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Compassion focused therapy - for mood in dementia

Submission date
16/08/2023

Recruitment status
Recruiting

Registration date
21/08/2023

Overall study status
Ongoing

Last Edited
26/03/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Of the 850,000 people with dementia in the UK, many experience depression, anxiety or both. This can worsen cognition (e.g., memory and language) and behavioural problems, lead to relationship difficulties, and increase care home admissions. With medications for mood in dementia often ineffective, recent trends have moved towards nondrug interventions. However, the lack of interventions available with proven effects results in significant unmet needs. Compassion Focused Therapy is a talking therapy which addresses feelings of shame and stigma. Our team tested Compassion Focused Therapy with seven people with dementia, finding small improvements in depression, anxiety and self-criticism. One person said: “I have accepted the fact that I have a ‘memory problem’ and am happy being me. I do not blame myself anymore for something that’s not my fault.”
This project will assess Compassion Focused Therapy in the form of a randomised controlled trial, following encouraging results from our feasibility study. Participants will be randomly allocated to either the intervention (twelve sessions of group Compassion Focused Therapy, delivered online or face-to-face) or the control group (usual care only). The outcome measures will be depression, anxiety, quality of life, cognition, self-compassion, relationship between caregiver and caregiver burden (where relevant) and costs, measured before and after the intervention period. These will be assessed at the start of the study, after the intervention, and at the 6-month follow-up. We will also explore participants’ preferences for how the therapy is delivered, differences between online and face-to-face groups, and factors that may influence how well the intervention works.
This randomised controlled trial builds directly on our earlier feasibility study, with that data included as part of the final analysis. Our aim is to see whether Compassion-Focused Therapy helps people with dementia who are experiencing low mood and whether it is a cost-effective approach.

Who can participate?
A person can put themselves forward to the research team if they:
1. Have been diagnosed with mild to moderate dementia
2. Experience symptoms of anxiety or depression
3. Have capacity to consent to take part in research
4. Can communicate in English

5. Have access to WiFi, enabling them to partake in online Compassion Focused Therapy groups, OR the ability to attend a face-to-face group
6. Are not participating in another interventional research programme concurrently
7. Have sufficient hearing to engage in group discussions (with or without hearing aids)
8. Aged 18 years and over
9. People can be included whether or not they have a caregiver

What does the study involve?
If a participant chooses to take part, they will be randomly assigned to either the Compassion Focused Therapy group or a 'control' group. There is an equal, 50/50 chance of them being in either group. If they are in the control group, they will not receive any additional treatment. The participants' preference towards virtual or face-to-face meetings will be recorded and we will aim to allocate delivery of these Compassion Focused Therapy sessions accordingly. If the participant is randomly allocated to the intervention group, they will be invited to attend twelve, 60-minute online or face-to-face small group Compassion Focused Therapy sessions. These will occur once a week for twelve weeks. The sessions will involve meeting with a clinical professional and other people with dementia to discuss topics such as low mood, memory problems, and coping mechanisms. During the sessions the participant will also do activities such as gentle breathing and self-compassion exercises. There will be time to reflect as a group on the emotional experience of living with dementia. Sessions will end with suggesting home practices, with participants given session summaries. There will be time for social interaction before and after the session, either over a video conference platform or face-to-face.
If the participant is randomised to the Compassion Focused Therapy group, we will run a brief workshop for carers/supporters (if applicable) around the beginning of the Compassion Focused Therapy programme. This will provide information on the principles of Compassion Focused Therapy, an outline of what we intend to do in sessions and tips on what can be done at home to support the person receiving therapy in between sessions.
Regardless of which group the participant is allocated to (Compassion Focused Therapy or control), they will continue to have access to their usual care, including input from health and social care professionals, dementia medication, and their usual day activities.
Following discussion of any questions they may have with a researcher and signing the consent form, all participants will be asked to:
1. Meet with a researcher for approximately 1.5 hours to answer questions about their mood, anxiety, quality of life, and thinking. If applicable, we will also invite carers/supporters to attend this meeting.
2. Meet with a researcher again after the 12 Compassion-Focused Therapy sessions to answer the same questions as before and again 6 months after the initial assessment. Each follow-up will take approximately 1.5 hours.

