability of the results to usual implementation of DCM™ in care practice, which is practitioner-led;
- No analysis of the process of change (Australia, Norway);
- Studies conducted in Australia, Norway and The Netherlands where care funding, regulations and processes are different to the UK.

These trials, therefore, whilst providing promising data on the effectiveness of DCM™ in Australian, Norwegian and Dutch care home settings, does not provide a robust evaluation of effectiveness or cost-effectiveness of DCM™ in UK settings. due to not being able to provide data directly applicable to a UK context, due to lack of comparability of usual care in non-UK care homes prior to DCM™ implementation and the different funding models of dementia care in each country.

In summary, there is a body of practice-based literature and experience that suggests DCM™ is an effective tool for enabling the sustained implementation of knowledge and skills gained through PCCT into care practice and that this may help to reduce BSC. However, there is very limited robust evidence for its effectiveness and no examination of its cost-effectiveness as a UK

healthcare intervention. Therefore, a definitive pragmatic RCT of DCM™ in the UK is urgently needed to inform the implementation of training and development within UK care homes and other clinical settings.

5 AIMS AND OBJECTIVES

Aim:
The aim of the DCM-EPIC trial is to evaluate the clinical and cost-effectiveness of DCM™ in addition to Usual Care (UC) compared to UC alone for people with dementia living in care homes in the UK.

Additional aims are to explore sub-group effects and the process, challenges, benefits and impact of implementing the intervention.

Primary objective:
To determine if DCM™ plus UC (i.e. the intervention) is (i) more effective in reducing agitation as measured by the total Cohen-Mansfield Agitation Inventory (CMAI) score and (ii) more cost-effective than UC alone (i.e. the control), sixteen months after randomisation of care homes.

Secondary objectives:
It is intended that the following are compared with the control:

Impact of the intervention on residents

(a) To investigate if the intervention is effective in reducing Behaviours Staff find Challenging (BSC) over time as measured by the CMAI and the Neuropsychiatric Inventory (NPI);
(b) To investigate if the intervention has an impact on the use of antipsychotic and other psychotropic drugs;
(c) To investigate the effects of the intervention on resident mood (i.e. depression, anxiety and apathy) and quality of life;

Impact of the intervention on staff

(d) To investigate the effects of the intervention on staff well-being and role efficacy;
(e) To investigate the quality of staff / resident interactions over time by arm, as measured by the Quality of Interactions Schedule (QUIS);

Safety monitoring

(f) To assess the safety profile as assessed by the number and types of hospital admissions occurring, by arm;

Potential moderators and mediators of the intervention effect and intervention implementation

(g) To explore if there are any differential predictors of the effects of the intervention (i.e. treatment-covariate interactions);
(h) To explore the process, challenges, benefits and impact of implementing the intervention.

6 DESIGN

This trial has been designed to be a pragmatic, multi-centre, cluster-randomised controlled trial of Dementia Care Mapping™ plus Usual Care (DCM™ + UC - 'intervention') versus Usual Care alone (UC - control). It will take place in residential, nursing and dementia care homes across West Yorkshire, Oxfordshire and the Thames Valley, and London, with residents with dementia. There will be an integral cost-effectiveness analysis and process evaluation. Seven-hundred and fifty residents from a random sample of fifty care homes will be registered and baseline assessments undertaken, with care homes then being randomised in a ratio of 3:2 to receive intervention or control. A training review will be conducted within each care home (and training provided as required) to ensure all care homes provide a minimum level of person centred care. Outcome measures will be obtained at 6 and 16 months following randomisation to reflect the effects of the first cycle of mapping and the effects of the full three cycles, respectively. The primary outcome will be agitation as measured by the CMAI. Following randomisation, care homes allocated to the intervention arm will receive training within as soon as able (dependent upon DCM^{TM} course schedule) to complete their first cycle at 3 months (or as soon as practicable), their second cycle at 8 months and their final cycle at 13 months post randomisation.

The pragmatic nature of the trial aims to ensure implementation of the DCM™ intervention reflects what is possible in a typical care home, thus maximising relevance to practice. Training will be provided via a nationally-recognised course given by the University of Bradford. Expert mapper support will be provided to each care home in the intervention group, during completion of their first cycle of mapping. This will maximise intervention fidelity across the intervention homes. Telephone support for DCM™ implementation will be available to all intervention homes thereafter, if required. Since it is not possible to limit the potential effects of using DCM™ in a care home setting to the care provided to a sample of residents only, a cluster design was deemed necessary. This leads to two important sources of clustering: cluster-randomisation and DCM™ treatment provision, with care homes nested within treatment arms. Due to this design we anticipate that the clustering effect will vary across arms, with a higher ICC in the intervention arm, providing the rationale for the unequal allocation of care homes.

Due to the nature of the intervention it will not be possible to blind care homes or staff to the allocation status. To minimise potential for bias the trained mappers will not be involved in providing any outcome measures data. To ensure consistency, where possible the same staff member will be asked to complete measures at each data collection point. All data will be gathered by trained researchers. Proxy completion by a relative / friend will also be sought where possible. Effort will be made to blind all trial researchers to allocation status. Therefore, the researcher doing the observations for the Pittsburgh Agitation Scale and abridged Cohen Mansfield Agitation Inventory will also measure fidelity to allow the outcome assessors to remain blind. The level of any unblinding will be measured.

7 CARE HOME ELIGIBILITY, RECRUITMENT AND CONSENT

7.1 CARE HOME ELIGIBILITY

INCLUSION CRITERIA

A care home meeting all of the following criteria at screening will be eligible for this trial:

1) Has a sufficient number of permanent dementia (based on a formal diagnosis or Functional Assessment Staging of Alzheimer's Disease (FAST) score of 4+) residents eligible to participate in the study in order to achieve a minimum of 10 Residents registered to take part prior to Care Home Randomisation;
2) Has a manager or nominated person agreeing to sign up to the trial protocol as research lead for the duration of the project, based on appropriate discussions and permissions;
3) Agrees to release staff for DCM™ training and subsequent mapping processes;
4) Is within catchment area.

* It is expected that Researchers will register a minimum of 10 residents to take part in the DCM EPIC trial data collection at each participating care home. There is no maximum limit on the number of residents able to take part, however the impact upon Researcher workload should be considered.

EXCLUSION CRITERIA

A care home meeting any of the following criteria will not be eligible for this trial:

5) In the view of the research team, is not suitable for inclusion due to being subject to CQC enforcement notices, admission bans or relevant moderate or major CQC compliance breaches;
6) Is receiving other special support for specific quality concerns, such as being currently subject to, or have pending, any serious safeguarding investigations, or receiving voluntary or compulsory admissions bans, is in receipt of local commissioning special support due to quality concerns;
7) Has used* DCM™ as a practice development tool within the 18 months prior to randomisation or is planning to use DCM™ over the course of trial involvement;
8) Is taking part, has recently taken part in, or is planning to take part, in another trial that conflicts with DCM™ or with the data collection during the course of their involvement in DCM EPIC.

* Use of DCM^{TM} refers to the completion of DCM^{TM} Mapping Observations.

Eligibility waivers to inclusion and exclusion criteria are not permitted.

Where the care home is a large multi-site or multi-floor establishment, one or two units* within the home may be selected to participate as one home. The chosen units will be identified by the home manager in discussion with the researcher and DCM™ lead using the following criteria:

i) Dementia units or units with the largest % of residents with dementia;
ii) Units where DCM™ is considered the most useful to implement.

* A maximum of 2 Units per home can participate due to the impact upon Researcher workload (completion of CH Level data) and the delivery of DCM^{TM} (i.e. 1 Mapper per Unit).

The care home's insurance and indemnity will apply for trained mappers implementing the intervention within the care home setting. Possession of appropriate insurance will be checked at point of recruitment of the care home to the study.

7.2 CARE HOME RECRUITMENT

7.2.1 Catchment areas will be selected within each recruitment hub (i.e. West Yorkshire, London and Oxford).

7.2.2 Care homes in the catchment areas around the recruitment hubs will be screened for initial eligibility via publicly available information (e.g. home type, number of beds, status with CQC).

7.2.3 Care homes deemed eligible at this point will be randomly ordered (i.e. care home size, care home postcode, network status (network / non-network)) for further contact.

7.2.4 Care home selection will be staggered across the recruitment period to limit the number of homes considered at any one time and minimise the time between first approach and inclusion in the trial.

7.2.5 In accordance with the care home recruitment strategy a sample of randomly ordered care homes from each hub will then be sent Invitation Information (i.e. Care Home Information Sheet) to provide details of the trial and outline that a Researcher will contact them to discuss participating. Care homes will be provided with contact details to opt out of further trial contact if they are not interested in participating.

7.2.6 Researchers will contact care homes invited to take part within 1-3 weeks of sending Invitation Information to discuss the trial, answer any queries and determine if care homes are interested in taking part at this stage.

7.2.7 If a care home expresses an interest in taking part the Researcher will schedule a mutually convenient time to complete eligibility assessments. If a care home is not interested in taking part the Researcher will thank the care home for their time and acknowledge that the trial team will not contact them further.

7.2.8 If the Researcher is unable to make contact with the care home following several attempts (i.e. on different date, at varying times) the Researcher will cease attempting to contact the care home.

7.2.9 For interested care homes the Researcher will complete initial eligibility screening via telephone ahead of scheduling a mutually convenient time to visit the care home to determine full eligibility (i.e. staff engagement) and complete the recruitment process (i.e. written agreement at the care home level and appropriate management permissions). Care homes will be asked to determine the management permissions required ahead of the care home visit.

7.2.10 Once all care homes within a sample have been contacted the Researcher will move onto the next randomly ordered sample (timelines dependent upon number of interested care homes in a sample and recruitment strategy) until sufficient homes have been recruited. If care homes who are within the catchment area volunteer to take part having received information from another source, they will be subject to the same recruitment process as randomly selected homes.

7.2.11 Documented reasons for ineligibility or declining participation at each stage will be closely monitored by the Trial Team as part of a regular review of recruitment process.

7.2.12 The target is for four homes to be recruited per month. Should recruitment not progress at expected rates, the research team will use their contacts to approach eligible homes, and may include details about the trial in a publicly available newsletter. Should more eligible homes express an interest in participation than is required; a random sample will be chosen from those interested, to be approached for formal consent. A list of reserve homes will be identified by each recruitment hub, to support swift response to under recruitment of residents or drop out of homes ahead of randomisation.

7.3 TRAINING REVIEW AND PROVISION OF DEMENTIA AWARENESS TRAINING

It is known that quality of dementia training is variable across the sector and that lack of training leads to poor quality or sub-standard care. Therefore, in order to ensure that each home in the trial at least meets minimum dementia training standards, a training review designed by the research team and based on national information regarding current minimum standards, will be conducted on recruitment of the home to the trial.

The review will be conducted by the researcher at the time when the care home is recruited, through review of training records, review of Care Quality Commission inspection reports (where available) and discussions with the home manager and/or staff. This will provide data on mandatory training, additional training, type, length and provider(s) of training and the percentage of staff that have completed this training.

If the training review finds that homes would benefit from some additional dementia awareness training (i.e. they fall below a minimum level of training defined by the TMG), staff will be provided with a half-day dementia awareness course. As a minimum care homes will be expected to deliver dementia awareness training to 20% of permanent direct care staff. The course, modified in consultation with service users, from an existing resource developed by Bupa and the University of Bradford [87] will be delivered by a trained mentor within each care home. Using a modified version of an existing dementia awareness package reduces development costs and ensures the package is reflective of a basic awareness package being implemented by one of the large, national care home providers. Based on CQC data [88], we expect up to 20% of homes to require this dementia awareness package.

8 RESIDENT ELIGIBILITY, RECRUITMENT AND CONSENT

8.1 RESIDENT ELIGIBILITY

INCLUSION CRITERIA

Residents meeting all of the following criteria at screening will be eligible for this trial:

1) Is a permanent resident within the care home - defined as a person residing in the care home and not present for receipt of respite or day-care;
2) Has a formal diagnosis of dementia or score 4+ on FAST [89] rated by the home manager or another experienced member of staff;
3) Is appropriately consented (in accordance with Mental Capacity Act [90] and clinical trials guidance on informed consent [91-93]);
4) Has an allocated member of staff willing to provide proxy data;
5) Has sufficient proficiency in English to contribute to the data collection required for the research.

Note that residents will NOT be excluded if they lack capacity to consent. Guidance on consent will be followed for residents assessed to lack capacity.

EXCLUSION CRITERIA

Residents meeting any of the following criteria will not be eligible for this trial:

6) Is 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;
7) Is permanently bed-bound/cared for in bed.
8) Is taking part, has recently taken part in, or is planning to take part, in another trial that conflicts with DCM™ or with the data collection during the course of their involvement in DCM EPIC.

Eligibility waivers to inclusion and exclusion criteria are not permitted.

8.2 RESIDENT RECRUITMENT

8.2.1 The researcher will meet with the care home manager and/or relevant senior staff to start the process of identification of all eligible residents to be approached to take part in the trial.

8.2.2 The manager or nominated lead will provide an up-to-date list of all residents in the care home and identify staff members who know each resident well, for example their key worker if such a system is in place.

