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OPTIMISED DEMCARE care home staff training to improve personal care assistance for people living with dementia (feasibility study)

Submission date
23/10/2026

Recruitment status
Not yet recruiting

Registration date
02/11/2026

Overall study status
Ongoing

Last Edited
02/11/2026

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

People living with moderate and advanced dementia need help with personal care activities such as, washing, dressing and going to the toilet. Sometimes people living with dementia refuse care, which is common in care-home settings. Consequences from refusals include poor hygiene, infections, and use of antipsychotic medication. The study team co-produced a care home staff train-the-trainer training intervention called OPTIMISED DEMCARE to improve personal care assistance for people with dementia in care homes. This study will examine if the training can be tested in a trial situation. The study aims to run a small study of the OPTIMISED DEMCARE training intervention in care homes to determine if a larger trial is feasibility.

Who can participate?

Care home residents living with dementia, and care home staff supporting care home residents living with dementia. The study aims to recruit eight care homes and residents and staff will be living or working in those care homes.

What does the study involve?

The study will compare the OPTIMISED DEMCARE Training intervention with current care as usual. After care homes have joined the study, residents and staff will be recruited and consent to the study. Family members may be consulted on a resident's behalf if necessary. Questionnaires will be filled in by staff about their confidence and competence providing dementia care and about residents' quality of life and refusals of care. Researchers will collect information from resident care records about their recent care. Care homes will then be randomly assigned to receive the OPTIMISED DEMCARE intervention (six care homes) or continue usual care (two care homes). Care home staff in the OPTIMISED DEMCARE Training intervention group will receive an OPTIMISED DEMCARE Pack for inhouse trainers to go through to become DEMCARE Champions. DEMCARE Champions will then train other staff. Staff from all eight care homes will fill in the same questionnaires about themselves and residents again, and researchers will collect information from resident care records, directly after the training period and at 6-months after randomisation.

A number of staff participants in the care homes with the OPTIMISED DEMCARE training will be asked to take part in an interview to find out their views and experiences of the training and being part of this study. Researchers will observe some training sessions.

What are the possible benefits and risks of participating?
There are no known benefits. Some people may feel empowered, enjoy taking part and feel good helping researchers. Care home staff and people living with dementia may benefit from the OPTIMISED DEMCARE training, providing and receiving improved personal care assistance and experiencing less refusals of care, although this will not be found out by the current study. Some care homes may use their involvement in research to demonstrate to the Care Quality Commission their outward looking perspective and links with other institutions. There are no known physical risks from taking part. Access to and review of resident care records creates a potential risk to confidentiality. All information about residents will be kept safe and secure.

Where is the study run from?
The University of East Anglia, Norwich, UK

When is the study starting and how long is it expected to run for?
January 2027 to October 2028

Who is funding the study?
An Advanced Fellowship funded by the National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?
Dr Tamara Backhouse, Tamara.Backhouse@uea.ac.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
375104

Central Portfolio Management System (CPMS)
74095

National Institute for Health and Care Research (NIHR)
303609

Study information

Scientific Title
Cluster randomised feasibility trial and process evaluation of the OPTIMISED DEMCARE training intervention versus usual care to improve personal care assistance and reduce refusals of care for people with dementia living in care homes 2026-2028

Acronym
OPTIMISED DEMCARE Feasibility

Study objectives
Undertake a cluster randomised feasibility trial of OPTIMISED DEMCARE to gain important information needed to design a future definitive trial. The study will:
1. Recruit 8 care homes in England, ideally 4 in each of two recruitment regions (East of England and East Midlands) assigning three to intervention and one to control in each.
2. Implement OPTIMISED DEMCARE in six intervention care homes, three per region.
3. Recruit and collect data from 10 care home staff per care home and 8 residents per care home at baseline, post-intervention and six-months post randomisation.
4. Calculate recruitment and attrition rates
5. Determine the potential of candidate outcome measures
6. Identify intervention and outcome data collection difficulties
7. Assess response and recording completeness
8. Assess intervention delivery in different contexts and intervention acceptability
9. Make an initial estimate of potential intervention effectiveness
10. Estimate outcome variability and intra-class correlation
11. Conduct an initial health economics evaluation to assess if this is feasible and provide an indication of intervention costs.
12. Conduct an embedded process evaluation to examine contextual factors acting as barriers or facilitators to the implementation of the intervention and proposed trial processes and to understand mechanisms of impact, acceptability, fidelity, reach, dose, and adaptability of the intervention:
12.1. Observe intervention delivery
12.2. Interview 10 staff members in each intervention care home
12.3. Collect descriptive and quantitative feedback
12.4. Produce a narrative account of the implementation experiences of the intervention via qualitative methods