What are the possible benefits and risks of participating?
We appreciate that when an individual experiences memory problems, it may be hard to talk about things like mood and quality of life. The researchers carrying out the assessment, intervention, and interview have clinical experience and are working under supervision. The participant will be encouraged but never forced to take part in a particular activity during the sessions.
Overall, the risks of taking part in this study are minimal. However, some people find that certain types of therapy do not help them or make them feel worse. If a participant finds any part of the study distressing, let us know and we can try to resolve the difficulty together or discuss other options of support. The participant is always free to withdraw from the study at any point.
If the participant loses capacity to consent, they will be withdrawn from the study and no further data will be collected; however, data collected up until that point will be retained for use in the study. Withdrawing from the study will not affect the standard of care the participant receives.

If a participant takes part in the study and is allocated to the intervention group, we hope that their attendance at the sessions is a helpful experience. Previous research into compassion suggests that people can experience greater awareness, acceptance, control, improved coping and wellbeing. Regardless of whether the participant receives the intervention or not, the information we get from this study may help us to support people with dementia and their carers /supporters better in future.

Where is the study run from?
Recruitment will primarily take place through the NHS Foundation Trusts of North East London, Oxford Health, Norfolk and Suffolk, Black Country Healthcare, Central and North West London, Lincolnshire Partnership, Cheshire and Wirral Partnership and Devon Partnership. We will also recruit through 'Join Dementia Research', an online recruitment platform.

When is the study starting and how long is it expected to run for?
November 2023 to October 2028

Who is funding the study?
National Institute for Health and Research, the Research for Patient Benefit Programme (UK)

Who is the main contact?
Melissa Melville, Melissa.melville@nelft.nhs.uk

Contact information

Type(s)
Scientific

Contact name
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Integrated Research Application System (IRAS)
327086

Central Portfolio Management System (CPMS)
57107

National Institute for Health and Care Research (NIHR)
203524

Study information

Scientific Title
Being kind to ourselves: A randomised controlled trial of compassion focused therapy (CFT) to improve symptoms of depression and anxiety in dementia

Study objectives
Secondary study objectives:
The aims/objectives will be to:
1. Evaluate the efficacy of CFT in improving depression (primary outcome, measured by the Cornell Scale for Depression in Dementia, anxiety, quality of life, cognition, self-compassion, and the caregiver-patient relationship in people with dementia, compared to TAU; at 16 weeks and 6 months.
2. Evaluate caregiver burden and caregiver perception of the caregiver-patient relationship (if caregiver is available to participate), compared to TAU, at 16 weeks and 6 months.
3. Assess the cost-effectiveness of group CFT compared to TAU at 16 weeks by estimating the incremental cost per 'Quality Adjusted Life Year' (QALY) gained.
4. Explore:
4.1. Differences in outcomes between face-to-face and online groups
4.2. Participants' preferences for delivery format and
4.3. Potential predictors of success in the intervention (such as baseline mood, cognitive impairment, engagement (or not) of a caregiver and demographic factors) as part of a secondary, exploratory analysis.

Previous study objectives:
As this is an unpowered feasibility study, we are not hypothesising significant changes in any outcomes. However, we will explore changes in outcomes pre- and post-intervention, comparing the treatment and control groups (TAU), and may expect some positive trends. We are also exploring the differences between online and f2f groups and have no current hypothesis in terms on superiority.
The main objectives of the study are:
1. To undertake a feasibility Randomised Controlled Trial (RCT) to assess critical elements of a full RCT of Compassion Focused Therapy (CFT) in dementia. These include eligibility rates, recruitment and attrition rates, data collection and intervention delivery;
2. To establish acceptability of CFT as an online or face-to-face intervention for people with dementia;
3. To assess intervention fidelity;
4. To establish preliminary intervention efficacy;
5. To establish suitability of study outcome measures including cost-effectiveness measures;
6. To gather data to inform the decision of the primary outcome for a full RCT and obtain estimates of parameters to inform the calculation of the required sample size for a full RCT;
7. To use qualitative and quantitative findings to modify the treatment manual (if required).

