CHALLENGE ResCare

TRIAL PROTOCOL

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ISRCTN02553381

1. Trial Identifier

1.1. Short Title: Challenge ResCare

1.2. Full Title: A cluster randomised trial of a dementia - challenging behaviour web-based training and decision support system, for staff working in residential and nursing homes

2. The need for a trial

The trial will be one of a series of inter-related studies that compose the National Institute for Health Research Programme entitled *Challenge Demcare (dementia care for 'behaviours that challenge')*. The aim of this trial is to test a web-based training and decision support system for care home staff supporting people with dementia. This system will provide them with 24-hour access to specialist knowledge of functional analysis-based intervention for challenging behaviours in dementia. In this context, challenging behaviours are the behaviours of people with dementia that are seen as difficult to manage or cope with within the care home, owing to environmental, resource and/or interpersonal factors. Such behaviours are also referred to as 'behaviours that challenge',[1] reflecting the interaction between staff distress and distress in the person with dementia; or, according to bio-medical constructs, as 'behavioural and psychological symptoms in dementia (BPSD)'. [2 3]

The trial will be important because:

- In the UK the cost of the target condition (dementia) is estimated at £18 billion per annum with numbers of people with dementia forecast to increase from current estimates of 680,000 to 940,000 by 2021. [4]
- "Challenging behaviours" (CB) or "Behavioural and Psychological Symptoms of Dementia" (BPSD) are common and constitute significant problems in providing care for dementia sufferers. Prevalence rates for CB / BPSD are over 90% during later stages of the illness, [5] resulting in breakdown of care at home, admission to long term care, hospital admissions, relocation across care homes [6,7] and increased costs;[8]
- In the UK there is an acknowledged need for greater knowledge of ways to support staff in the management of CB. The NICE - SCIE Guideline 'Dementia: Supporting People with Dementia and their Carers' [9] recommends 'specific behaviour analysis conducted by trained professionals for family carers and care staff';
- Intervention models to meet this need have not been fully developed or properly evidenced.

Hence there is a substantial gap between the policy aim and current practice. This trial of a systematic protocol for behaviour management and staff training, with its economic evaluation component, will make a significant contribution to addressing that gap.

2.1. The problem to be addressed

The trial will address the need for evidence-based interventions in the management of CB in dementia. Pharmacological treatments to control BPSD have been widely used for a number of years. However this practice has raised major concerns about the resulting increased risk of adverse events including cerebro-vascular events, falls, accelerated cognitive decline and reduced quality of life for the people with dementia. [10,11] The increased risk of mortality in people with dementia who are prescribed antipsychotic medication has highlighted the need for less hazardous alternatives in the long-term management of BPSD. [12] [13]

The increased long-term risk of mortality in people with dementia who are prescribed antipsychotic medication has highlighted the need for less hazardous alternatives in the long term management of BPSD. [14] [15] The National Service Framework for Older People[16] reinforces the growing emphasis on 'behavioural management' as a first line approach and 'Everybody's Business: Integrated Mental Health Services for Older Adults'[17] recommends training and support for care staff in what can be an emotionally demanding area of work. Functional analysis[18,19,20,21] is an individually-tailored psychological treatment for CB developed to support family and staff carers and has been recommended as the treatment of choice.[22] One study of staff training in the use of functional analysis in care homes showed initial improvements (i.e. reduction in CB following training) but this was not sustained a year later, possibly due to staff turnover or reduced access to ongoing training and support over time.[23] There are no other UK studies showing significant improvements in CB following use of functional analysis-based interventions in dementia. This trial will address that problem by testing the effectiveness of a protocol-driven training and decision support system based on functional analysis and developed for use by staff in care homes. The system will be web-based, thus allowing staff ongoing access to training and support.

2.2. Principal research questions to be addressed

2.2.1. Primary Question

Does the experimental intervention reduce the frequency and severity of reported CB in people with dementia in care homes?

2.2.2. Additional Research Questions:

Does the experimental intervention:

- Reduce the emotional impact of CB on care home staff?
- Result in care home staff having a more positive and person-centred attitude to people with dementia?
- Improve staff self-efficacy in caring for people with dementia?
- Enhance quality of life in care home residents as a whole (including those without dementia)?
- How cost-effective is the experimental intervention in terms of:
    - reducing CB?
    - its cost per Quality Adjusted Life Year (QALY) relative to usual care?