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 29/09/2026, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8143; bradfordleeds.rec@hra.nhs.uk), ref: 26/YH/0194

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
A cluster randomised, feasibility trial with process and health economic evaluations

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
A training intervention to improve personal care assistance and reduce refusals of care for people living with dementia in care homes

Interventions
This is a cluster randomised, feasibility trial incorporating process and economic evaluations comparing the OPTIMISED DEMCARE train-the-trainer intervention against usual care for people living in care homes. A feasibility trial was chosen to gain important information needed to design a future definitive trial.

Eight care homes will take part. Six will be randomised to intervention care homes and receive the OPTIMISED DEMCARE train-the-trainer training and two will continue with usual care. Care homes will be randomised in a 3:1 ratio. The study aims to recruit 10 care home staff in each care home (total 80) and 8 residents (total 68).

As this is a feasibility trial, there is no primary outcome, but it will look at refusals of care as a potential candidate primary outcome for future research. Care homes will be identified from the Care Quality Commission publicly available database or through Research Delivery Network contacts. They will:
• Be situated in England ideally in one of two recruitment regions (East of England and East Midlands)
• Be registered as specialising in dementia (51% of all care homes) on the CQC website
• Have a manager (and if appropriate, owner / higher management) who is prepared to commit to the study
• Have at least ten residents who meet the resident eligibility criteria
Care home will be excluded if they have:

• Participated in dementia training intervention research within the last six-months
• A refusal of care programme similar to OPTIMISED DEMCARE in place

RECRUITMENT
Care home managers will first be approached by the local RDN contact, through provider meetings, or letter or email with follow up phone call from the research team. A follow up meeting/telephone call will be held with interested managers to discuss the research and confirm eligibility. Care home managers in eligible care homes who want their home to take part will be asked to sign an agreement. After agreement, care home demographics will be collected including care home type, care provided, location, dementia training, number of beds, number of residents, collated demographics of residents (such as number of males/females/non-binary; numbers under age 85 and aged 85 and over), number of staff, numbers of staff on shift, care recording system, and resident funding types.

Care home staff will identify eligible participants and personal consultees where appropriate and provide participant and consultee information. If potential participants/consultees are interested and agree, they will be introduced to a researcher at the care home or have their contact information passed on to a researcher who will arrange to meet them or have a conversation with them via telephone or online. Researchers will take consent directly or staff and consultees may request and use an online link. Some care homes may want researchers to present the research to their staff or use posters to make staff aware of the research opportunity. The study team will work with each care home regarding their preferred way providing information about the research.

BASELINE DATA
Following consent/consultee declaration, baseline data including demographics will be collected. Participating staff will be asked to complete two short questionnaires (max time to complete 20 minutes) regarding their sense of competence and confidence in dementia care (SCIDS, CODE). For participating residents, data will be collected via proxy questionnaire and from routine data held in care records. A carer who knows the resident well will be asked to complete proxy measures (max time to complete 20 minutes) regarding refusals of care (RoCIS), Dementia Care Interaction Scale (DCIS), quality of life (QUALID), ability with activities of daily living (BRISTOL ADL Scale), and wellbeing (ICECAP-A Proxy). Data collected from routine care records will include refusals of care, hospitalisations, formal best interest decisions for care, safeguarding incidents, contact with professionals, antipsychotic medication use, personal care assistance during the month prior to baseline.

INTERVENTION
After baseline data collection, care homes will be randomised and allocated using simple randomisation, stratified by region, on intervention to control ratio of 3 to 1; Participants will receive either the OPTIMISED DEMCARE train-the trainer training intervention or proceed with usual care. Intervention homes will receive and implement the training intervention alongside usual care. Non-intervention homes will continue providing usual care.