8.2.3 The home will be allocated a range of Resident Screening Numbers by the CTRU ahead of the eligibility assessment process, with one Screening Number assigned to each resident by the home. The names of residents will remain confidential to the manager and care home staff for the purposes of eligibility screening, with details of resident names linked to screening numbers and nominated staff members maintained by the care home.

8.2.4 Each resident will be reviewed for eligibility and basic demographics, and this data will be recorded by the Researcher through discussions with the manager / senior staff, identified only by their screening number. Reasons for ineligibility will be recorded.

8.2.7 All residents listed by care homes and on whom eligibility screening was completed, will be entered onto a linked-anonymous Resident Screening Database hosted by CTRU. The data will include:

- Date of screening;
- Resident age;
- Resident gender;
- Resident ethnicity;
- Resident length of stay;

- Staff assessment of capacity to consent at screening;
- Reasons for ineligibility (where applicable);
- Reasons for not consenting (where applicable);
- Reasons for non-registration (where applicable);
- Resident Identification Number (Resident ID) (where registered).

Documented reasons for ineligibility or declining participation will be closely monitored by the Trial Team as part of a regular review of recruitment processes.

8.3 RESIDENT INFORMED CONSENT

Once all eligible residents are identified, the home manager or senior staff member will undertake a documented initial assessment of the capacity of each eligible resident to consent to take part in the trial. All residents will be assumed to have capacity to consent unless assessed to lack capacity in accordance with Mental Capacity Act 2005 [90] guidance. If it is believed that a resident does not have the capacity, the care home will contact the main carer on the researcher's behalf in the first instance. If they are uncertain about a resident's capacity, the home manager or senior staff member will approach the resident and ask their permission for the researcher to speak with them alongside a member of staff who knows them well. If at this point the staff member deems the resident has the capacity to make the decision to speak to the researcher and they give verbal consent, this will be documented and the researcher will gain access to the resident name. If the staff member deems the resident does not have the capacity to make this decision then they will be deemed to lack capacity to consent to participate in the trial.

The researcher will then approach each resident who was deemed to have capacity and whom agreed to speak to the Researcher. The researcher will be supported by a relevant member of staff, and undertake a further documented assessment of capacity.

If the resident is deemed not to have capacity to consent, the care home will contact the main carer on the researcher's behalf as a next step. See section 8.3.2.

Where a resident is deemed to have capacity the member of staff supported by the researcher will discuss the trial with the resident and provide them with the Resident Information Sheet. At least 24 hours later, at a follow-up meeting with the researcher-staff dyad at which a relative or close friend of the resident may be present, the resident will be given the opportunity to ask any further questions they might have. Formal consent to participate in the trial will then be sought by the researcher.

There will be a nominated person within each care home (usually a senior member of staff), whom residents can approach with any questions or concerns. Residents will also be provided with the name of a contact person (their recruitment hub lead) whom they can contact during their participation in the trial if they have a question or concern.

8.3.1 Consent for those with capacity

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. In the case of residents who lose capacity during the course of the trial, appropriate guidance on consent in the light of changed capacity will be followed [94]. This will include appointment of a personal consultee or nominated consultee at this point, in accordance with the processes adopted for residents who lack capacity at the outset of the trial (see section 7.3.2). The consultee will provide advice on the resident's continued involvement in the trial. A capacity assessment will be conducted at each data collection point by the researcher for residents who have capacity upon initial consent to take part in the trial, to assess continued capacity at each data collection point.

Where a resident has capacity and consents to taking part in the trial, documented written consent to approach his/her main carer regarding potential participation as a proxy informant is included in the standard consent form.

8.3.2 Consent for those without capacity

Where a resident is assessed to lack capacity to give informed consent a 'Personal Consultee' will be appointed who can be consulted about what the Resident's wishes would be if they did have capacity. This will normally be a relative or close friend. Where the Resident has no close family or friend able or willing to act as Personal Consultee, another appropriate independent person, usually a member of staff in the care home who knows them well but who is not actively involved in any elements of the research process, will be appointed as a 'Nominated Consultee'.

The following process will be followed to appoint a consultee and gain their advice on the resident's wishes.

Following the capacity assessment, the Researcher will ask the staff member to identify the Resident's main carer.

If the main carer is present, the staff member will ask if s/he would be willing to speak to the researcher, and the Researcher will then provide him/her with a Relative / Friend Personal Consultee Information Sheet, talk through its contents and explain the assent form attached. They will also be asked for written informed consent to hold their personal details on record to enable the Researcher to contact them directly from this point - if they decide not to provide consent for the Resident to participate in the study, these contact details will not be held by the research team. The carer will then be given at least 24 hours to think about it and to talk to the resident and other relatives/friends. They will be provided with a shorter version of the Resident Information Sheet, designed for residents who lack capacity, to help explain the main trial issues in a format appropriate for people with dementia who lack capacity. They can use this to explain the trial to the Resident and to ascertain, where possible, a view on their feelings about taking part. If they are willing to sign the assent form, they will be asked to return it, by post, directly to the researcher, expressing their advice on what they feel the resident's wishes are/would be in relation to taking part in the trial. They will be asked to do this within a week of being given the Relative / Friend Personal Consultee Information Sheet. The Researcher will send a follow up reminder a week later if the form has not been returned. If after a further week the form has not been returned the process of appointing a Nominated Consultee will be followed.

If the main carer is not present in the care home, the Researcher will ask the care home to send the identified person a Relative / Friend Personal Consultee Information Sheet, the associated Resident Information Sheet and Personal Consultee Declaration form and a shorter form of the Resident Information Sheet on his/her behalf, and wait a week for a response. If there is no response, the care home will phone the main carer or speak to them if they visit the care home to check that they have been received. If there is still no response after a further week then an appropriate staff member from the care home will be approached and sent a Staff Nominated Consultee Information Sheet, the Resident Information Sheet and Nominated Consultee Declaration form and a shorter form of the Resident Information Sheet.

In all cases, the carer (Personal Consultee) or staff member (Nominated Consultee) will be given the opportunity to speak to the researcher over the phone about taking on this role. After undertaking appropriate consultation with the Resident (using the short version of the resident information sheet) and their relatives/close friends and colleagues within the home, where appropriate, the consultee will be asked to complete and return the assent form directly to the Researcher.

A Personal or Nominated Consultee can approach the researchers at any time to indicate they feel the person they are representing has changed their mind about participating in the trial, and to

withdraw them from participation. Likewise if the researchers feel that during the trial, the wishes of a person who lacks capacity may have changed in regard to participating in the trial, they will seek advice from the personal or nominated consultee about the resident's continued inclusion.

Given the length of the trial there is a possibility Personal Consultees may lose capacity themselves during the trial period. Therefore an annual review of personal consultee capacity will be undertaken by the Researcher during the period each Resident is participating in the trial. This will be undertaken at a data collection point when collecting proxy data or via a telephone/face-to-face review with the consultee where the former is not possible.

9 STAFF ROLES, ELIGIBILITY, RECRUITMENT AND CONSENT

9.1 STAFF ROLES

Active involvement of care home staff is crucial to the trial; this will initially be ascertained by the home manager in parallel to the home manager considering participation on behalf of the home. There are five possible staff roles, although some roles are mutually exclusive (see notes below):

i) To act as a nominated consultee for residents (see section 8.3.2);
ii) To provide data relating to their role (staff measures) (see section 9.2);
iii) To provide proxy data relating to residents they know well (proxy informant) (see section 10.2);
iv) To become trained DCM™ mappers (see section 12.2);
v) To participate in the process evaluation (see section 14).

Note: that if a staff member acts as nominated consultee for residents they cannot provide staff measures data, proxy informant data, be a trained mapper or participate in the process evaluation. If a staff member is a trained mapper they cannot provide proxy informant data on residents. The below table (table 1) summarises what each role can and cannot do:

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	✓	✓

9.2 STAFF MEASURES

INCLUSION CRITERIA

Staff meeting <u>all</u> of the following criteria <u>will be</u> eligible to provide data on the staff measures for this trial:

1) Is a permanent, contracted, agency or bank member of staff at time of data collection;
2) Provides consent to providing data for the trial through return of the Staff Measures booklet;
3) Has sufficient proficiency in English to contribute to the data collection required for the research.

EXCLUSION CRITERIA

Staff meeting the below criterion will not be eligible to provide data on the staff measures for this trial:

4) Be acting as a Nominated Consultee for any residents participating in the trial.

Eligibility waivers to inclusion and exclusion criteria are not permitted.

Staff recruitment will take place at baseline and at each further data collection point, due to often high turnover rates of staff in care home settings. Prior to each data collection visit, the home manager will be asked to produce an up-to-date list of all staff working in the care home during the visit. The home will be provided with copies of the Staff Information sheet, Staff Measures booklet and Staff Details Questionnaire around two weeks prior to each data collection visit and will be asked to distribute one copy of each to each eligible staff member. Staff will have the opportunity to ask any questions they have by contacting the home manager or nominated research lead, through contacting the researcher, or by speaking to the researcher directly during the data collection visit. Staff will be asked to complete the Staff Details Questionnaire and questionnaires and return them in a sealed envelope to a box located within the care home or post directly to the research office in the stamped addressed envelope provided.

The researcher will provide the home manager or care home research lead with the names of staff who have returned the questionnaires at the start of the data collection week. The manager or research lead will check this against the full list of staff and will provide one further reminder to those who have not responded.

The Staff Details Questionnaire will include the following data:

- Staff member's name;
- Care Home ID;
- Follow-up time point (i.e. baseline, 6 months or 16 months follow-up);
- Date of completion of questionnaires;
- Staff date of birth;
- Staff gender;
- First language (if not English);
- Length of time spent working in this care home;
- Highest qualification;
- Previous dementia-specific training and timing;
- Previous DCM™ training and / or experience and timing;
- Current job role.

Staff will also complete the GHQ-12 and the SCIDs as part of the Staff Measures Booklet.

For staff completing the staff measures, completion and return of questionnaires will signify their consent to participate. CTRU will assign Staff Identification Numbers upon receipt of the questionnaires.

10 PROXY ELIGIBILITY, RECRUITMENT AND CONSENT

As a significant proportion of residents recruited into the trial will not be able to complete the data relating to them, it is important to collect proxy data from a consistent informant who knows them well. In this trial, Relatives / Friends and staff members will provide data on residents they know well whether or not the resident lacks the capacity to consent or loses the capacity to consent mid trial. In this way Relatives / Friends and Staff will be regarded as informants alongside the resident, where they are able to complete the questionnaires.

The resident may participate without the involvement or assent of their Relative / Friend to provide proxy data about them, and the Relative / Friend may act as personal consultee without providing data on the resident for the trial.

However, the resident may not participate without the identification of a Staff member willing to provide proxy data.

10.1 RELATIVE / FRIEND AS INFORMANTS

To be eligible to provide proxy data (i.e. Quality of Life data) about a resident, Relatives / Friends must meet all of the following criteria:

1) Visit the resident on a regular basis over the past month (i.e. at least once per week);
2) Be willing to provide data at a time convenient to them, within the care home, in person, during the data collection week, or by telephone;
3) Has sufficient proficiency in English to contribute to the data collection required for the research.

Eligibility waivers are not permitted.

Relative / Friend recruitment will take place at baseline (or later in the trial if a Relative / Friend withdraws and a new Relative / Friend proxy informant is required), and eligibility will be reassessed at each subsequent data collection point due to the fact that Relatives / Friends may no longer meet eligibility criteria over time. Where a Relative / Friend no longer meets eligibility criteria a suitable 'new' Relative / Friend will, where possible, be sought to provide the proxy data. Where possible however, the same Relative/Friend will provide proxy data throughout the trial.

The Resident supported by the home manager or a senior member of staff who knows the Resident well, will be asked to identify one relative or close friend, who visits regularly, to be approached to provide proxy data for the trial. Where the resident lacks capacity to consent to take part in the research, the relative or close friend identified may be the same person identified to act as consultee for the Resident. However, the Resident and/or staff may identify a relative/friend who is not the Personal Consultee, but who may be more appropriate to provide proxy data for the Resident. Therefore, the person providing proxy data may be different from the Resident's Personal Consultee, where one is appointed.

The home will produce and maintain a list of names and addresses of Relatives / Friends linked to Residents. The Researcher will not have access to this initially. Once Relative / Friend informants are identified, the Researcher will provide the home with written information about the trial (i.e. the Relative / Friend Proxy Information Sheet and Consent Form that the home manager can either give to the Relative / Friend personally on their next visit, or post to them. After a week, the Researcher will inform the care home of the Relatives / Friends who have responded and will ask the home manager to send out one further reminder to the remaining Relatives / Friends. The Relative / Friend will be informed they can withdraw from the trial at any stage without any adverse impact on the care of the Resident, and without affecting the Resident's continued involvement in the trial. Receipt of the consent form will provide the researcher with a list of Relative / Friend names and addresses that they will maintain for the duration of the trial.

CTRU will assign Relative / Friend Identification Numbers upon receipt of the questionnaires.

For each Relative / Friend associated with each resident, data collected will include;

- Relative / Friend age;
- Relative / Friend gender;
- Relative / Friend date of birth;
- Distance to travel to the care home;

- Relationship to resident;

- Number of visits over past month and indication of whether this is representative of usual visiting pattern;
- Visit patterns (weekdays/weekends, mornings/afternoons/evenings).