2.3. Why the trial is needed now

The government has identified dementia as a national priority. One of the objectives in the Department of Health's Dementia Care Strategy[24] is improving quality of care for people with dementia living in care homes, and more specifically to ensure an informed and effective workforce. Given that it is estimated 200,000 people[25] with dementia live in residential or nursing care homes in England alone[26], the development of new interventions to improve dementia care is particularly relevant. In addition, the 2006 NICE-SCIE Guideline identified an urgent need for research to improve the evidence base on four topics before the scheduled guideline update. The Challenge ResCare trial directly addresses one of these identified research priorities, namely: Does training of staff in dementia-specific person-centred care reduce both challenging behaviour in people with dementia and the prescription of medication to control such behaviour in comparison with current practice? (pp 37-38). This timely trial will test, and if successful make available, a new dementia-specific, psychologically-based treatment option for people with a common and highly debilitating condition.

2.4. Relevant systematic reviews

There are systematic reviews of: the association between BPSD and burden of care[27]; the effectiveness of non-pharmacological interventions in general and as a first line approach to the management of CB in particular[28]; and functional analysis - based interventions for CB in dementia. [29] These all support the need for this trial.

2.5. How the results of this trial will be used

If the intervention is successful in reducing challenging behaviours in dementia, the results of the trial may be used locally in the development of services within the area of the study, and more widely to support dissemination and implementation of the web-based training and decision support system, not only across the UK, but in English-speaking countries across the world, and, with subsequent translation and modification, world-wide.

2.6. Risks to the safety of participants in the trial

Though we expect no risks to the safety of participants in this trial, this will be monitored as part of the research. We shall adopt a standard operating procedure for reporting serious adverse events very similar to those in use in parallel NIHR trials. Furthermore, a multi-disciplinary clinical team including old age psychiatrist, elderly medicine physician, specialist mental health pharmacist, clinical psychologist and CMHN will take responsibility for risk management.

3. The Proposed Trial

This pragmatic cluster randomised trial will evaluate an interactive, web-based training and decision support system developed to help care home staff to manage CB in people with dementia living in care homes. The trial will include a cost-consequence analysis.

3.1. The proposed trial design

This will be a pragmatic cluster-randomised controlled trial testing the experimental intervention with a sample of residents receiving long-term care in care homes for older people. The sample will be cluster-randomised by care home, with all recruited residents in a given care home being allocated to either the experimental or control arm. **Appendix 1** is a flow diagram showing the stages of the trial**.**

3.2. The planned trial interventions

3.2.1. Experimental

Participants in the experimental arm (i.e. all residents in homes randomised to receive the intervention) will be cared for under a regime in which care staff have:

- access to the web-based training and decision support system designed for the trial; and
- continued access to the web-based system to guide their care plans for residents with CB during the trial;

Appendix 2 describes the experimental intervention in more detail.

3.2.2. Control

Participants living in homes allocated to the control arm will receive long term care from care staff 'as usual'. Staff working in these homes may have access to training materials available commercially and from organisations such as the Alzheimer's Society as well as training courses that are offered by a variety of providers. Information on such training will be recorded and collated.

3.3. Proposed practical arrangements for allocating participants to trial groups

3.3.1. Identification of homes (clusters)

The trial will initially be conducted in North and East Yorkshire, including the cities of Hull and York. Within the trial area, an invitation to participate in the trial will be sent to care homes with 25+ beds listed on the website of the Care Quality Commission (CQC)[30] as old age care homes, with a rating of 'good' or 'excellent', (a) with nursing care and (b) without nursing care. Homes specialising in care of residents with dementia will not be excluded. Thus, for the geographical area in which this trial will take place, almost 80% of the homes listed on CQC as having 25+ beds would be eligible for inclusion in this study. The inclusion criterion of a rating of 'good or excellent' allows an assumption that there is a certain level of consistency in terms of quality of care across the homes. In the event that it proves impossible to recruit sufficient homes in this area to yield the desired participant sample, the trial will either be extended to other areas in the UK, or to homes rated lower than 'good' by CQC.