The OPTIMISED DEMCARE train-the-trainer training intervention aims to enhance staff's emotional intelligence and provide evidence-based guidance and strategies to improve personal care assistance and reduce refusals of care. It is delivered through a series of practical and participatory activities. It includes problem solving and adaptation of caregiver approaches to build trust with the person with dementia through making a positive connection, making personal care manageable for the person, and giving the person a sense of control over their personal care.

For care homes randomised to receive the OPTIMISED DEMCARE train-the-trainer intervention, a DEMCARE pack will be delivered including information for managers, a formal commitment for the manager to sign, information for relatives, and a DEMCARE Champion training pack. One to three DEMCARE Champions will be identified and appointed inhouse by the care home manager. DEMCARE Champions will be:
1. Aged 18 and above, and
2. Staff member with equal to or more than 6-months experience of care work, willing and able to take on the DEMCARE Champion role (for example, inhouse trainer, senior staff member, nurse, capable care worker) who is working regularly in the care home. or
3. Trainer/senior role working across a group of care homes where one is an intervention care home; usually working at the care home at least twice a week.

The DEMCARE Champions will work through the training pack (this takes up to 3-hours). The pack includes materials for training colleagues (such as, activity instructions and materials, DEMCARE guide, posters, and certificates). Care homes will have 2 weeks for the DEMCARE Champions to be appointed and work through the training pack.

The DEMCARE Champions will organise and train up to 10 colleagues at a time in 2-hour staff training sessions over a 6-week implementation period. Staff to be trained include those physically assisting people with dementia with personal care, and may include activity coordinators, seniors/managers, and other staff as well as carers as each care home deems appropriate. After the training sessions DEMCARE Champions will provide ongoing peer support beyond the training, which includes a reflective staff activity and reflective chat. Champions can contact the research team with any questions regarding the DEMCARE training during the 6-week implementation period.

FOLLOW-UP VISITS
Following up visits will be scheduled at Week 12 +/- 1 week and Week 26 +/- 1 week. Researchers will arrange to visit care homes and collect the same data as at baseline from care records/notes regarding refusals of care, hospitalisations, formal best interest decisions for care, safeguarding incidents, contact with professionals, antipsychotic medication use, and personal care assistance regarding the previous month. At each timepoint care home staff will repeat completion of the questionnaires completed at baseline about themselves and also the proxy questionnaires about participating residents.

END OF TRIAL
At the end of the trial, care homes randomised to intervention will be able to retain all materials provided, and care homes in the usual care arm will be offered an OPTIMISED DEMCARE train the-trainer pack.

PROCESS EVALUATION
An embedded process evaluation will be undertaken in the 6 intervention care homes and aims to learn about the reach, dose, fidelity, acceptability and adaptability of the OPTIMISED DEMCARE train-the-trainer intervention, as well as contextual factors affecting implementation. Staff taking part in the trial will be asked to consent to the process evaluation as optional questions on the consent form. Non-trial participant staff attending the training when it is being observed and the care home manager/deputy and DEMCARE Champions will also be invited to take part in the process evaluation.
Methods of data collection will include: observations of the training being delivered (up to 2 training sessions per home) and interviews with care home staff (10 per intervention care home,

up to 30 mins per interview) focusing on those delivering the training, those who have received the training, and those in senior/management positions face to face in the care homes or online as preferred by each participant.

Additionally, staff receiving the training will be asked to complete questionnaires (NOMAD and a DEMCARE bespoke questionnaire) to provide feedback on the training and how it is being implemented (post training and at 6-months post randomisation). Anticipated to take approximately 10 minutes.

At the end of the intervention training period, collated numbers and roles of staff attending the training (reach) and how much of the training they received (dose) will be collected anonymously from the DEMCARE Champions from their training logs which are part of the intervention documentation.