There will be a nominated person within each care home (usually a senior member of staff), whom Relatives / Friends can approach with any questions or concerns. They will also be provided with the name of a contact person (their recruitment hub lead) whom they can contact at any time during their participation in the trial if they have a question or concern.

10.2 STAFF AS INFORMANTS

INCLUSION CRITERIA

To be eligible to provide proxy data on a resident, staff must meet all of the following criteria:

1) Be a permanent or contracted member of staff;
2) Know the resident well, as assessed by their key worker status and/or the judgement of the home manager.

EXCLUSION CRITERIA

Staff meeting any of the following criteria will not be eligible:

3) Working in the home as agency or bank staff;
4) Be a trained DCM™ mapper;
5) Have acted as nominated consultee for any residents in the trial.

Eligibility waivers to inclusion and exclusion criteria are not permitted.

In advance of each data collection visit, the home manager will be asked to review the list of staff that knows each recruited Resident well, including the nominated staff member. Where possible the same staff member will provide proxy data throughout the trial. If a new staff informant is required they will undergo the same process of screening and recruitment as the previous informant.

Staff identified as potential proxy informants, will be approached by the Researcher, who will give them verbal and written information about the trial (i.e. Staff Proxy Informant Information Sheet).

Where the staff member is not willing to provide data about a resident, a new staff member will be identified instead. Staff participants who show their willingness to provide data will be advised that they are free to withdraw from the trial at any time without adverse impact.

11 REGISTRATION AND RANDOMISATION

11.1 REGISTRATION OF RESIDENTS

Residents will be registered with the CTRU after care home recruitment and the training review at the care home level, and after confirmation of eligibility, informed consent and collection of baseline data (including Independent Assessments) at the resident level. Registration of residents will be performed using the CTRU automated 24-hour registration system, which will provide each resident with a unique Resident Identification Number. Authorisation codes and PINs, provided by the CTRU and used by researchers, will be required to access the registration system.

The following details will be required at registration:

- Resident Screening Number;
- Resident details: initials, date of birth;
- Name of person undertaking the registration;
- Confirmation of eligibility;
- Confirmation of informed consent;
- Confirmation of baseline assessment;
- Confirmation of staff proxy informant identification.

The Resident ID number from the registration process will be added to the Screening Form by the researcher to enable those providing consent to be linked.

11.2 RANDOMISATION OF CARE HOMES

Once all Residents have been registered, care homes will be randomised using the 24-hour automated randomisation system based at the CTRU University of Leeds.

Care homes that fulfil the eligibility criteria, have signed up to the protocol and have signed a written agreement to participate will be randomised, following recruitment of Residents, Staff and Relatives / Friends, and completion of baseline assessments, on a 3:2 basis to receive either DCM™+UC or UC. A computer generated minimisation programme, based on that recommended by Kuznetsova and Tymofyeyev [95], incorporating a random element will be used to ensure treatment arms are balanced for the following care home characteristics, details of which will be required at randomisation:

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

The following information will also be required at randomisation:

- Care Home ID;
- Use of DCM^{TM} in the home over the last 5 years (yes, no)
- Name of person undertaking the randomisation;
- Number of registered residents in care home (minimum acceptable=10);
- Confirmation of eligibility;
- Confirmation of baseline assessment for all registered residents.

The randomisation call will be performed by CTRU Data Management, following necessary confirmations from the Researcher. As such, personnel within the CTRU will not be kept blind to treatment allocation. Following randomisation, the CTRU will inform the DCM™ lead of those homes allocated to DCM™ + UC, so that arrangements for training can be made. CTRU will inform the Care Home Manager of the treatment allocation by confirmation email or fax. The Researchers will not be informed and efforts will be made to keep them blinded to the allocation throughout the trial. Other personnel involved in the trial will only be informed of treatment allocation if this is required to undertake their role associated with the trial.

12 INTERVENTION DETAILS

12.1 USUAL CARE (BOTH ARMS)

Usual Care (UC), defined as normal care delivered within the setting, will continue in both arms. No restrictions will be imposed on current practices or on homes undertaking additional development or training as part of usual care, with the exception of control arm homes being required not to implement DCM™ during their trial involvement period. As outlined in the background section, person-centred care is considered best practice within dementia care [55] and as such, care homes are expected to provide staff with appropriate training to deliver care of this type [67]. Details regarding any changes in usual care practice during the course of the trial will be documented by the EPIC Researcher at follow-up visits.

A list of GPs that serve the care home and other relevant visiting professionals will be provided by the care home. All GPs and visiting professionals will be provided with generic best practice guidance about the implementation of person-centred care and managing BSC, irrespective of whether the residents they support are participating in the trial. We will not be informing individuals' GPs about residents who are participating in the trial. This will facilitate a person-centred primary care response where care homes seek support.

12.2 DEMENTIA CARE MAPPING™ (INTERVENTION ARM ONLY)

Dementia Care Mapping™ (DCM™) [12, 13, 96, 97] is an observational tool designed to assess quality of care in formal dementia care settings. It is grounded in the philosophy of person centred care and was designed to be used in a series of developmental evaluations over time. Through a process of preparation and feedback, staff members are empowered to consider care from the point of view of the person with dementia. On the basis of these observations and subsequent feedback to the care team, changes can be made to care plans and practice. DCM™ can be used to monitor change and provides positive reinforcement for the provision of person-centred care over time. The use of DCM™ as an evidence based, service user focussed, quality monitoring and improvement tool has been commended by the Audit Commission [98] and the Commission for Health Improvement [99, 100].

The intervention in this trial comprises:

a) Training in DCM™;
b) Implementation of three cycles of briefing, observation, feedback and action planning and implementation of action plans, in accordance with the British Standard best practice guideline [31] and additional intervention fidelity guidelines provided by the research team.

12.2.1 Mapper identification and consent

Two staff* in each home will be identified to be trained to use DCM™ (referred to forthwith as trained mappers). Two mappers will be approached and consented at baseline in all homes prior to randomisation (in homes then randomised to the intervention arm, these identified mappers will undertake DCM™ training, as per 12.2.2).

* If two units within a home are taking part one staff member from each unit will be approached and consented to participate.

INCLUSION CRITERIA

To be eligible to be trained, staff must meet <u>all</u> of the following criteria:

1) Be a permanent or contracted member of staff;

2) Have the right skills and qualities as assessed by the home manager in accordance with guidance provided by the research team;
3) Provide consent to becoming a mapper, to implementing the DCM™ process in accordance with the research protocol and to providing intervention fidelity data;
4) Provide consent to complete interview and focus group data for the trial (Process Evaluation).

EXCLUSION CRITERIA

Staff meeting any of the following criteria will not be eligible:
5) Working in the home as agency or bank staff;
6) Acting as a nominated consultee or providing proxy data for any residents participating in the trial.

Staff eligible to become mappers will be identified by the home manager. The staff chosen to undertake DCM™ training will then be identified by the home manager in discussion with the DCM™ lead.

Potential mappers will initially be approached by the home manager who will be provided with written information about the role and responsibility of the mappers. Once verbal consent has been obtained by the home manager, the potential mappers will be approached by the researchers who will again explain the role and responsibility of the mappers before gaining their written informed consent to participate. Should a mapper leave the care home before the end of the trial, where feasible a further suitable member of staff will be identified, consented and trained to ensure continuity of DCM™ implementation within the home.

12.2.2 Training

DCM™ training is only available through licensed DCM™ trainers, delivering courses registered with the University of Bradford. This ensures consistency of training in the tool nationally and internationally. The DCM™ training consists of a standardised four-day course including an assessment of competency in use of the tool on the final day. A pass mark of 60% is required in order to use DCM™ following the training. Resit assessments are available for students not achieving a pass mark at the first attempt.

All mappers will attend a Bradford or London based DCM™ course. The course trainers will report on mappers' successful completion of the course to CTRU to ensure a register is maintained of all qualified mappers taking part in the trial.

12.2.3 Implementation

Implementation of DCM™ involves a practice development cycle of briefing the staff team, observation, data analysis, feedback to the staff team, action planning and remapping. Ahead of each mapping cycle the CTRU will contact each mapper via SMS to remind them of the upcoming cycle.

Briefing
Mappers run one or more briefing sessions 1-2 weeks prior to undertaking the mapping observations. Briefing sessions inform the care home staff about DCM™ and the process of implementation. It provides an opportunity for staff to ask questions about the process and for mappers to address any worries staff may have about what will happen.

Resident consent for mapping

Prior to mapping, appropriate residents are selected to be mapped through discussions between the care team and mappers. This is usually completed during the briefing session. Residents are usually selected for observation on the basis of being reflective of a range of abilities or having particular care needs or behaviours staff members have difficulties meeting or understanding. DCM™ will be implemented in the intervention homes as part of care quality monitoring and improvement processes. Consent from residents to be observed as part of the intervention implementation will be gained verbally, by the trained mappers, prior to each DCM™ cycle. The process for this will be in accordance with the usual consent process utilised in DCM™. Residents observed as part of the intervention do not have to meet the research eligibility criteria, or be participating in the research. They will be selected for observation, by the trained mappers, according to guidance provided within the DCM™ tool. Any resident data collected as part of the DCM™ process will be owned and used by the trained mappers within the home. Any data used for monitoring intervention fidelity or for any other purposes within the research, will be anonymised at the care home level before being accessed by the research team.

Observation
DCM™ will involve continuous observation of between 5 and 8 people with dementia (depending on the experience of the mapper), over a period of up to 6 consecutive hours, producing what is called a 'map' of the experience of care. Every 5 minutes the observer, or mapper, will record 2 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 (or time frame). The ME Value encapsulates the associated mood and engagement level of the person with dementia and is chosen from a 6-point scale. The mapper will also record 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 will be recorded as and when they occur. When recording and feeding back PDs and PEs, the mapper will be careful not to identify the individual staff members involved.

Since DCM™ is grounded in person-centred care, for reasons of privacy and dignity, observations will only take place in communal living areas, such as the lounge, dining room and corridors. A mapper will not observe in bedrooms or bathrooms. If a resident is at risk of an accident or a fall, or in the case of a medical emergency, a mapper will intervene immediately and offer assistance to staff as required. They will not continue to map in a setting which is experiencing a crisis or other such difficulties. Once data has been collected it will be analysed by the trained mappers and presented in a standardised report format for the purposes of feedback to the care team.

Data analysis
Mappers will analyse the data they produce to present it in a format that the staff team are able to engage with during feedback. There is a standardised set of data a mapper produces for feedback purposes including the percentage of time individuals and the group spend in each behaviour category and ME Value. A summary of PDs and PEs is also produced. The data will be presented in a report format that is used during the feedback session. This includes graphs of the summarised data and some key discussion points to be addressed during feedback.

Feedback and action planning
Mappers will run one or more feedback sessions with as many of the staff team as possible in order to share the DCM™ data with them and to engage them in considering what this means for improving practice within the setting. On the basis of the discussions during the feedback session an agreed, achievable action plan will be produced with short, medium and longer term goals. Progress on these actions is monitored during the next mapping cycle.

The first cycle of mapping will be supported by an expert DCM™ user provided by the research team, to support establishment of inter-rater reliability of DCM™ coding between the trained mappers within each care home and assessment of this across the 30 intervention sites. This will also support intervention fidelity through supported implementation of DCM™ to the required standard during the first mapping cycle.

The care home's insurance and indemnity will apply for trained mappers implementing the intervention within the care home setting. Possession of appropriate insurance will be checked at point of recruitment of the care home to the study.

12.3 MONITORING INTERVENTION DELIVERY

Adherence to the prescribed processes for intervention delivery will be monitored at each round of the intervention.

Monitoring will aim to determine:

1) Adherence to the processes – are trained mappers delivering the intervention in accordance with training and 'as intended';
2) Quality of intervention delivery (fidelity) – are trained mappers delivering the intervention with sufficient quality.

Measurement of Adherence and Fidelity will take the form of a sliding scale, rather than an absolute value, since this is a complex intervention with multiple facets, where giving a rating of compliant or non-compliant will not be possible.

12.3.1 British Standards

PAS 800 [76] sets out a standard for implementing DCM™ within a care provider organisation. It will provide the basis for the principles underpinning the adherence to intervention delivery.

12.3.2 Briefing

Briefing 'adherence' will be measured by achieving the following:

- Use of standardised briefing documentation provided by the research team and adapted to the individual care home;
- At least 50% of the direct care staff on the unit to be mapped to have attended a formal briefing session (at each round of mapping);
- 100% of staff on the unit to be mapped to have received written briefing documentation (at each round of mapping).

12.3.3 Observation

Observation 'adherence' will be measured by achieving the following:

- Two mappers having completed at least 4 hours of observations over a 1 week period;
- At least five residents observed in total with at least 3 hours of available data on each resident;
- Mappers using all four of the coding frames (BCC, ME, PD and PE) and making additional qualitative notes to accompany the mapping data.

12.3.4 Reporting

Reporting 'adherence' will be measured by achieving the following:

- Use of a standardised report template;
- Data analysis and presentation completed using software provided by the research team.

Anonymised copies of all feedback reports will be provided to the Research team at CTRU by the mappers in order to assess intervention fidelity.