Prior to speaking to staff and residents in a specific care setting, the company owning the home will be contacted to achieve organisational support, where possible. Once the appropriate support has been obtained, the home manager will be contacted and the implications of participating in the study will be discussed. Assuming the home manager agrees, each home will then be visited by a member of the research team, when the trial will be explained in detail and a questionnaire collecting data on the home, its staff, its services and its resident population (i.e. descriptive data), will be administered.

3.3.2. Recruitment of participating staff

As outlined below, trial subjects will be care home residents. However the care home staff will also act as research participants. They will be required to act as 'informants' for participating residents as well as to provide data on themselves as participants. Some will also be recipients of the experimental intervention. As each home is recruited to the trial, explanation of the research, and information sheets, will be given to all staff, who will then be asked to provide written consent to take part in the study.

3.3.3. Recruitment of home residents

The home manager will be asked to provide a list of residents and to indicate those who fall within the primary exclusion criteria described in Section 3.5. Once an initial challenging behaviour screen has been completed for all residents with care staff and it has been established that there are sufficient numbers of residents with challenging behaviours for the home to be eligible (as per section 3.3.5), a member of the research team will then approach residents to explain the study, give information leaflets, and obtain written consent. Residents will be given as long as they wish to consider taking part. This will provide the option of consent being taken as soon as the information sheet and explanation of the study has been given if that was agreed with the resident, but will also allow for longer periods too. Residents will have the opportunity to ask questions and researchers will ensure that they have understood the information they are given and if the resident is then happy to proceed consent will be taken. However the researchers will ask if the resident wishes to be given additional time to consider taking part and if so will then return to take consent following whatever period the resident requested. Appropriate procedures will be used where residents lack capacity to give their consent (see **Appendix 3** "Consent and the Mental Capacity Act").

Numbers of homes and of potential participants will be recorded at all stages of the trial, for example, homes and people who did not meet the inclusion criteria, people who refused to give consent to be included in the trial and those that went through to follow-up. As per the CONSORT (Consolidated Standards of Reporting Trials) statement[31], this is needed to enable a flowchart of participants through each of the stages to be produced.

As noted above, care staff will be interviewed for two purposes – as informants to provide information on residents and in their own right. A list will be drawn up with the help of the home manager, allocating previously consenting care staff to groups of residents for whom they can act as informants. In doing this, every effort will be made to ensure care staff members have to act as informants for approximately equal numbers of residents, and to include as many members of care staff as possible.

Interviews will be carried out with each of the residents that have agreed to take part; an attempt will be made to do this interview in all cases, including those admitted to the study following Mental Capacity Act procedures.

(Prior to individual interviews with residents an abbreviated Challenging Behaviour Scale will be completed by staff in relation to all residents as part of the home screening process to determine whether the home is eligible.)

- **In homes with sufficient numbers of people with challenging behaviour interview with residents will include the following:**
  1. brief 'demographic' information and personal history;
  2. EuroQol -5D (EQ-5D) [32];
  3. Quality of Life in Alzheimer's Disease (QOL-AD) [33];

The interviews with relevant staff acting as informants for residents will be undertaken in blocks after the residents have consented to take part. These will be split into the following sections:

- **In relation to each resident for whom the staff member is acting as informant:**
  1. Brief demographic information and personal history of resident
  2. EQ-5D (proxy version)
  3. QOL-AD (informant elements)
  4. DSM-IV
  5. Challenging Behaviour Scale (CBS) [34]

  And for those selected for inclusion in the challenging behaviour sample (see section 3.3.4.) then the following additional measures will be taken:
  6. Neuropsychiatric Inventory with Caregiver Distress Scale (NPI-D) [35]
  7. Clinical Dementia Rating [36]
  8. Cohen-Mansfield Agitation Inventory (CMAI)[37]
  9. (Adapted) CSRI [38]
  10. Structured Medication Inventory (SMI

- **In relation to the staff member**:
    1. Brief demographic and personal history
    2. EQ-5D
    3. Attitudes to Dementia (ADQ) [39]
    4. Maslach Burnout Inventory (MBI), Human Services Survey [40]
    5. Self-Efficacy Scale [41]
    6. (Adapted) Client Service Receipt Inventory (CSRI) [42]
    7. Visual, Auditory, Kinesthetic (VAK) Learning Styles Self-Assessment Questionnaire [43]

3.3.4. Selection of participants with CB

Sample requirements have been calculated in relation to the subset of residents in participating homes who exhibit CB at the time of initial assessment. Participants may be selected for inclusion in the **CB sample** if they:

- Meet the diagnostic criteria for dementia, based on DSM-IV; AND
- Score at least 4 for 'number of problems' on the CBS; AND
- Score at least 4 for the 'management difficulty' domain of the CBS.