ECONOMIC EVALUATION
An economic evaluation will be undertaken to test the feasibility of collecting resource use and outcome data in order to inform the decision as to how cost and benefit data should be collected /estimated in any subsequent definitive trial. The number of refusals of care will be recorded in trial outcomes and approximate time associated with these will be explored in interviews and with the DEMCARE bespoke questionnaire. The ICECAP-A proxy outcome will measure capability and wellbeing. The DEMCARE Champion/s associated with each care home will be asked to estimate the time taken to work through the DEMCARE training pack and subsequently train other care home staff. Post-training, care home staff will also be asked if the time taken to provide personal care (including any associated refusals/leave and returns) has changed since completion of the training in the DEMCARE bespoke questionnaire and in interviews and estimate associated changes in times (if applicable).

PUBLIC INVOLVEMENT
This study has a Lived Experience Advisory Group including care home staff, relatives, and residents who meet regularly and have advised on the study design and information sheets. The OPTIMISED DEMCARE training intervention was co-produced with care home staff, relatives and a resident and was informed by a stakeholder consultation of 35 people including residents and people living with dementia.

Intervention Type
Behavioural

Primary outcome(s)
1. Refusals of care, as a candidate primary outcome, measured using the Refusal of Care Informant Scale (RoCIS), usual recording in care records, and the Dementia Care Interaction Scale (DCIS) for staff at baseline, Time 1 (post-intervention) and Time 2 (6-months)

2. Quality of life measured using the Quality of Life in Late-Stage Dementia Scale (QUALID) at baseline, Time 1 (post-intervention) and Time 2 (6-months)

Key secondary outcome(s)

Completion date
30/10/2028

Eligibility

Key inclusion criteria
Care homes
1. Situated in England ideally in one of two recruitment regions (East of England and East Midlands)
2. Registered as specialising in dementia (51% of all care homes) on the CQC website
3. Manager (and if appropriate,owner / higher management) is prepared to commit to the study
4. Have at least ten residents who meet the resident eligibility criteria

Trial participants: care home staff
1. Aged 18 and over
2. Work in a study care home regularly,at least 16-hours weekly
3. Providing physical assistance with personal care (for example,washing,dressing,going to the toilet) to people with dementia (e.g.,seniors,carers)
4. Willingness to be trained if their care home is randomised to intervention
Optional
5. Willingness to take part in an interview if invited
6. Willingness to be observed during training sessions if invited
7. Willingness to fill in feedback questionnaires about the intervention if applicable

Trial participants: care home residents
1. Aged 18 and over
2. Moderate or advanced stages of dementia (scores of 6 or 7 on FAST (Reisberg,1988) a functional assessment staging tool with seven stages,a score of six represents moderately severe dementia and seven severe dementia).
These residents are likely to have regular physical assistance with personal care.
3. Receiving daily physical assistance with their personal care
4. Living in a participating care home

Process evaluation ONLY participants: care home staff (not participating in the trial)
• Aged 18 or over
• Staff working in an intervention home,receiving or facilitating the training or senior care home staff
• Willingness to fill in feedback questionnaires about the intervention
Optional
• Willingness to take part in an interview if invited
• Willingness to be observed during training sessions if invited

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Care homes
1. Participated in dementia training intervention research within the last six-months
2. A refusal of care programme similar to OPTIMISED DEMCARE in place

Trial participants: care home staff
1. Agency staff not working regularly in the care home
2. Staff not providing assistance with personal care to people with dementia
3. Taken part in other dementia training research in the last six-months

Trial participants: care home residents
1. Care-home staff consider the resident at end-of-life - for example,bed care,receiving 2-4-hourly turns and/or mouthcare via swabs and/or sponges
2. Temporary resident of the care home – for example respite or rehab and reablement residents
3. Not receiving physical assistance with personal care

Date of first enrolment
04/01/2027

Date of final enrolment
02/04/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of East Anglia
Norwich Research Park
Earlham Road
Norwich
England
NR4 7TJ

Sponsor information

Organisation
University of East Anglia

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
De-identified individual participant data underlying the results reported in the main study publication may be made available from the corresponding author upon reasonable request to tamara.backhouse@uea.ac.uk (Tamara Backhouse) after publication. Data access will be considered for scientifically sound research purposes, subject to approval by the study investigators, applicable ethical and institutional requirements, and appropriate data protection safeguards. Requests should be directed to the corresponding author. No directly identifiable participant information will be shared.

IPD sharing plan summary
Available on request