12.3.5 Feedback

Feedback 'adherence' will be measured by achieving the following:

- Use of a feedback guideline to ensure required balance of positive and developmental feedback is given during each feedback session;
- At least 25% of the direct care staff on the unit attending a formal feedback session;
- 100% of staff on the unit having access to the final written report and a mechanism for inputting their feedback and ideas into the action planning process.

12.3.6 Action Planning and Implementation

Action planning and implementation 'adherence' will be measured by achieving the following:

- Use of a standardised format for action plans;
- Development of minimum of one and maximum of four action points per resident;
- Development of at least 6 and maximum 12 home level action points;
- Action points to be written as SMART (Specific, Measurable, Achievable, Realistic, Time limited);
- Action points to be developed in consultation with, and agreed by, staff team.

12.4 WITHDRAWAL

It is possible that entire care homes, care home staff, mappers, Relatives / Friends and residents could withdraw during the course of the trial. Where the wish to withdraw is expressed, the reasons for this will be discussed with the research team and the type of withdrawal clarified.

Care homes will sign a written consent agreement prior to randomisation detailing their commitment, reducing the likelihood of withdrawal. However, where they choose to withdraw, the options open to them will be for the home to withdraw from treatment only or from both treatment and further data collection (in the case of the latter, the care home will have the consent of all the residents, Relatives / Friends and staff to this).

Where a mapper wishes to withdraw they may withdraw from providing research data (i.e. participation in final interviews for the process analysis) for the trial, but may still wish to continue in their role as mapper, or may withdraw from both. If a mapper does not wish to provide further intervention fidelity data then they will be judged to also be withdrawing from their role as a mapper within the home. In the case of withdrawing from the role of mapper, where feasible a new mapper will be identified and trained from the staff team.

Care home staff may leave their employment or change their caseload mid-trial, altering their status as the nominated staff member to provide data regarding specific residents. If this occurs then a replacement staff member will be identified and the original staff member will no longer provide data for all or specific residents.

Where a Relative / Friend wishes to withdraw, a further Relative / Friend (where possible) will be identified by the resident and the home manager and the consent process will be followed.

At each visit, the resident's willingness to continue, once initial consent has been secured, will be ascertained. During data collection weeks in the home (baseline, 6 months and 16 months) the researcher will, where possible, be gathering quality of life data directly from the person with dementia. When the researcher speaks to the resident they will remind them who they are and why they are visiting the home. They will check the person with dementia is still happy to provide interview data for the trial on that visit. If they are not then the researcher will not collect any direct data from them on that day. If it is appropriate they may approach the resident again later. This permits residents to choose to be 'non-compliant' in providing interview data about their quality of life at any given data collection point, without withdrawing from the trial. It also gives the resident opportunity to express a desire to withdraw from the trial as a whole at each data collection point,

making consent an on-going process.

Residents will be advised that they are free to withdraw from data collection at any time without adverse impact. Like their Relatives / Friends, however, they will be encouraged to continue providing data on a subset of measures only (i.e. proxy-completed/resident-completed /notes and records data).

Residents transferred out of the Care Home during the course of the trial will not be considered as a withdrawal but termed as lost to follow-up. Researchers will document the date of transfer, and if transferred to a new Care Home will document the address to confirm if this Care Home is also taking part in the study. If transferred to another Care Home participating in the study the Residents participation will be reviewed and relevant consent obtained (i.e. Staff Proxy Informant).

It is assumed that the implications of withdrawal will take effect from the point of withdrawal.

12.4.1 Withdrawal from trial due to death

All deaths occurring from the date of consent to participate in the trial up to sixteen months post-randomisation must be recorded on the Death Form. The original form should be submitted to the CTRU within a week of the researcher becoming aware of the event. The researcher will contact the home and arrange for a convenient time to review the participant's care records.

13 DATA COLLECTION / ASSESSMENTS

Recruiting hubs (i.e. West Yorkshire, London and Oxford) will be expected to maintain a file of essential trial documentation (i.e. Hub Site File), which will be provided by CTRU. Original CRFs will be sent to the CTRU and stored centrally.

Assessments will be undertaken at the following time points:

- Screening (prior to consent);
- Baseline (prior to resident registration);
- 6-months post-randomisation;
- 16-months post-randomisation.

Required data, assessment tools, collection time-points and processes are described in detail in sections 13.1 to 13.5. This is summarised in Table 2 below.

Table 2: Summary of Assessments

Assessment	Type	Method of Completion	Timeline			
			Screening	Baseline	6 Months	16 Months
Care Home Eligibility	CRF	Researcher Assessment	X			
Training Review	CRF	Researcher Assessment	X			
Dementia Awareness Training	CRF	Dementia Awareness Trainer	X			
Resident Screening (Demographics)	CRF	Researcher Assessment	X			
Staff Mapper Screening	CRF	Researcher Assessment	X			
Consent (Staff Mapper, Resident (incl. Personal/Nominated Consultee), Staff Proxy Informant, RF Proxy Informant)	Consent Form	Self-completion (Witnessed)	X			
Participant Eligibility (Staff Mapper, Resident, Staff Proxy Informant, RF Proxy Informant)	CRF	Researcher Assessment	X			
Participant Contact Details (Resident, Staff Proxy Informant, RF Proxy Informant)	CRF	Researcher Assessment	X			
Cohen Mansfield Agitation Index (CMAI) abridged	Questionnaire Booklet	Independent Researcher Observations (R)		X	X	X
Pittsburgh Agitation Scale (PAS)	Questionnaire Booklet	Independent Researcher Observations (R)		X	X	X
Care Home Manager Demographics	Questionnaire Booklet	Researcher Interview (CM)		X	X	X
Care Home Demographics	Questionnaire Booklet	Researcher Interview (CM)		X	X	X
Group Living Home Characteristics (GLHC)	Questionnaire Booklet	Researcher Assessment (CH)		X	X	X
Environmental Audit Tool (EAT)	Questionnaire Booklet	Researcher Observations (CH)		X	X	X
QUality of Interactions Schedule (QUIS)	Questionnaire Booklet	Researcher Observations (R/S)		X	X	X
Staff Proxy Informant Demographics	Questionnaire Booklet	Researcher Interview (SP)		X	X	X
Resident Demographics	Questionnaire Booklet	Researcher Assessment		X	X	X
RF Proxy Informant Demographics	Questionnaire Booklet	Researcher Interview (RF)		X	X	X
Cohen Mansfield Agitation Index (CMAI)	Questionnaire Booklet	Researcher Interview (SP)		X	X	X
Neuropsychiatric Inventory (NPI-NH)	Questionnaire Booklet	Researcher Interview (SP)		X	X	X
Functional Assessment Staging (FAST)	Questionnaire Booklet	Researcher Interview (SP)		X	X	X
Clinical Dementia Rating (CDR)	Questionnaire Booklet	Researcher Interview (SP)		X	X	X
DEMQOL Proxy	Questionnaire Booklet	Researcher Interview (SP/RF)		X	X	X
EQ 5D 5L	Questionnaire Booklet	Researcher Interview (SP/RF/R)		X	X	X

Assessment	Type	Method of Completion	Timeline			
			Screening	Baseline	6 Months	16 Months
QUALID	Questionnaire Booklet	Researcher Interview (SP/RF)		X	X	X
QOL-AD	Questionnaire Booklet	Researcher Interview (R)		X	X	X
Resident Comorbidities	Questionnaire Booklet	Researcher Assessment		X	X	X
Healthcare Resource Use	Questionnaire Booklet	Researcher Assessment		X	X	X
Prescription Medications	CRF	Researcher Assessment		X	X	X
Resident Registration	Questionnaire Booklet	Researcher Assessment		X		
Staff Demographics	Questionnaire Booklet	Self-Completed (S)		X	X	X
General Health Questionnaire (GHQ-12)	Questionnaire Booklet	Self-Completed (S)		X	X	X
Sense of Competence in Dementia care Staff (SCIDS)	Questionnaire Booklet	Self-Completed (S)		X	X	X
Safety Reporting	CRF	Researcher Assessment		Monthly following Randomisation		
RUSAE Report	CRF	Researcher Assessment		As highlighted.		

			Mapper Training	3 months	8 Months	13 Months
Mapper Training	CRF	DCM Trainer	X			
DCM Adherence	Questionnaire Booklet	DCM Expert		X		
DCM Briefing Summary	CRF	CH Mapper		X	X	X
DCM Feedback Summary	CRF	CH Mapper		X	X	X

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

The main informant will be the nominated staff member who knows the resident well. This is to ensure there is a consistent data set available for each resident at each time point. The staff proxy data will be supplemented, where possible, by information provided by the resident (where they are able) and their Relative / Friend carer (where available).

13.1 SCREENING DATA

Screening data will be collected on care homes and residents. This will allow eligibility and consent to be established and provide basic information that will be helpful in demonstrating generalisability and imputing data where this is missing.

13.1.1 Home manager-completed data

The following data will be collected from the Home Manager at screening, prior to the relevant consents (that is, the written consent agreement for the care home, consent/assent for the resident, staff and Relatives / Friends):

- Care Home Eligibility Checklist;
- Number of residents with dementia including (i) formal diagnosis or (ii) FAST.

This will be collected over two to three interviews: one for the care home data, one for the resident data, and one for the proxy data.

13.1.2 Researcher-completed data

The following data will be collected by Researchers from the home records:

- Training Review.

This will be collected following care home consent.

13.2 REGISTRATION AND RANDOMISATION DATA

See Sections 11.1 and 11.2 for data collected at registration and randomisation respectively.

13.3 PILOT DATA

Baseline data collection visits will commence approximately two months earlier in two care homes, in order to assess how manageable the data collection burden is. Following this, the data collection schedule will be reviewed by the Trial Management Group and a decision will be made about whether (and how) to reduce the burden on informants. Strategies for obtaining data from staff and Relatives / Friends may also be refined. The data collected during this pilot will be used in the main trial and the usual timelines will be followed for these homes. In effect these homes are just commencing the trial in 'isolation' before bringing other homes on board.

13.4 BASELINE DATA

The baseline data collection visit will be scheduled to last one week in each home with two Researchers present.

The researcher will also get in touch with Relatives / Friends who have consented to take part to arrange appointments to collect data on residents, and will send out staff measures to the home to be distributed to staff. If appointments cannot be made in advance, the researcher will fit these into their schedule during the visit.

13.4.1 Resident-completed data

Residents will complete the following data where they are able, irrespective of whether they have the capacity to consent or not. The FAST rating at each time point will permit analysis of data to be analysed on the basis of dementia severity:

- QOL-AD;
- EQ-5D-5L.

The Resident measures will be completed by researcher interview.

13.4.2 Home manager-completed data

The following data will be collected from the Home Manager during their scheduled meeting:

- Care home demographics;
- Home manager demographics;
- Staffing including turnover, agency/bank use, levels (accessed via home records);
- Group Living Home Characteristics Questionnaire (GLHC).

The home measures will be completed by researcher interview.

13.4.3 Staff-completed data

The following measures will be chased by the researcher during the visit:

- Staff Details Questionnaire;
- General Health Questionnaire (GHQ-12);
- Sense of Competence in Dementia Care Staff (SCIDS) Scale.

If measures are not completed during this visit they may be posted directly to the CTRU in pre-paid envelopes, with one follow-up after two weeks permitted if questionnaires still have not been returned.

The following will be completed by Staff acting as proxy-informants as part of a researcher interview:

- Cohen Mansfield Agitation Inventory (CMAI);
- Neuropsychiatric Inventory (NPI);
- QUALID;
- DEMQOL-Proxy;
- EQ-5D-5L-Proxy;
- Clinical Dementia Rating scale (CDR);
- Functional Assessment Staging of Alzheimer's Disease (FAST);

13.4.4 Relative / Friend -completed data

The following will be completed by the Relative / Friend as part of a researcher interview:

- RF Proxy Informant Demographics QUALID;
- DEMQOL-Proxy;
- EQ-5D-5L-Proxy.

If measures are not completed during this visit they may be;

a. Completed via telephone interview within 2 weeks of the follow-up time point;
b. Self-completed and returned directly to the CTRU in pre-paid envelopes. Guidance on self-completion of questionnaire will be provided by the Researcher.

13.4.5 Researcher-completed data

The following data will be collected by researchers from the home records or observation of residents and staff:

- Environmental Audit Tool (EAT);
- Pittsburgh Agitation Scale (PAS);
- Abridged Cohen Mansfield Agitation Index (CMAI);
- Quality of Interactions Schedule (QUIS);
- Resident co-morbidities
- Prescription Medications;
- Healthcare Resource Use from review of care records.

13.5 FOLLOW-UP DATA

The two follow-up data collection visits (at 6 and 16 months) will be scheduled to last one week in each home. Researchers will contact participating Relatives / Friends to arrange appointments at the care home to collect data on residents, and send out staff measures booklets to be distributed to staff. If appointments cannot be made in advance, the researcher will slot these into their schedule during the visit.

13.5.1 Resident-completed data

Residents will complete the following data at 6- and 16-months where they are able to, irrespective of whether or not they have the capacity to consent:

- QOL-AD;
- EQ-5D-5L.

The resident measures will be completed by researcher interview.