The CBS cut-points have been selected following examination of data from two relevant studies. [44, 45]

3.3.5. Randomisation

Remote randomisation of homes between experimental and control groups will be undertaken by the North Wales Organisation for Randomised Trials in Health (N-WORTH), which is a trials unit recognised by the UKCRC and funded by the Clinical Research Collaboration Cymru (the Welsh arm of the UKCRC) notably for trials in neurology and dementia.

Once all the homes have been screened and agreed to take part the fieldwork team will provide N-WORTH with the following information about the care homes:

- ID number of each home;
- number of registered beds;

N-WORTH will randomly allocate the homes to experimental or control arm, stratifying for size of home and inform the appropriate member of the research team of the result.

Additional homes in other areas of England may be recruited as the trial progresses if it becomes apparent that this will be necessary to achieve the required CB sample.

3.4. Proposed methods for protecting against other sources of bias

It will not be possible to guarantee that the fieldwork team will be blind to the status of the homes (experimental or control), since staff training and support for use of the interactive materials will be delivered in the experimental homes only and care home staff will probably refer to it in conversation. However the fieldwork team will take no part in delivering the intervention; those who deliver the intervention training and provide support for use of the web-based training and decision support system will take no part in interviewing, assessment, or other data collection activities that are part of outcome measurement.

Remote randomisation and data analysis will be carried out by different members of N-WORTH. Data analysis will be carried out in accordance with a pre-specified analysis plan, using blinded datasets (with allocations recoded to 'A' and 'B') wherever feasible.

There will be monitoring of the care staff's use of the web-based training and decision support system, using inbuilt electronic tracking methods and a retrospective assessment of the extent to which the various team members were blind to the randomised allocation.

3.5. Planned inclusion / exclusion criteria

Participants will be screened for inclusion in the CB sample as described above. The following criteria will apply at the beginning of participant recruitment (see Section 3.3 above):

Inclusion Criteria:

- All residents of recruited care homes

Exclusion Criteria:

- Residents whose stay in the home is not, in the judgement of the home manager, likely to be for long term care – for example those receiving respite care.
- Residents who are in the palliative stages of a disease at the time of recruitment.
- Residents who are unable to speak / understand English.
- Residents who enter the home part way through the study or who are out of the home (for example in hospital) at the time of data collection.

3.6. Proposed duration of treatment period

In those homes randomised to the experimental group care staff will have access to the intervention, the web-based training and decision support system, for the duration of the homes' involvement in the study, i.e. until their last follow-up 12 months after randomisation. Although the system is designed to be user-friendly, even for those who are not particularly familiar with computers, a member of the research team will visit the intervention homes on a few occasions to support its use. This is to ensure that all staff are familiar with using computers, including managing the mouse and key board, access and logging on to the appropriate web address for the system. Each participating care staff member will be encouraged to work through the whole system within a period of 2 weeks, but they will also be able to access the system throughout the follow-up period.

3.7. Proposed frequency and duration of follow up

There will be two follow-up periods of data collection, similar to that undertaken during the pre-intervention (baseline) phase (see 3.8 and 3.9). These will occur 4 and 12 months post intervention for participants, regardless of whether they are in the CB sample or not. However, for those in the CB sample additional measures will be completed by the staff informants.

Proposed outcome measures

A number of outcome measures will be required to address the principal research questions listed in Section 2.2. The primary outcome measure will be the Neuropsychiatric Inventory with Caregiver Distress Scale (NPI-D).[46] This is a validated measure based on informant interview and designed to rate 'frequency', 'severity' and 'caregiver distress' for 12 CB categories – delusions, hallucinations, agitation / aggression, depression / dysphoria, anxiety, elation / euphoria, apathy / indifference, disinhibition, irritability / lability, aberrant motor behaviour, sleep, appetite / eating disorders. The primary research question will be addressed by analysis of the frequency and severity scores.