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 11/08/2023, London Riverside (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 20 7104 8150; riverside.rec@hra.nhs.uk), ref: 23/LO/0535

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dementia

Interventions
Current interventions as of 26/03/2026:
This will be a single-blind randomised controlled trial of group CFT versus treatment as usual (TAU). 304 participants will be randomised to either the intervention group or control group (TAU). Randomisation will occur after baseline assessments are completed. Where possible, assessments will be collected by a researcher who is blind to group allocation. Assessments will be delivered virtually or face-to-face, depending on patient preference. Demographics and general information will be collected including age, gender, ethnic group, use of medication (including antidepressants, anxiolytics and cholinesterase inhibitors), treatment preference, participation in other activities and presence / absence of a carer/ supporter. Baseline assessments will include measures of quality of life, symptoms of depression and symptoms of anxiety, a measure of self-compassion, cognitive function, resource use, relationship with caregiver and caregiver burden (if applicable). Each arm will have approximately 150 participants and they will be allocated to one CFT group with up to 7 participants in each group.

The duration of the intervention will be 15 weeks, consisting of 12 CFT therapy sessions. Given that it can prove difficult to always fit the 12 sessions into 12 consecutive weeks (due to factors such as weather issues, therapist annual leave, strikes, illness), the additional 3 weeks provides a buffer and may increase the likelihood that participants could receive all 12 sessions. There will be assessments at baseline during the week prior to randomisation, and at the end of the intervention at 16 weeks and at 6 months follow-up. Twelve, 60-minute virtual or face-to-face group CFT sessions including three phases. Phase 1 involves setting up and introducing CFT including psychoeducation on emotion regulation systems, formulation and goal setting. Phase 2 teaches people techniques to develop self-compassion, including imagery and the writing of compassionate letters. Phase 3 teaches techniques to tolerate difficult feelings, focusing on ending and maintaining benefits. Sessions will include a core CFT practice, for example ‘soothing rhythm breathing’ which involves slowing and deepening the breath. Each session will introduce a new concept, such as the qualities of compassion, mindful awareness and understanding the function of self-criticism. There will be time to reflect on the emotional experience of living with dementia, e.g., how the diagnosis can be experienced as a ‘threat’ to the self and future, triggering fear, anxiety and disconnection. Sessions will end with suggesting home practices, with participants given session summaries. CFT will be adapted to compensate for cognitive changes, including frequent repetition and use of visual and verbal information. Building on the experience of running CST groups, groups will consist of approximately five people. We will factor in time for social interaction before and after the session, either virtually or face-to-face.

Additional carer/supporter workshop: we will run a brief workshop (flexibility for online or face-to-face) for primary carers/supporters (if available) towards the beginning of the CFT programme. This will educate carers on the principles of CFT, providing an outline of what we intend to do in the sessions and giving people tips on what can be done at home to encourage and support the therapy (for example, reminding the person to do breathing or relaxation exercises).

The intervention group will continue to have access to their usual care, which includes input from health and social care professionals, anti-dementia medication and their usual day activities.

Control group:
Defined as standard treatment available to people with dementia and depression and/or anxiety, which might include medication, other therapies, day care, input from health and social care professionals such as psychiatrists, psychologists and social workers or no treatment. We will collect information on all health and care services used by people with dementia (which we can compare with ongoing observational studies such as IDEAL) to describe what TAU involves for each participant; this can be taken into account in a future, fully powered trial. As both groups will have access to TAU, this study will look at the additional impact of CFT.