13.5.2 Home manager-completed data

The following data will be collected from the Home Manager during their scheduled meeting at 6- and 16-months:

- Care home demographics;
- Home manager demographics;
- Staffing including turnover, agency/bank use, levels (accessed via home records);
- Group Living Home Characteristics Questionnaire (GLHC).

The home measures will be completed by researcher interview. Additionally at 16-months the Home Manager will be interviewed as part of the process evaluation (see Section 14).

13.5.3 Staff-completed data

The following measures will be chased by the researcher during the 6- and 16-month visits:

- Staff Details Questionnaire;
- General Health Questionnaire (GHQ-12);
- Sense of Competence in Dementia Care Staff (SCIDS) Scale.

If measures are not completed during this visit they may be posted directly to the CTRU in pre-paid envelopes, with one follow-up after two weeks permitted if questionnaires still have not been returned.

The following will be completed by Staff acting as proxy informants at 6- and 16-months as part of a researcher interview:

- Cohen Mansfield Agitation Inventory (CMAI);
- Neuropsychiatric Inventory (NPI);
- QUALID;
- DEMQOL-Proxy;
- EQ-5D-5L Proxy;
- Functional Assessment Staging (FAST)
- Clinical Dementia Rating (CDR)

Additionally at 16-months staff will form part of the focus groups conducted as part of the process evaluation (see Section 13).

13.5.4 Relative / Friend -completed data

The following will be completed by the Relative / Friend at 6- and 16-months as part of a researcher interview:

- RF Proxy Informant DemographicsQUALID;
- DEMQOL-Proxy;
- EQ-5D-5L-Proxy.

If measures are not completed during this visit they may be;

a. Completed via telephone interview within 2 weeks of the follow-up time point;
b. Self-completed and returned directly to the CTRU in pre-paid envelopes. Guidance on self-

completion of questionnaire will be provided by the Researcher.

13.5.5 Mapper-completed data

The trained mappers at those homes allocated to the UC + DCM^{TM} arm of the trial will be asked to complete and return data at each cycle of mapping. Data will be collected on:

- Mapping practice at each stage of the mapping cycle (briefing, observation, data analysis, feedback, action planning) including for example number of staff in the care home who received a formal briefing;
- Number of hours of mapping;
- Number of residents mapped;
- Number of staff attending feedback sessions and number of action plans developed. Mappers will be provided with a standard reporting template to gather this information.

13.5.6 Researcher-completed data

The following data will be collected at 6- and 16-months by Researchers from the care home records or observation of Residents and Staff;

- Prescription Medication;
- Usual Care data;
- Pittsburgh Agitation Scale (PAS);
- Abridged CMAI;
- Quality of Interactions Schedule (QUIS);
- Resident co-morbidities
- Healthcare Resource Use from review of care records.

The PAS and abridged CMAI will be completed by an Independent Researcher (blinded to care home allocation and completed Proxy Informant Measures). Efforts will be made to maintain blinding of the researchers to the care home's intervention allocation. Occurrences of researcher un-blinding will be documented and reported to CTRU.

13.6 ASSESSMENT INSTRUMENTS

Agitation (Cohen Mansfield Agitation Inventory (CMAI) [38, 39]):
The CMAI measures 29 agitated or aggressive behaviours [101]. 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 last two week period. A total score is obtained by summing the 29 individual frequency scores, yielding a total score that ranges from 29 to 203.The CMAI has good psychometric properties [102] including construct validity and factor structure [103], concurrent validity [104] reliability [105] and test-retest reliability [106] when used in a care home setting. There is also available data on expected points change from previous similar studies supporting accurate sample size calculation. The CMAI will be completed in accordance with the CMAI Manual [39].

The abridged CMAI is rated on a four-point scale (1-4) ranging from "never" to "several times an hour", based upon observations over one day. The abridged CMAI data collection will be standardised to complete observations of registered (consented) residents within communal areas between 10:00 – 17:00.

BSC (Neuropsychiatric Inventory (NPI-NH) [107]):
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 specifically designed for use with nursing home/care home populations. The NPI-NH is both reliable and valid [107].

Quality of life (DEMQOL-Proxy [108]):
The DEMQoL (version 4) is a quality of life questionnaire designed specifically for use in dementia samples. It has 29 items covering mood, behavioural symptoms, cognition and memory, physical and social functioning and general health that are administered by an interviewer. The DEMQoL-proxy has 32 items covering the same dimensions as the DEMQoL. It is completed by a carer of the person with dementia and administered by an interviewer. The DEMQOL and proxy have acceptable psychometric properties for measuring quality of life in dementia [109]. The measures have recently been valued to enable the derivation of preference based indices (utility values). As a result the DEMQOL and DEMQoL proxy measures will provide dementia-specific utility values that will be employed in secondary cost-utility analyses [110].

Quality of life (EQ-5D-5L/EQ-5D-5L Proxy [111]):
EQ-5D is an accepted standardised measure of health outcome that provides a single index value for health status [112, 113]. The EQ-5D is a five-item measure covering the following five dimensions: 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).

Quality of life (QUALID) [114]:
The QUALID is an 11-item scale that rates the presence and frequency of behaviours over the previous seven days. 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.

Quality of life (QOL-AD) [115]:
The adapted version of the QOL-AD[116] is a 15-item questionnaire developed specifically for use in Care Homes uses simple language and a four-response answer which is consistent across all questions (poor, fair, good, excellent). The QOL-AD has good reported internal reliability, test-retest reliability and convergent validity[[115]] andis reported to be reliable in use with people with mild to moderate dementia (11 or greater on the MMSE [[117]]. Subsequent studies have shown it is reliable and valid in people with more severe dementia (MMSE of >2) [118], [119]. The revised version includes minor changes to the 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 live with others and ability to make choices) and had good reported internal consistency [116].

Use of healthcare services (healthcare resource use measure):
This measure is adapted from one currently being piloted in a care home feasibility trial.

Clinical Dementia Rating Scale (CDR) [120]:
The CDR is a well utilised, standardised scale for rating the severity of dementia from no cognitive impairment to severe or advanced dementia [121]. Impairment on six cognitive categories is rated and an algorithm used to calculate the overall severity rating. Severity is rated by a trained assessor via informal interview/conversation with the person.

Functional Assessment Staging (FAST)[89]:
The FAST is a scale designed to capture the functional severity of dementia. It is particularly designed for use in more moderate to severe dementia when the MMSE may no longer be useful in capturing clinically meaningful changes in progression of dementia. It is completed by proxy report from a caregiver.

Agitation (Pittsburgh Agitation Scale [122]):

This is an observational rating of agitation. The scale has good reported reliability and validity [122]. Observations are conducted for between 1 and 8 hours. Data collection will be standardised to complete observations of registered (consented) residents within communal areas between 10:00 – 17:00. Observation scales have been shown to have good convergence with informant measures of agitation [123].

Work stress (General Health Questionnaire 12-item) (GHQ-12) [124]:
This is a measure of stress/psychological well-being and is used with the general population. It has good reported psychometric properties [125].
Job or role efficacy (Sense of Competence in Dementia Care Staff (SCIDS) Scale) [123]:
The SCIDS is a user-friendly, self-complete 17-item scale, across four sub-scales. It has acceptable internal consistency and test-retest reliability.

Care quality (Quality of Interactions Schedule (QUIS)) [126]:
The QUIS has reported adequate inter-rater reliability and sensitivity [127]. The QUIS will utilise researcher observations, via a time-sampling technique in each setting. In accordance with QUIS guidelines a sample of interactions over a period of time will be gathered [126, 128]. Observations will record interactions for 15-minute intervals, in communal areas in the care home. Observations will be 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 within the home. Ratings are made at the care home level on the quality and quantity of interactions.

Care home environment, context and organisation (Environmental Audit Tool (EAT) [129]):
This is an organisational climate measure and a questionnaire about additional home (size, type, ownership, geography, staff turnover, staff ratios, resident demographics, etc.), manager (qualifications, length of time in post, leadership style etc.) and staff (qualifications, length of time in post, English as first language etc.) demographics. The EAT is a valid and reliable instrument that can be used to differentiate between the quality of design in various types of dementia care facilities.

Group Living Home Characteristics Questionnaire (GLHC)[130]:
This is a measure of the style of care being delivered in the home. It examines how 'home-like' care delivered is. It includes five-subscales each containing at least three related statements.

13.7 DEFINITION OF END OF TRIAL

The end of the trial is defined as the date of collection of the last participant's last data item, where the last data collection is expected 16 months after randomisation of the last care home.

14 PROCESS EVALUATION AND ASSESSMENT OF TREATMENT IMPLEMENTATION

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

Formal assessment of treatment implementation will permit monitoring of adherence to the required components of intervention delivery and assess quality (or fidelity) of delivery.

The process evaluation and implementation assessment will support refining and improving of intervention efficacy and the sustainable implementation of the intervention over time, if the intervention is found to be effective [131]. Assessment of adherence and fidelity will utilise data from the mapping cycles (including dates of sessions, briefing documentation, feedback documentation and action plans).

Additional data will be collected at the 16 month follow-up via semi-structured interviews with 5 residents, the home manager and mappers, and separate focus groups comprising key staff and Relatives / Friends (these semi-structured interviews and focus groups will take place after the outcome data has been collected).

14.1 Resident feedback

INCLUSION CRITERIA

At the 16 month follow-up residents meeting all of the following criteria will be eligible:

1) Resident consented to taking part in the additional interview (established capacity to consent);
2) Deemed able to take part in an interview by the researcher at 16 month follow-up;
3) Provide written consent to take part in the interview at 16 month follow-up.

Eligibility waivers are not permitted.

Where there are more than 5 residents meeting the first 2 eligibility criteria, the researcher will select a random sample of 5 to approach initially until the maximum of 5 have been recruited for interview.

The interview will be conducted using a semi-structured format based on a standardised interview schedule.

14.2 Staff feedback

Staff will be recruited for the process evaluation at the 16 month data collection visit.

INCLUSION CRITERIA

Staff meeting all of the following criteria will be eligible:

1) A permanent or contracted member of staff;
2) Have participated in at least one cycle of Dementia Care Mapping™ including attending a briefing and feedback session;
3) Provide consent to participating in a tape recorded interview or focus group.

EXCLUSION CRITERIA

Staff meeting any of the following criteria will not be eligible:

4) Working in the home as agency or bank staff.

Eligibility waivers to inclusion and exclusion criteria are not permitted.

Staff eligible to participate in the data collection (i.e. interviews and focus groups) related to the process evaluation will be identified by the care home manager in discussion with the researcher. A sample of 10 eligible staff, reflecting the different roles within the care home, will be approached by the researcher to take part in a focus group. The care home manager and other key members of senior staff will be asked to participate in individual interviews.

Staff participating in the interviews or focus groups will be provided with verbal and written information about the interview/focus group and if they are willing to participate will be asked to sign an appropriate consent form. They will have at least 24 hours to decide if they are willing to participate.

The interviews/focus groups will be conducted using a semi-structured format based on a standardised interview schedule.

14.3 Mapper feedback

Mappers will consent to taking part in the process evaluation as part of their initial consent to become mappers. Mappers meeting all of the following criteria will be eligible:

1) Have completed at least one cycle of mapping within the care home;
2) Provided consent to participating in a tape recorded interview.

Eligibility waivers are not permitted.

All Mappers will be interviewed in pairs where possible. The interviews will be conducted using a semi-structured format based on a standardised interview schedule.

14.4 Relative / Friend feedback

Relatives / Friends will be recruited for the process evaluation at the 16 month data collection visit. Relatives / Friends meeting all of the following criteria will be eligible:

1) Have visited the home regularly (at least once per month) over the trial period;
2) Provide consent to participating in a tape recorded interview or focus group.

Eligibility waivers are not permitted.

Relatives / Friends eligible to participate in the data collection related to the process evaluation will be identified by the care home manager in discussion with the researcher. A sample of up to 5 eligible Relatives / Friends will be approached by the researcher to take part in a focus group held in the care home, or an individual telephone interview.

Relatives / Friends participating in the interviews or focus groups will be provided with verbal and written information about the interview/focus group and if they are willing to participate will be asked to sign an appropriate consent form. They will have at least 24 hours to decide if they are willing to participate.

The interviews/focus groups will be conducted using a semi-structured format based on a standardised interview schedule.

14.5 Data analysis and storage

The interviews and focus groups will be audio recorded using a digital audio recording device and will be professionally transcribed. During transcription, any potentially identifying information about the participant(s) that may be contained in the interview/focus group discussions will be anonymised or removed. Only the research team and the transcriber will listen to the interview audio files.

Audio files will be securely transferred in encrypted format, and securely stored at the Sponsor offices, accessible to only those members of the trial team requiring such access.

15 RESIDENT SAFETY

The baseline inclusion criteria for participating care homes will ensure that all participating homes are either already providing at least adequate person centred care or will be supported with a dementia awareness training package to enable the provision of adequate person centred care as part of their usual care provision. All participants in all care homes will therefore be receiving good

quality usual care over the course of the intervention. All residents in those care homes additionally delivering DCM^{TM} will be exposed to the potential enhancements of care related to the use of DCM^{TM} to improve person centred care practice.