The research questions and the full range of related outcome measures to address these questions (for those consenting to take part in the trial) are set out below.

Research question	**Outcome measure(s)**	**Which participants does this measure relate to?**
Does the experimental intervention reduce the frequency and severity of CB in care homes?	NPI-D (frequency and severity sub-scales) CMAI	CB sample (staff as informant) CB sample (staff as informant)
Does the experimental intervention reduce the emotional impact of CB on care home staff?	NPI-D CBS MBI EQ-5D	CB sample (staff as informant) All residents (staff as informant) Staff Staff
Does the experimental intervention result in care home staff having a more positive and person-centred attitude to people with dementia?	ADQ	Staff
Does the experimental intervention improve staff self-efficacy in caring for people with dementia?	Self-Efficacy Scale	Staff
Does the experimental intervention enhance quality of life in care home residents as a whole (including those without dementia or CB)?	EQ-5D QOL-AD	All residents All residents

Research question	Outcome measure(s)	Which participants does this measure relate to?
How cost-effective is the experimental intervention as compared with usual care in terms of reducing CB?	(Adapted) CSRI SMI NPI-D (freq & severity sub-scales)	CB sample & Staff CB sample CB sample (staff as informant)
How cost-effective is the experimental intervention as compared with usual care in terms of reducing costs per QALY?	EQ-5D QOL-AD	All residents & Staff All residents
What were the staff's opinion of the web-based training and decision support system?	Mix of pre-coded and open-ended questions built into web system	Staff – Experimental Group

3.8. Measurement of outcomes at follow up

All outcomes, as described in section 3.7, will be measured at four and 12 month follow-up after randomisation. The Clinical Dementia Rating, although not itself an outcome, will also be used at follow up for the purpose of covariate analysis against other outcome measures.

3.9. Proposed sample size

Only homes with at least 25 residents will be included in the study. 48 homes will be recruited, with the expectation that it will be possible to recruit an average of 13 CB participants in each home (i.e. 624 in total). Taking into account the likely loss to follow up (see Section 3.13) it is estimated that, on average 11 of the 13 will be followed up at 4 months, giving a total sample size of 528 from an original recruitment of 624 CB participants.

The primary outcome measure will be the NPI-D. This trial will be cluster randomised to take account of the fact that the participants live together in care homes. Reanalysis of data from previous studies suggests that intra-home correlation coefficients rarely exceed 0.03.[47] As the 'variance inflation factor' (VIF) of this cluster randomised trial [1 + (11 - 1) x

0.03] = 1.3, the likely usable sample of 528 CB participants will give 80% power using a significance level of 5% to detect an effect size of 0.3 standard deviations. This is judged to represent a plausible and clinically important effect size.

Although levels of CB in dementia patients are not thought to be associated with home type [48] it is considered prudent to stratify for type of home (i.e. care home with / without nursing).

Recruitment will cease when the targets of 48 homes and 624 CB participants are reached, even if there is an imbalance between groups, since this would not affect statistical power. However statistical power would be affected if 624 participants were recruited from less than 48 homes. If the number of CB participants per home is substantially smaller than expected, more homes may be recruited. Residents admitted to the care home after the first period (baseline) of data collection will not be included in the study. They may, of course, still be affected by the staff's use of the web system should that care home be in the intervention group.

Participants not included in the CB sample will only be used for secondary analyses.

3.10. Planned recruitment rate

Because of the nature of the study environment and the wide inclusion criteria, it is expected that recruitment will proceed evenly at the pace with which the fieldwork team is able to complete all interviewing in one home and move on to the next. The planned work rate is two homes per week. The proportion of participants selected for the CB sample is expected to vary but the evidence suggests 85% of care home residents may be eligible.[49]

3.11. Likely problems with compliance

Evidence from a relevant study [50] suggests the rate of participant refusal, both initially and on follow up is unlikely to exceed 5%. Past studies indicate that the target recruitment of 13 per home can be achieved with refusal rates more than twice this value.