For those who do not own a tablet and wish to complete the online intervention, ten tablets will be purchased and lent to those participants, aiming to maximise inclusivity.

Previous interventions:
This will be a single blind, feasibility randomised controlled trial of group CFT versus treatment as usual (TAU). Fifty participants will be randomised to either the intervention group or control group (TAU). Randomisation will occur after baseline assessments are completed. Where possible, assessments will be collected by a researcher who is blind to group allocation. Assessments will be delivered virtually or face-to-face, depending on patient preference. Demographics and general information will be collected including age, gender, ethnic group, use of medication (including antidepressants, anxiolytics and cholinesterase inhibitors), treatment preference, participation in other activities and presence / absence of a carer/ supporter. Baseline assessments will include measures of quality of life, symptoms of depression and symptoms of anxiety, a measure of self-compassion, cognitive function, resource use, relationship with caregiver and caregiver burden (if applicable). Each arm will have approximately 25 participants and they will be allocated to one CFT group with up to 5 participants in each group.

The duration of the intervention will be 15 weeks, consisting of 12 CFT therapy sessions. Given that it can prove difficult to always fit the 12 sessions into 12 consecutive weeks (due to factors such as weather issues / therapist annual leave, strikes, illness), the additional 3 weeks provides a buffer and may increase the likelihood that participants could receive all 12 sessions. There will be assessments at baseline during the week prior to randomisation, and at the end of the intervention at 16 weeks and at 6 months follow-up. Twelve, 60-minute virtual or face-to-face group CFT sessions including three phases. Phase 1 involves setting up and introducing CFT including psychoeducation on emotion regulation systems, formulation and goal setting. Phase 2 teaches people techniques to develop self-compassion, including imagery and the writing of compassionate letters. Phase 3 teaches techniques to tolerate difficult feelings, focusing on ending and maintaining benefits. Sessions will begin with a core CFT practice, for example ‘soothing rhythm breathing’ which involves slowing and deepening the breath. Each session will introduce a new concept, such as the qualities of compassion, mindful awareness and understanding the function of self-criticism. There will be time to reflect on the emotional

experience of living with dementia, e.g., how the diagnosis can be experienced as a 'threat' to the self and future, triggering fear, anxiety and disconnection. Sessions will end with suggesting home practices, with participants given session summaries. CFT will be adapted to compensate for cognitive changes, including frequent repetition and use of visual and verbal information. Building on the experience of running CST groups, groups will consist of approximately five people. We will factor in time for social interaction before and after the session, either virtually or face-to-face.

Additional carer/supporter workshop: we will run a brief workshop (flexibility for online or face-to-face) for primary carers/supporters (if available) towards the beginning of the CFT programme. This will educate carers on the principles of CFT, providing an outline of what we intend to do in the sessions and giving people tips on what can be done at home to encourage and support the therapy (for example, reminding the person to do breathing or relaxation exercises).

The intervention group will continue to have access to their usual care, which includes input from health and social care professionals, anti-dementia medication and their usual day activities.

Control group:
Defined as standard treatment available to people with dementia and depression and/or anxiety, which might include medication, other therapies, day care, input from health and social care professionals such as psychiatrists, psychologists and social workers or no treatment. We will collect information on all health and care services used by people with dementia (which we can compare with ongoing observational studies such as IDEAL) to describe what TAU involves for each participant; this can be taken into account in a future, fully powered trial. As both groups will have access to TAU, this study will look at the additional impact of CFT.

For those who do not own a tablet and wish to complete the online intervention, ten tablets will be purchased and lent to those participants, aiming to maximise inclusivity.