Given the facts that: a) the intervention is at a care home level, b) it is very low risk and is non-invasive, and c) trial consent is purely for collection of data, there will be minimal reporting of safety data to the REC and Sponsor.

It is anticipated that the trial population (elderly care home residents) are likely to experience a number of adverse events (AEs). However, as the trial intervention confers minimal risk to residents, safety reporting will only collect adverse events serious in nature (SAEs). Safety data will only be obtained for residents whom consent to collect trial data has been obtained.

A review of resident safety will be conducted on a monthly basis following resident recruitment (registration) and Care Home Randomisation. Researchers will liaise with Care Home Managers / Research Leads to determine if any registered residents (excluding deaths/withdrawals) have experienced an SAE in that month, reporting all events highlighted for individual Residents (using resident ID) on a Safety Reporting Form. Safety data will be returned to CTRU and stored centrally. Summaries of SAEs will be reviewed annually by the trial DMEC. Urgent safety concerns will be escalated to DMEC members for interim review if necessary.

To ensure accurate reporting of serious adverse events (SAEs) an annual summary of registered resident hospitalisations with be collected via the Health and Social Care Information Centre's (HSCIC) centrally available datasets. Annual summaries will be timed to combine with the annual review of safety data by the trial DMEC.

15.1 GENERAL DEFINITIONS

An adverse event (AE) is:

- Any unintentional, unfavourable clinical sign or symptom;
- Any new illness or disease or the deterioration of existing disease or illness.

A serious adverse event (SAE) is defined in general as an untoward event which:

- Results in death;
- Is life threatening;
- Requires or prolongs existing hospitalisation;
- Is significantly or permanently disabling or incapacitating;
- Constitutes a congenital anomaly or a birth defect; or
- Is otherwise considered medically significant by a clinician.

Judgement should be exercised in deciding if an AE should be classified as serious in other circumstances. This should include other AEs that are not immediately life-threatening or do not result in death or hospitalisation, but may jeopardise the participant and may require intervention to prevent one or more of the outcomes listed under SAEs above.

15.2 DCM-EPIC OPERATIONAL DEFINITIONS AND PROCEDURES

15.2.1 Serious Adverse Events

It is expected that residents will be admitted to hospital in the event of an SAE, therefore the safety reporting form will collect information on hospitalisation, including reason, duration, and outcome of hospitalisation.

<u>Deaths</u>
We expect that around 25% of participating residents will die during the course of the trial. All

deaths occurring from the date of consent up to the last data collection visit will be recorded on a trial Death Form and reported to CTRU within 1 week of becoming aware.

All SAEs should be reported on a trial Safety Reporting form. The Safety Reporting form will be completed by the researcher during discussion with the Care Home Manager/Research Lead on a monthly basis.

15.2.2 Related and Unexpected Serious AEs

An SAE occurring to a resident which, in the opinion of the Care Home Manager / Lead and Chief Investigator, is related to research procedures and is unexpected will be reported to the main Research Ethics Committee (main REC).

The National Research Ethics Service (NRES) defines related and unexpected SAEs as follows:

- 'related' – that is, it resulted from administration of any research procedures; and
- 'unexpected' – that is, the type of event is not listed in the protocol as an expected occurrence.

Care home staff and / or researchers must report all related and unexpected SAEs (RUSAEs) to CTRU within 24 hours of becoming aware of the event. All RUSAEs will be reviewed by the Chief Investigator **within 1 working day** of CTRU becoming aware of the event and will be subject to expedited reporting to the main REC, HTA, DMEC and Sponsor by the CTRU on behalf of the Chief Investigator **within 15 days of being made aware of the event**.

For each RUSAE the following information will be collected:

- full details in medical terms with a diagnosis, if possible;
- duration (start and end dates; times, if applicable);
- action taken;
- outcome.

Any follow-up information should be faxed to CTRU as soon as it is available. Events will be followed up until the event has resolved or a final outcome has been reached.

CTRU FAX NUMBER FOR REPORTING RELATED/UNEXPECTED SERIOUS ADVERSE EVENTS: 0113 343 1471

Expedited reporting of events to the main REC and the Sponsor will be subject to current NRES guidance, CTRU SOPs and Sponsor requirements.

15.2.3 Deaths

All deaths occurring from the date of consent up to the last data collection visit should be highlighted to the study researcher by the care home (within a week of becoming aware).

Once notified the Researcher should complete a death form, and send this to CTRU within one week of becoming aware of the event.

Death reports will be reviewed by the Chief Investigator on a monthly basis. The Trial Steering Committee (TSC), Data Monitoring and Ethics Committee (DMEC), funding body (HTA) and Sponsor will be informed of deaths on a regular basis (to be agreed by the relevant parties).

Reporting of deaths will support avoidance of inappropriate contact by the researchers, with the resident's family following a death. The researcher will contact the care home to ascertain resident status prior to any contact with a Relative / Friend.

As deaths are expected within the trial population they will not be subject to expedited reporting to the main REC, unless the DMEC advises that the frequency of deaths observed within the trial population is significantly higher than that expected in the general population.

15.2.4 Responsibilities

Care Home Manager / Nominated Lead
Care home Managers or the Nominated Lead person at each participating Care Home should be vigilant for residents experiencing SAEs.

The Manager/Lead should ensure all SAEs (see section15.2.1) are reported to the researchers during monthly discussions.

The Manager/Lead should ensure timely liaison (see section 15.3) with study researchers regarding deaths and RUSAEs to ensure these are reported within specified timelines to CTRU, as per trial specific guidance which will be provided by CTRU.

Researchers
The researchers are responsible for recording all SAEs on the appropriate Case Report Form (CRF) and returning original copies to the CTRU.

Chief Investigator (CI)
The Chief Investigator is responsible for reviewing all events assessed as Related / Unexpected in the opinion of the manager / lead. In the event of disagreement between local assessment and the CI, the local assessment may be upgraded or downgraded by the CI prior to reporting to the main REC.

CTRU
The CTRU are responsible for:
- Expedited reporting of RUSAEs to the main REC and Sponsor within required timelines;
- Flagging and reviewing deaths with the Chief Investigator on a monthly basis, and escalating these to the DMEC if deemed necessary;
- Preparing annual safety reports to main REC and annual safety reports to the DMEC;
- Notifying participating care homes of Related / Unexpected SAEs which compromise participant safety.

Data Monitoring and Ethics Committee (DMEC)
The DMEC are responsible for:
- Periodically reviewing unblinded overall safety data to determine patterns and trends of events, or to identify safety issues, which would not be apparent on an individual case basis;
- Making recommendations to the TSC on whether there are any ethical or safety reasons why the trial should not continue.

Trial Steering Committee (TSC)
The TSC are responsible for:
- Consideration of recommendations of the Data Monitoring and Ethics Committee and taking appropriate action to escalate issues of concern.

Responsibilities of the Chief Investigator, CTRU, TSC, DMEC, HTA and Sponsor will be detailed in trial specific guidance.

15.2.5 Safeguarding criteria and procedures

It is possible the researchers may observe poor or potentially abusive practice while visiting the

care homes participating in the trial. The definition of abuse detailed in the Department of Health [132] guidance on procedures to protect vulnerable adults from abuse will be used to identify when observed practice may potentially be abusive. The definition states abuse is 'a violation of an individual's human and civil rights by any other person or persons … and may result in significant harm to, or exploitation of, the person' (p9). The consensus guidance on the different forms of abuse will be used by the researchers to identify practices that will be reportable. That is:

- ***physical abuse,*** *including hitting, slapping, pushing, kicking, misuse of medication, restraint, or inappropriate sanctions;*
- ***sexual abuse,*** *including rape and sexual assault or sexual acts to which the vulnerable adult has not consented, or could not consent or was pressured into consenting;*
- ***psychological abuse,*** *including emotional abuse, threats of harm or abandonment, deprivation of contact, humiliation, blaming, controlling, intimidation, coercion, harassment, verbal abuse, isolation or withdrawal from services or supportive networks;*
- ***financial or material abuse,*** *including theft, fraud, exploitation, pressure in connection with wills, property or inheritance or financial transactions, or the misuse or misappropriation of property, possessions or benefits;*
- ***neglect and acts of omission,*** *including ignoring medical or physical care needs, failure to provide access to appropriate health, social care or educational services, the withholding of the necessities of life, such as medication, adequate nutrition and heating; and*
- ***discriminatory abuse,*** *including racist, sexist, that based on a person's disability, and other forms of harassment, slurs or similar treatment.*

Any or all of these types of abuse may be perpetrated as the result of deliberate intent, negligence or ignorance. [132 p9]

Each Local Authority and care organisation has a safeguarding adults policy and process which clearly outlines the reporting process and investigation procedures for any case of suspected abuse. The appropriate local Safeguarding Adults Process documentation will be sourced for each care home upon recruitment into the trial. Given the regional recruitment of centres it is likely the majority of homes will fall under a small number of Local Authorities and so the same processes will apply for multiple homes. Should any cases of suspected abuse be observed during research site visits the appropriate local reporting process will be consulted and implemented by the researcher in consultation with and support from the Recruitment Centre Lead.

16 HEALTH ECONOMICS

The economic evaluation will be conducted by a health economist from the University of Leeds who will be blinded to treatment allocation. The proposed primary endpoint and methods for the economic evaluation follow the reference case set out by NICE [133]. The primary economic analysis will be a cost-utility analysis over 16 months presenting incremental cost-effectiveness ratios (ICER) for intervention (UC +DCM™) versus control (UC), with effects expressed in terms of quality-adjusted life years (QALY). The analysis will adopt the perspective of the service provider including the costs of health and social care. As the clinical efficacy analyses will use agitation as its primary endpoint, a secondary cost-effectiveness analysis based on change in CMAI will also be conducted. Analysis of the uncertainty surrounding the ICER will be undertaken using non-parametric bootstrap simulation (10,000 simulations) and presented on a cost-effectiveness plane. The simulated net benefit values will also allow the generation of the Cost-Effectiveness Acceptability Curve illustrating the probability that the intervention is cost-effective given a value range of NHS willingness to pay values per incremental QALY (which is commonly considered to be £20,000) [134]. Deterministic sensitivity analysis will test the robustness of the results to parameter uncertainty. For example, we will re-run analyses exploring the impact on results of different approaches to handling missing data and by altering the costs and benefits by ±20%. We will also conduct scenario analyses – for example, calculating the ICER assuming that some proportion of the care homes are provided by the private sector.

A net benefit regression approach will also be employed using the model selected for the clinical effectiveness analysis [135].

Net monetary benefit (NMB) is derived for each patient thus:

$$NMB = (\lambda * QALYs) - Costs$$

A positive incremental NMB suggests the intervention is cost-effective. NMB regression will allow traditional statistical analyses where it is possible to control for care home, user characteristics and baseline utility and agitation scores. It will also allow a clustered analysis in line with the model employed for the efficacy analysis. Assuming the intervention has no long-term benefit, costs and effects will only be calculated for the trial period with no modelling forward of benefits. Discounting at the NICE preferred rate of 3.5% per annum for costs and effects will be conducted for values post 12 months. No interim analysis is planned unless requested by the Trial Steering Committee (TSC).

Resident- and proxy-reported health-related quality of life data will be reported and analysed separately. However, given that only a proportion of residents will be able to complete the questionnaires, we will compare these two sets of reports and explore whether it is valid to use one source of data as a substitute for the other. This may help deal with missing data and ensure that we have a full set of data-points for each resident. However preference will be given to self-reported data if it is found to be reliable.

Missing values

Missing data is expected at the item, scale and visit levels. Where scales have published scoring protocols, detailing the handling of missing item data, these will be followed. If not, items will be prorated where 75% or more items for a scale are available. Mechanisms for missing data on key scales/variables will be explored and a multiple imputation model built covering the main analyses. Sensitivity analyses will explore the impact of employing different missing data handling strategies.

17 ENDPOINTS

17.1 PRIMARY ENDPOINT

The primary endpoint is agitation at 16 months following randomisation. The primary measure of agitation is the Cohen-Mansfield Agitation Inventory (CMAI) rated by staff members who know the residents well. The Pittsburgh Agitation Scale (PAS) and the abridged CMAI, rated by independent researchers, will provide concurrent validity addressing the issue of potential bias of staff responses, based on the inability to blind them to allocation status.

17.2 HEALTH ECONOMIC ENDPOINTS

Effects

Health state utilities will come from two sources. In accordance with the NICE reference case, utility will be measured using the EQ-5D and the UK general population time-trade-off tariff [136]. However, the EQ-5D may not be a suitable measure for this population as there are high ceiling effects in reports from persons with dementia and considerable patient-proxy report disparities [137]. Although NICE prefers EQ-5D utilities to be the basis of cost-utility analyses they concede that condition-specific utility may be used if it is thought the EQ-5D may not capture the intervention effects. Considering this and the short-comings of the EQ-5D, utility values will also be calculated using the DEMQOL which has recently been valued in a preference elicitation trial (HTA trial: 08/53/99 [110]). While the main cost-utility analyses will be presented using EQ-5D utility, these will be supplemented by analyses based on DEMQOL utilities. Residents will self-report where able or the EQ-5D-Proxy or DEMQOL-Proxy will be used. Our experience with this tool suggests 25-30% of residents may be able to self-report. Therefore, where possible, both versions will be collected to enable a comparison of patient and proxy reports and to allow adjustments to be made to values.