3.12. Likely rate of loss to follow up

The study cited above in relation to refusals [51] suggests that approximately 39% of care home participants may be lost to follow up over a period of 12 months, due to deaths, movement to other accommodation or care settings, or illness too severe to allow for completion of follow up assessments. If this loss is evenly spread 13% of recruited participants (less than two out of thirteen) would be lost by 4 months.

3.13. Number of centres involved

48 care homes will be involved, unless difficulties in recruiting the CB sample in a given home necessitate inclusion of additional homes.

3.14. Details of planned analyses

Because the trial is cluster-randomised, analyses will use multi-level modelling. Where available, baseline values of the outcome variables will be allowed for by analysis of covariance (ANCOVA); and other potential covariates at both the home and individual level will be investigated for significance. Outcome measures that are highly skewed may be transformed before analysis.

The analysis will use intention-to-treat principles, so that all homes randomised will be included in the analysis, even if some or all of the staff have not completed the modules of the web-based training and decision support system.

3.15. Planned subgroup analyses

Possible differences between nursing and residential homes will be investigated. However for most outcomes this can be done by inclusion of an additional factor in the overall model (in section 3.16 above) rather than by separate sub-analyses, for which the trial is not adequately powered.

3.16. Proposed frequency of analyses

Data analysis will be carried out once when all data, including all follow up data have been collected, unless the Data Monitoring Committee requires any interim analyses to be conducted.

3.17. Economic issues to be addressed

The economic analysis will take a multi-agency public sector perspective, spanning the NHS (Dementia Services, primary and secondary care), care homes and local government social services. It will proceed as follows:

- Fully cost the development and operation of an interactive, web-based decision support system for managing CB in care home residents with dementia.
- Record study participant primary and secondary care health service, care home and other social care use, using an interviewer administered CSRI, and care home staff use of services, costed using National unit costs.[52, 53]
- Conduct a primary cost effectiveness analysis using NPI-D as the measure of effectiveness.
- Conduct a secondary cost-utility analysis using EQ-5D as a measure of utility, benchmarked against a disease specific measure i.e. QoL-AD, to generate a cost per QALY for comparison with the NICE ceiling of £30,000.[54]
- Through bootstrapping, generate cost effectiveness acceptability curves to communicate to policy makers the probability that the intervention is cost-effective. [55, 56, 57, 58, 59, 60]

3.18. Key Milestones

The Challenge Demcare Programme is funded for five years; the trial itself, without the preliminary work involved in designing the intervention, will last approximately 3 years. The key milestones of the Programme, in relation to the Challenge ResCare trial are detailed below.

2008/2009
Protocol development, intervention design & testing, Ethics & R&D submissions

2010
Jan-May Review of web system (intervention) prior to feasibility study

May-Jul	Feasibility study
Aug	Adjustments to web system prior to main trial
Sep	Main trial commences

2011

Jan	4 month (after randomisation) follow-up data collection begins
Mar	Recruitment of homes complete (all randomised)
Jul	4 month follow-ups complete
Sep	12 month follow-ups commence

2012

Feb	Data collection complete
Feb-Jul	Analysis & report writing
Jul	End of Challenge Demcare Programme

4. Details of the Trial Team

4.1. Trial management

The trial will be managed as part of the NIHR Collaborative Research Programme, *Challenge DemCare (Dementia Care for Behaviours that Challenge),* which has received a Programme Grant of approximately £2m. The following management structures are in place:

- A Programme Management Committee, comprising the Chief Investigator, a further grantholder, the Programme Manager and host organisation representatives including finance, service operations and business personnel.
- A Data Monitoring and Ethics Committee (DMEC) which will oversee both this trial and a second trial within the overall Challenge Demcare Programme. This will include independent clinical experts. The DMEC will be chaired by Martin Bland, Professor of Health Statistics in the Department of Health Sciences, University of York. Professor Bland will also act as independent statistician for the trial.
- A Programme Steering Committee (PSC) comprising the grantholders, other independent professionals, care providers and service user representatives. The PSC will have an independent chair, namely, David Jolley, Professor of Old Age Psychiatry, University of Manchester.
- The day to day operation of the trial will be managed by the Programme Manager and a trial co-ordinator. Fieldwork staff are in place to support recruitment to the trial and data collection.