Qualitative interviews will be used to gather participant, carer/supporter and clinician perspectives on the value, acceptability and feasibility of the intervention.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcomes as of 26/03/2026:
Symptoms of depression measured by the Cornell Scale for Depression in Dementia (Cornell) at 16 weeks (post-intervention)

Previous primary outcomes:
Feasibility outcomes:
1. Feasibility of recruitment and retention, assessed by:
1.1. Successful recruitment of the target sample (50 people) in 14-months
1.2. Retention rate of at least 75% of participants to 16 week follow up. We will also evaluate how feasible it is to recruit anxious people to a group intervention how anxiety impacts upon uptake.
2. Acceptability of the intervention, assessed by:
2.1. Overall attendance and retention rates amongst the CFT participants (over 60%)
2.2. Any negative or adverse events related to the intervention
2.3. Level of engagement in the sessions, measured using participation forms developed

alongside the CFT manual, (d) preference of virtual or face-to-face.
3. Fidelity, assessed by:
3.1. Therapist completion of the fidelity checklist following each session and
3.2. Audio recording all sessions and an independent researcher rating fidelity with a random 10% of the recordings. A total, mean fidelity score and percentage will be calculated for each CFT session. These scores will be compared across site and provider. We will also compare self-report with observer ratings, providing some idea about the utility of self-report in a future trial.

Key secondary outcome(s)

Current secondary outcomes as of 26/03/2026:
1. Symptoms of depression measured by the Cornell Scale for Depression in Dementia (Cornell) at 6 months
2. Symptoms of anxiety measured by the Rating Anxiety in Dementia Scale (RAID) at 16 weeks (post-intervention) and 6 months
3. Quality of life and proxy quality of life measured by the Dementia Quality of Life Scale (DEMQOL) at 16 weeks (post-intervention) and 6 months
4. Health-related quality of life measured by the EQ-5D-5L at 16 weeks (post-intervention) and 6 months
5. Cognitive function measured by the Montreal Cognitive Assessment (MoCA) at 16 weeks (post-intervention) and 6 months
6. Self compassion measured by the Short Self-Compassion Scale (SCS-SF) at 16 weeks (post-intervention) and 6 months
7. Relationship with caregiver measured by the Quality of Caregiver and Patient Relationship scale (QCPRS) at 16 weeks (post-intervention) and 6 months
8. Resource use measured by the Client Service Receipt Inventory (CSRI) at 16 weeks (post-intervention) and 6 months
9. Relationship with caregiver, from both the perspective of the person with dementia and the caregiver, measured by the 10. Quality of Caregiver and Patient Relationship scale (QPCR) at 16 weeks (post-intervention) and 6 months
11. Caregiver burden measured by the Zarit Burden Interview (ZBI) at 16 weeks (post-intervention) and 6 months

Previous secondary outcomes:
1. Symptoms of depression are measured by the Cornell Scale for Depression in Dementia, at baseline (pre-intervention), 16 weeks (post-intervention) and 6 months.
2. Symptoms of anxiety is measured using the Rating Anxiety in Dementia Scale (RAID) scale, at baseline (pre-intervention), 16 weeks (post-intervention) and 6 months
3. Quality of life is measured using the EQ-5D-5L scale, at baseline (pre-intervention), 16 weeks (post-intervention) and 6 months
4. Quality of life is measured using the DEMQOL scale, DEMQOL-proxy is collected from the carer (if available), at baseline (pre-intervention), 16 weeks (post-intervention) and 6 months
5. Carer burden is measured using the Zarit Burden Interview scale, at baseline (pre-intervention), 16 weeks (post-intervention) and 6 months
6. Resource use is measure by the Client Service Receipt Inventory, at baseline (pre-intervention), 16 weeks (post-intervention) and 6 months
7. Relationship with caregiver is measured by the Quality of Caregiver and Patient Relationship scale (QCPR) at baseline (pre-intervention), 16 weeks (post-intervention) and 6 months
8. Self compassion is measured by the Short-Self-Compassion Scale (SCS-SF), at baseline (pre-intervention), 16 weeks (post-intervention) and 6 months
9. Cognitive function is measured by the Montreal Cognitive Assessment (MoCA), at baseline (pre-intervention), 16 weeks (post-intervention) and 6 months