We will conduct a secondary, cost-effectiveness analysis based on change in the CMAI.

To reduce potential bias of staff who are delivering care also completing outcome measures, we will conduct a sensitivity analysis, substituting data from the resident self-report and Relative / Friend proxy-reports of outcomes measures into the analysis to evaluate whether staff under or over-report agitated behaviour, other behaviours staff find challenging and quality of life. We recognise that self-report and the proxy completion of measures by Relatives / Friends may differ from the proxy reports of staff. Therefore the sensitivity analysis will look at trends rather than utilising or expecting a like-for-like comparison of scores. We will use recommended best practice when consolidating patient and proxy reports on the EQ-5D and DEMQoL and will consult the instrument developers in each case.

Costs

The assumption for the analysis will be that the local authority pays for the provision of care home care for residents. As such these costs would be included in the healthcare provider (NHS) and social care cost perspective which will be the perspective of the main analysis. As some residents (having over a threshold amount of financial assets) will contribute to their care, we will include a sensitivity analysis where a proportion of residents are considered to pay toward their care home costs. Other cost scenarios will be explored - for example, where private care homes cover the cost of DCM™. On recruitment to the trial each care home will be asked the proportion of residents in the setting who are self-funding and the cost of a self-funded place. An average of this figure from across all care homes recruited will be used for the economic evaluation.

It is assumed that additional staff time will not be required for staff to attend DCM™ briefing and feedback sessions, but that these will be arranged at handover and other convenient times for staff to attend as part of their usual duties. It is assumed that the staff undertaking the DCM™ cycles will need a standard number of working hours to undertake the DCM™ process and that they will not be expected to be included on the care delivery rota during this time. The PAS 800 (BSI 2010) British Standard document, *Use of Dementia Care Mapping for improved person-centred care in a care provider organisation: Guide,* details the estimated amount of time a DCM™ process will take that is based on the experiences of experts using DCM™ in practice settings. This time guide will be used as the basis of the DCM™ implementation protocol provided to care homes in the intervention arm. This will be used to calculate the average staff time needed to deliver the DCM™ intervention. The total cost of DCM™ will incorporate the costs of training staff and staff time spent delivering the intervention as well as travel costs and any other expenditure (e.g. on training materials).

The final definitive resource capture strategy will be determined after discussions with care home managers and staff and after several data capture methods have been explored in the pilot phase. Researchers will collect healthcare resource use data for each resident participating in the trial at month 0, 6 and 16 months using individual care home records and care plans. This will be supplemented by care home level data collection which will enable some validation of individual-level data. Separate resource use questionnaires will be developed to capture this information. The forms will capture 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 any other costs (e.g. adapted beds and other aids). Medication use will be collected as part in the main CRFs for the trial. Finally, we will also explore resource use data capture from hospital episode statistics. Resource use will be averaged out across adjacent measurement points.

A supplementary analysis will adopt a societal perspective where we would capture any resident or family costs and care home that may be incurred, including out-of-pocket expenses and productivity loss, staff turnover and absences, etc. However, our current assessments judge that costs are likely to be low/negligible given the trial location is care home settings. This must be

weighed against the burden to resident (or staff proxies) and Relative / Friend participants of completing regular questionnaires about costs and may mean capture of this data is not worthwhile. However, we will consult with our service user and carer (PPI) representative group regarding potential costs to residents and family carers and the potential for capturing this within the trial.

Unit costs for health service staff and resources will be obtained from national sources such as the Personal Social Services Research Unit, the British National Formulary and NHS reference cost database. Should national costs not be available the finance departments of the care homes involved will be requested to provide local cost data. The mean of these costs will be used as the unit cost estimate in the analysis. We will use the National Institute for Health and Care Excellence (NICE) willingness to pay per incremental QALY threshold (Lambda [λ] =£20,000) to determine cost-effectiveness. Interventions with an ICER below the threshold range of <£20,000 - £30,000 per QALY will generally be considered cost-effective.

17.3 SECONDARY ENDPOINTS

Secondary endpoints relating to residents are:

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

Secondary endpoints relating to staff are:

- General Health Questionnaire (GHQ-12);
- Sense of Competence in Dementia Care Staff (SCIDS) Scale.

Secondary endpoints relating to homes are:

- Intervention Fidelity;
- Quality of Interactions Schedule (QUIS).

All other data are potential mediators or moderators of the treatment effect.

18 STATISTICAL CONSIDERATIONS

18.1 SAMPLE SIZE

These calculations assume an average of 40 residents in each care home and that at least 60% of these (i.e. 24) will meet the eligibility criteria. We estimate that 65% of those eligible will be willing to provide informed consent, therefore, we anticipate that 15 participants can be recruited from each care home. The sample size calculation is based on the primary outcome measure - the difference between randomised groups in mean CMAI scores at 16 months. We calculate the number of participants required based on detecting a moderate standardised effect size of 0.4. If we assume the SD will be similar to that observed in a recent trial in UK care home (7.5 points, [61]), the moderate effect size translates to a minimum difference to be detected of 3 points. If we observe greater variation in CMAI scores, such as the SDs ranging from 15 to 20 points as reported by Zuidema [105], then for the same effect size we will be able to detect a difference of 6 to 8 points respectively. A difference of 8 points on the CMAI is seen as indicative of real behavioural change [105]. Fifty care homes, each recruiting 15 participants, will result in 750 participants overall and provide 90% power at 5% significance level to detect a clinically important difference of 3 points (SD 7.5 points). The sample size takes account of 25% loss to follow-up (as seen in Chenoweth et al., [58]) 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 [61]). The assumption that the ICC will be no larger than 0.1 is based on an ICC for CMAI reported by Fossey et al. [61] when evaluating the effectiveness of psychosocial care on antipsychotic use in nursing home residents with dementia. If the loss to follow-up is higher than anticipated (but no greater than 35%), the sample size of 750 participants will still provide more than 85% power at the 5% significance level to detect the moderate effect size of 0.4. As provision of care is a further source of clustering, the ICC is anticipated to be higher in the intervention arm, so an allocation ratio of 3:2 will be used, giving 30 (450) and 20 (300) care homes (participants) in the treatment and control arms respectively, 50 (750) overall.

18.2 ACCRUAL

Recruitment hubs will be located in West Yorkshire, London and Oxford facilitating recruitment from Yorkshire, London, the South East and the South West. Selection of care homes will be facilitated by review of publicly available data (i.e. CQC, www.carehomes.co.uk) immediately prior to commencement of recruitment, to ensure appropriate sampling of potentially eligible care homes.

A process of care home recruitment (as described in section 7.2) will be followed and repeated, if necessary, until a sufficient number of care homes are selected. This trial is low risk and therefore we can assume higher consent rates than for higher risk or invasive studies. Sixty per cent is a conservative estimate of the number of residents with probable dementia who will meet the eligibility criteria in most care homes. Dementia specialist homes will have 100% of residents with dementia. The trial hubs have a sufficient care home population and the trial team members have sufficient contacts within their geographical area to support the required recruitment. Therefore, difficulties recruiting the required 50 care homes and 15 residents in each home are not anticipated. However, reserve homes in each locality will be kept on record and approached should recruitment rates fall below those needed. Recruitment will be phased with an estimated 4-5 homes initiated each month. It is anticipated that twenty-one homes will be recruited from the West Yorkshire hub and twenty-nine homes from across the London and Oxford recruitment hubs.

19 STATISTICAL ANALYSIS

19.1 GENERAL CONSIDERATIONS

Statistical analysis of the quantitative elements of the trial is the responsibility of the CTRU Statisticians. The analysis plan outlined in this section will be reviewed and a Statistical Analysis Plan (SAP) will be approved before any formal analysis is undertaken. The SAP will be drafted in accordance with current CTRU standard operating procedures and will be finalised and agreed by the trial statistician and supervising statistician, the Chief Investigator, and other appropriate members of the research team. Any changes to the final SAP, and reasons for change, will be documented.

Missing data is expected at the item, scale and visit levels. Where scales have published scoring protocols, detailing the handling of missing item data, these will be followed. If not, items will be prorated where 75% or more items for a scale are available. Mechanisms for missing data on key scales/variables will be explored, with the proportion of missing data to be compared between intervention and control groups, and a multiple imputation model built covering the main analyses. As it is expected that a sizeable proportion of residents will be missing from the main analyses, and that missing data can be predicted by known variables, the principal method for handling missing scale data will be multiple imputation under the Missing at Random (MAR) assumption. Sensitivity analyses will be carried out to assess the impact of the choice of imputation model and of assuming data are Missing Not at Random (MNAR), as appropriate.

As the primary clinical effectiveness analysis involves a single primary outcome and a single treatment comparison, there are no multiplicity considerations for the primary analysis and a 2-

sided 5% significance level will be used. Where results are combined when interpreting the treatment effect (e.g. across secondary outcomes), consideration will be given to the family-wise error rate and appropriate adjustments made.

Randomisation of care homes to treatments and provision of DCM™ to care homes impose clustering effects, whereby resident outcomes are expected to be correlated. The impact of cluster randomisation is expected to be equal across arms but that of treatment provision is not. As such, the principal method for handling clustering effects will be to fit a multilevel model that allows care home and resident level variances to differ across arms. Sensitivity analyses will be conducted fitting a random intercept model assuming equal total variances.

19.2 FREQUENCY OF ANALYSES

No formal interim analyses are planned. Blinded interim reports will be presented to the TSC and DMEC containing descriptive information. This will include data on recruitment, follow-up, adherence, safety and data quality. This will be presented by randomised arm if specifically requested as such. A single final analysis is planned when all follow-up data has been databased, cleaned and locked.

19.3 ANALYSIS POPULATIONS

The primary analyses will be carried out on an intention to treat basis, utilising all available follow-up data, comparing allocated treatments. A complier average causal effect (CACE) analysis, comparing treatments received, will be considered if more than 10% of care homes do not implement the intervention as intended. This decision will be made without reference to the effectiveness data.

19.4 PRIMARY ANALYSIS

The resident-level primary outcome of agitation (continuous CMAI score) will be analysed at 16 months post randomisation using a linear two-level heteroscedastic regression model (allowing the care home and resident variances to differ across arms), adjusting for design factors, with a contrast for intervention and control. The model will be adjusted for the following fixed effects: care home covariates (home type and size, provision of dementia awareness training and prior use of DCM™ in the home) – level 2, and resident level covariates (severity of dementia, age and baseline CMAI score) – level 1. Unadjusted and adjusted ICCs, estimates and corresponding 95% confidence intervals will be presented.

19.5 SECONDARY ANALYSIS

Secondary outcome measures (Behaviours Staff find Challenging, mood, use of antipsychotic drugs, and use of other psychotropic drugs, resident quality of life, staff well-being and role efficacy, care quality and the quality of staff/resident interactions) will be analysed using a similar modelling strategy as described for the primary analysis. Where outcomes are continuous, linear models will be fitted; where binary, logistic models will be fitted. Continuous distributions will be transformed where residuals are non-normal. Change in primary and secondary outcomes over time (6, 16 months) will be analysed with three-level multilevel models with contrasts for treatment, time and the treatment-by-time interaction, in which outcomes are nested within residents and care homes. A similar correlation structure will be assumed for care homes and residents, but correlation over time will also be considered at the outcome level.

19.6 SUB-GROUP ANALYSES

A number of exploratory sub-group analyses are planned which will be specified in detail in the Statistical Analysis Plan. These will include care home and resident level factors such as type of care home, severity of dementia and NPI subgroup clusters.

20 TRIAL MONITORING

20.1 DATA MONITORING

Data will be monitored for quality and completeness by the CTRU, using established verification, validation and checking processes. Missing data, except individual data items collected via questionnaires, will be chased until they are received, confirmed as not available, or the trial is at analysis.

Inter-rater reliability will be established between researchers prior to commencing the trial. Independent rating of a random sub-sample of interaction quality judgements will be made from researcher notes, by another researcher, to ensure on-going reliability of use of the tool throughout the trial.

The CTRU/Sponsor reserves the right to intermittently conduct source data verification on a sample of residents, staff and care homes. Source data verification will involve direct access to resident notes at participating care homes and other relevant investigation reports.

A monitoring schedule will be defined and agreed by the DMEC, TSC and TMG. This will detail the timing and content of reports to these committees and will include:

- Screening (of care homes and residents including reasons for exclusion and barriers);
- Recruitment (registrations, randomisations, refusals; rates per month);
- Resident, staff and Relative / Friend retention;
- Data quality/completeness (in particular the key data items);
- Protocol adherence (including intervention adherence);
- Safety;
- Losses to follow-up due to death, withdrawal and loss of contact;
- Variance of the primary outcome
- Evidence of training requirements, outliers or bias in relation to the primary outcome, using reference data from the abridged CMAI and the PAS.

A Quality Lead for the trial will be responsible for researcher training and ensuring inter-rater reliability on measures throughout the trial.

20.2 DATA MONITORING AND ETHICS COMMITTEE

An independent DMEC will be established to review the safety and ethics of the trial. Contents of the unblinded reports will be agreed between the DMEC and CTRU at the DMEC meeting during set-up. These annual reports will be prepared by the CTRU for the DMEC during recruitment and follow-up and details of these will be specified in the DMEC Analysis Plan.