4.2. Participating centres

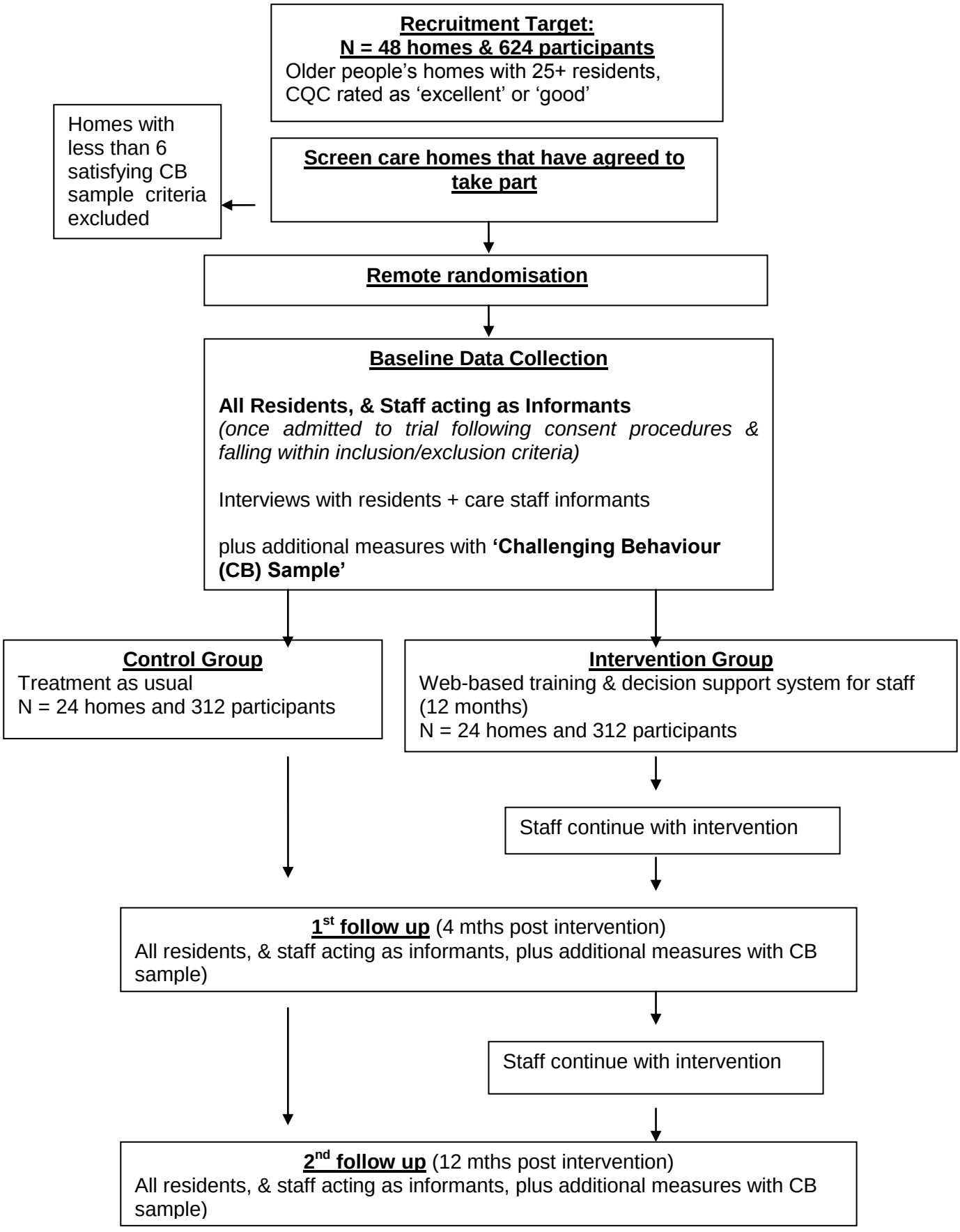
An invitation to participate in the trial will be sent to all homes meeting the required criteria in North and East Yorkshire (including the cities of York and Hull). The invitation will be extended outside that area if it proves necessary, in order to recruit 48 homes and the required participant sample.

5. Feasibility

In advance of the proposed trial, feasibility work will be carried out in four care homes in the study area that will not subsequently be used for the main trial. This will include recruitment and consent of participants as for the main trial, but it will be made clear to participants that this is feasibility work prior to the main study. Interviews will be carried out and data collected using the instruments proposed for the main trial, before and after the intervention is introduced. The intervention materials and introductory training will also be tested with staff. The views of residents and staff who participate will be sought. Any substantial amendments that are made to the study as a result of this process will be submitted for ethical approval in the usual way.

Appendix 1

Flow Diagram: Stages of the Challenge ResCare Trial



Appendix 2

The Experimental Intervention: A web-based training and decision support system for carers of people with dementia with challenging behaviours

(For this trial the carer is a member of care home staff and will be the person using this web system).

The intervention is a user-friendly web-based training system offering three training modules, which include interactive video-clips, which the care worker progresses through sequentially. At the end of the three modules the care worker will be able to:

1) Understand that behaviour 'problems' in dementia care represent (sometimes extreme) variants of normal behaviour, which is greatly influenced by the situation and circumstances and by our interpretation of the behaviour.

2) Accurately observe and report on the immediate functional relationships between the behaviour shown by a person with dementia and its consequences.

3) Understand the range of factors that must be considered in assessing challenging behaviour in dementia, and the potential sources of information.

4) Assemble an action plan based on an understanding of the factors contributing to challenging behaviour in case vignettes.

Upon satisfactory completion of the three training modules, the care worker then has access to a fourth module, which guides the care worker through an assessment and action planning process for the people with dementia the care worker is providing care for. This module incorporates a number of widely-used and validated check-lists, and algorithms enabling the system to suggest areas of assessment and potential action plans for the care worker to consider using and incorporating in an action plan. The assessment and action plan will automatically be saved on the secure remote server. It will also be possible for that plan to be printed off for insertion in the care notes specific to that client.

N.B. In terms of data security, the data that people submit to the system will be kept physically under lock-and-key at the remote server, which will also be protected by a ‘firewall, meaning that it is secure against electronic attack. Data in transit over the internet will be encrypted (encoded), which means that anyone ‘eavesdropping’ on the data will not be able to make sense of it. In addition, information on users' computers will only be displayed once a password, only known to the individual user, is entered. This password ensures that registered users only see data in relation to the person with dementia they are responsible for the care of.

APPENDIX 3:
Consent and the Mental Capacity Act

This trial is linked to treatment of an impairing condition (dementia) that is likely to cause incapacity in some potential participants. Since the subject matter of the research concerns behavioural and psychological symptoms in dementia it would be rendered ineffective if only people with capacity were able to participate. The research is capable of benefiting participants by improving the quality of the care they receive from staff in the home; and is not thought to carry any risk to participants. Some potential participants, including many with a degree of cognitive impairment, will have capacity to consent to participation. Capacity will be assumed and signed consent obtained if possible, including consent to access the participant's GP records for collection of data on service use if necessary, and consent for entering participant's details into the care plan writer module of the web system. Any potential participant who, having capacity, declines to participate in the study will be excluded from any involvement. During the discussion that a suitably trained researcher will have with each potential participant about the study, the researcher will assess the person's ability to make a decision about participating in the project, in line with the Code of Practice developed under the Mental Capacity Act 2005 (the Act), considering the following questions:

- Does the person have a general understanding of the decision they are being asked to take and why they need to make it?
- Does the person have a general understanding of the likely consequences of making, or not making, the decision?
- Is the person able to understand, retain, use and weigh up information relevant to the decision?
- Can the person communicate their decision? Would special equipment or specialist skills be helpful for this?

If (having tried any special communication arrangements) the researcher concludes that the person lacks capacity to give consent, an appropriate family member or other consultee will be approached, as required by the Act. Throughout the trial the wishes and feelings of the participant will be respected; interviews will be terminated if it is felt that this is causing the participant distress or if they object.

Access by participants to urgent treatment will not be affected by the trial. All interviews and other assessments will be carried out in the care home where each participating resident is receiving long term care. Medical attention will be obtained as usual if required by a participant, via the care home manager and the participant's GP.

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