20.3 TRIAL STEERING COMMITTEE (TSC)

A TSC will be established to provide overall supervision of the trial, including trial progress, adherence to protocol, resident safety, and consideration of new information. The committee will meet once during the set-up period and six monthly thereafter for the duration of the trial, unless further meetings are called by the Chief Investigator (CI) where additional advice on trial conduct or management is required.

The TSC will include an independent Chair, at least two independent members with appropriate methodological and clinical expertise (including knowledge of adult safeguarding procedures), two patient and public involvement representatives (ideally a carer and person with dementia), the CI and other relevant members of the Trial Management Group. An observer from NIHR will be invited to attend each TSC meeting. A representative from the host institution (University of Bradford) will attend as an observer.

20.4 CLINICAL GOVERNANCE ISSUES

The Sponsor for the trial is Leeds Beckett University. The Sponsor will ensure responsibility and accountability for trial conduct and procedures associated with the protocol. Individual care homes remain responsible for participant care as usual. Trial Researchers will have the opportunity to highlight any safeguarding issues of concern with the TSC and to individual care homes, in line with relevant guidance from the local authority, care home, and the trial team.

21 QUALITY ASSURANCE AND ETHICAL CONSIDERATIONS

21.1 QUALITY ASSURANCE

The trial will be conducted in accordance with the principles of the ENRICH toolkit, Good Clinical Practice (GCP) in clinical trials, and through adherence to CTRU Standard Operating Procedures (SOPs) and trial specific guidance implemented to ensure delivery of the trial in accordance with this protocol.

21.2 SERIOUS BREACHES

Care Home staff and Researchers are required to promptly notify the CTRU of a serious breach (as defined in the latest version of the National Research Ethics Service (NRES) SOP). This is defined as a breach of the protocol or of the conditions or principles of GCP which is likely to affect to a significant degree the safety or physical or mental integrity of the trial subjects, or the scientific value of the research.

In the event of doubt or for further information, Staff and Researchers should contact the Trial Manager at the CTRU (who will escalate any concerns in line with CTRU Standard Operating Procedures).

21.3 ETHICAL CONSIDERATIONS

The trial will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland, 1996. Informed written consent will be obtained from the care homes, staff and residents prior to entry into the trial. The right of participants to refuse participation, without giving reasons, must be respected. The participant must remain free to withdraw at any time from the trial without giving reasons and without prejudicing the further treatment or involvement of residents or other staff members. The trial will be submitted to, and approved by, a main REC and will obtain appropriate local permissions for each participating care home prior to entering residents into the trial. The CTRU and / or Chief Investigator will provide the main REC with a copy

of the final protocol, resident, Relative / Friend and staff information sheets, consent forms and all other relevant trial documentation.

21.4 RESEARCH STAFF TRAINING

All staff collecting research data will complete a comprehensive training program which will cover good clinical practice (GCP) for research, mental capacity and consent, training in the specific instruments used in the trial, safeguarding and ethical issues. The training will be supported by standardised guidance, summarising the key issues covered in the training program and stating the key rating rules for each of the instruments. The training programme will also include DVDs showing each of the assessment instruments being completed. Inter-rater reliability checks between the researchers, for completion of the outcome measures, will be undertaken using case studies and DVD training materials for the primary outcome and key secondary outcome measures. The training sessions will also be filmed so that refresher sessions can be undertaken at each centre and to enable the training of any new researchers who join during the trial.

21.4.1 Capacity to Consent

All researchers will receive appropriate training on the consent processes and protocols prior to recruitment of residents with dementia and their Relatives / Friends to the trial. Where they do not already have prior expertise in this area, the researchers will receive specialist training on assessing capacity to consent in accordance with the Mental Capacity Act [90], from clinical experts, as well as training in advanced communication techniques that can help to facilitate the consent process with people with dementia.

21.4.2 Data Collection Tools and Scales

Training will be provided to all the researchers on correct use of all tools and scales by the KCL recruiting site lead. This will include achieving appropriate levels of inter-rater reliability on each tool.

21.4.3 Good Clinical Practice

Researchers should work to the principles of MRC Good Clinical Practice.

Should researchers observe any potentially harmful or abusive practice in any of the settings during the research, they will follow required reporting procedures.

22 CONFIDENTIALITY

All information collected during the course of the trial will be kept strictly confidential. Information will be held securely on paper and electronically at the CTRU. The CTRU and the trial researchers will comply with all aspects of the 1998 Data Protection Act and operationally this will include:

- Consent from participants to record personal details including name, date of birth, address and telephone number (for all participants), GP name and address (for resident participants).
- Appropriate storage, restricted access and disposal arrangements for participant personal and clinical details.
- Consent from residents to access their medical records by responsible individuals from the research team, where it is relevant to trial participation.
- Consent from participants for the data collected for the trial to be used to evaluate safety and develop new research.
- All Resident data collection forms (baseline, 6 months, 16 months) will be transferred to or from the CTRU with identification numbers and two other identifiers, usually the participant's initials and date of birth.
- All Staff and Relative / Friend data collection forms completed at Baseline will be transferred to or from the CTRU with two identifiers, usually the participant's initials and date of birth. Follow-up (6 / 16 months) data collection forms will be coded with identification numbers in addition to the two identifiers.
- Where anonymisation of documentation is required (i.e. removing cover sheets with names to help to ensure correct linkage with identifiers), care homes and researchers are responsible for ensuring only the instructed identifiers are present before sending to CTRU. Any identifiable data will be sent separately to trial data.
- Researchers must ensure that data sent to CTRU and to the Sponsor organisation is done so in line with trial specific guidance provided, and in line with the principles of the 1998 Data Protection Act.

22.1 ARCHIVING

At the end of the trial, data collected for the purposes of the trial will be securely archived at the CTRU for a minimum of 5 years (arrangements for confidential destruction will then be made).

23 STATEMENT OF INDEMNITY

This trial is sponsored by Leeds Beckett University and Leeds Beckett University will be liable for negligent harm caused by the design of the trial. The Care Home organisation has a duty of care to residents, whether or not the resident is taking part in a clinical trial, and the Care Home remains liable for clinical negligence and other negligent harm to residents under this duty of care.

Further details regarding Sponsor Indemnity please contact the Sponsor (details listed under Key Contacts).

24 TRIAL ORGANISATIONAL STRUCTURE

24.1 RESPONSIBILITIES

Detailed responsibilities are outlined in relevant Organisational sub-contracts, below provides a summary of general responsibilities.

Sponsor
The Sponsor (Leeds Beckett University) is the organisation that takes responsibility for arrangements to initiate, manage, monitor and finance the trial. The Chief Investigator is based at Leeds Beckett University.

Chief Investigator
The Chief Investigator is responsible for the design, management and reporting of the trial.

Clinical Trials Research Unit (CTRU)
The CTRU are responsible for the day to day conduct of the trial in accordance with the Research Governance Framework, where applicable, MRC GCP standards and the principles of CTRU SOPs.

Recruitment Centre Leads
Recruitment Centre Leads will be responsible for management of the researchers, recruitment of the care homes within their locality and ensuring accurate and effective implementation of the research protocol within their recruitment centre.

Health Economists
The Health Economics collaborators will assist the TMG in protocol and CRF development and will be responsible for the selection and/or design of the economic questionnaires, collation of unit costs, and the conduct, interpretation and writing up of the economic evaluation.

Care Homes
Care Homes will be the key collaborators for this trial. Each home will have close links with the researcher and CTRU via the Trial Manager. They will be responsible for adhering to this research protocol including identifying appropriate staff to be trained in DCM™, maintaining lists of staff, residents and Relatives / Friends prior to consent being obtained for trial participation, allowing staff time to complete data with researchers, implementing DCM™ in accordance with the research protocol.

Researchers
Trial-specific researchers will have responsibility (alongside the relevant care home staff) for the identification, consent, assessment and follow-up of residents, Relatives / Friends and staff in the trial.

DCM™ Experts
Experts in use of DCM™ will be responsible for helping trained mappers in each intervention arm home to undertake their first round of mapping in accordance with the standards set out within the research protocol and additional guidance. This will include establishing an adequate level of inter-rater reliability and supporting completion of the DCM™ process in accordance with specified intervention fidelity indicators.

Trial Manager
The Trial Manager will be responsible for the day to day co-ordination of the trial. He/she will be based within the CTRU and his/her role will include administrative tasks for gaining ethical approval, ensure sites and researchers have relevant essential documents and guidance, liaison with the trial team and trial recruitment hubs.

KCL Recruiting Site Lead
The KCL Recruiting Site Lead (or delegate) will be responsible for training of the researchers to use the data collection tools and scales and ensuring initial and on-going inter-rater reliability of scoring.

Treatment Leads (UC and DCM™)
Standardisation of UC and DCM™ will be overseen across the trial by the Treatment leads for UC and DCM™ respectively.

24.2 OPERATIONAL STRUCTURE

Trial Management Group (TMG)
The TMG, comprising the Chief Investigator, CTRU team and co-investigators will be assigned responsibility for the clinical set-up, on-going management, promotion of the trial, and for the interpretation of results**.** Specifically the TMG will be responsible for (i) protocol completion, (ii) CRF development, (iii) obtaining approval from the main REC, and supporting the care home approvals process, (iv) completing cost estimates and project initiation, (vi) appointing and facilitating the TSC, (vii) reporting of serious adverse events, (vii) monitoring of screening, recruitment, consent, and follow-up procedures, safety, data quality and compliance, and (viii) interpretation of results and contribution to publications.

Clinical Trials Research Unit (CTRU)
The CTRU will provide set-up and monitoring of trial conduct to CTRU SOPs and MRC GCP standards including randomisation design and implementation, database development and provision, protocol development, CRF design, trial design, monitoring schedule and statistical analysis of clinical endpoints for the trial. In addition the CTRU will support main REC and care home approval submissions and set-up, ongoing management including training, monitoring reports and promotion of the trial(in collaboration with Hub Leads and Researchers). The CTRU will be responsible for the database administrative functions, data management, safety reporting, all statistical analyses of clinical endpoints and drafting of publications. The CTRU will have responsibility for the conduct of the trial in accordance with the Research Governance Framework and CTRU SOPs.

Trial Steering Committee (TSC)
The Trial Steering Committee, with an independent Chair, will provide overall supervision of the trial, in particular trial progress, adherence to protocol, patient safety and consideration of new information in accordance with the TSC Terms of Reference.

Data Monitoring and Ethics Committee (DMEC)
The DMEC will review the safety and ethics of the trial by reviewing data during the recruitment and follow-up periods in accordance with the DMEC Terms of Reference.

25 PATIENT AND PUBLIC INVOLVEMENT

Service users and carers will play an integral role throughout this programme of research to ensure the work is based on the principles of Patient and Public Involvement (PPI). PPI will be fulfilled in partnership with the Alzheimer's Society via involvement of members of their Research Network, and via inclusion of PPI representatives (relatives and persons with Dementia) on the Trial Management Group. Specifically PPI representatives will be involved in the review of participant information and general aspects of trial design. They will input to the content of the basic dementia awareness package for care home staff and have involvement in all decisions made by the TMG. Where recruitment issues are identified they will be consulted regarding barriers and opportunities to improve recruitment, as well as advising on appropriate researcher approaches to residents and their family and friends. The intention is to involve service users in the interpretation of results and appropriate dissemination of information at the end of the trial.

26 PUBLICATION POLICY

The trial will be registered with an authorised registry, according to the International Committee of Medical Journal Editors (ICMJE) Guidelines, prior the start of recruitment.

A detailed publication policy will be developed and agreed by the Trial Management Group (TMG) and Trial Steering Committee (TSC) in line with the funding body (NIHR HTA) and Sponsor requirements.

The success of the trial depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated in the trial, through authorship and contributorship. Uniform requirements for authorship for manuscripts submitted to medical journals will guide authorship decisions. These state that authorship credit should be based only on substantial contribution to:

- conception and design, or acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content;
- and final approval of the version to be published;
- and that all these conditions must be met (www.icmje.org).

In light of this, the Chief Investigator, Recruitment Centre Leads and relevant senior CTRU staff will be named as authors in any publication. In addition, all collaborators will be listed as contributors for the main trial publication, giving details of roles in planning, conducting and reporting the trial. Authorship of other publications associated with the trial will be decided taking into account the above authorship and any additional funder requirements.

To maintain the scientific integrity of the trial, data will not be released prior to the first publication of the analysis of the primary endpoint, either for trial publication or oral presentation purposes, without the permission of the Trial Steering Committee. In addition, individual collaborators must not publish data concerning their participants which is directly relevant to the questions posed in the trial until the first publication of the analysis of the primary endpoint."

NIHR Health Technology Assessment (HTA) programme requirements

In accordance with the NIHR HTA programme's requirements, all materials to be submitted for publication (written, audio/visual and electronic) should be sent to the NIHR Co-ordinating Centre for HTA (NCCHTA) at the time of submission or at least 28 days before the publication date, whichever is earlier. This applies to all publications regardless of whether or not the primary results have been published.

All publications must acknowledge NIHR HTA as the trial's funding source and include an appropriate disclaimer regarding expressed views and opinions (example text is provided on the HTA website).

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