10. Secondary outcomes also include the post intervention qualitative interviews with carers /supporters, service managers, clinical professionals facilitating CFT and participants receiving CFT. Qualitative interviews will be used to gather participant, carer/ supporter and clinician perspectives on the value, acceptability and feasibility of the intervention. We will conduct semi-structured, audio-recorded interviews (performed over videoconferencing software or face-to-face) with up to 20 participants with dementia (including up to 10 control group participants with dementia, in order to explore trial procedures from perspective of those who did not participate in the intervention). We will also interview up to 15 carers / supporters (including those who did not attend the workshop to better explore barriers to attendance). We will approach and plan to interview up to 10 NHS personnel (including group facilitators and service managers) for qualitative interviews to determine feasibility of implementation. Qualitative analysis will follow Braun and Clarke's methods of thematic analysis and will be done using NVivo.

Completion date
31/10/2028

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/03/2026:
1. Meet Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) for dementia of any type
2. Mild to moderate dementia as determined by the following:
2.1. A confirmed dementia diagnosis based on DSM-IV criteria for any type of dementia, AND
2.2. A Clinical Dementia Rating (CDR) score of 0.5, 1, or 2 (Morris, 1997).
3. Experience symptoms of depression and/or anxiety as determined by either:
3.1. A HADS score ≥ 8 on the anxiety and/or depression subscale (Zigmond & Snaith, 1983), OR
3.2. A HADS score of 5–7, accompanied by evidence of low mood as reported by a caregiver or clinician, OR
3.3. Significant psychological distress, as assessed by a clinician or researcher, regardless of the HADS score.
4. Have capacity to consent to take part in research
5. Can communicate in English
6. Have access to WiFi, enabling them to partake in virtual CFT groups, OR the ability to attend a face-to-face group
7. Are not participating in another interventional research programme concurrently
8. Have sufficient hearing to engage in group discussions (with or without hearing aids).
9. Aged 18 years and over
10. People can be included whether or not they have a caregiver.

Previous inclusion criteria as of 05/09/2024:
1. Meet Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) for dementia of any type
2. Mild to moderate dementia as determined by the Clinical Dementia Rating (CDR)
3. Experience symptoms of depression and/or anxiety (8 ≥) as measured by the Hospital Anxiety and Depression Scale (HADS) OR a minimum score of 5 and experience of depression and/or anxiety as reported by either the caregiver or clinician
4. Have capacity to consent to take part in research
5. Can communicate in English
6. Have access to WiFi, enabling them to partake in virtual CFT groups, OR the ability to attend a

face-to-face group
7. Are not participating in another interventional research programme concurrently
8. Aged 18 years and over
9. People can be included whether or not they have a caregiver.

Original inclusion criteria:
1. Meet Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) for dementia of any type
2. Mild to moderate dementia as determined by the Clinical Dementia Rating (CDR)
3. Experience symptoms of depression and/or anxiety (8 > =) as measured by the Hospital Anxiety and Depression Scale (HADS);
4. Have capacity to consent to take part in research;
5. Can communicate in English,
6. Have access to WiFi, enabling them to partake in virtual CFT groups, OR the ability to attend a face-to-face group;
7. Are not participating in another interventional research programme concurrently.
8. Aged 18 years and over
9. People can be included whether or not they have a caregiver.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Communication is significantly impaired by cognitive decline
2. Unable to speak English
3. The participant is currently participating in another interventional research programme.
4. The participant has severe cognitive impairment as measured by the Clinical Dementia Rating scale.

Date of first enrolment
08/11/2023

Date of final enrolment

30/09/2027

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
England
RM13 8GQ

Study participating centre
Oxford Health NHS Foundation Trust
Warneford Hospital
Warneford Lane
Headington
Oxford
England
OX3 7JX

Study participating centre
Norfolk and Suffolk NHS Foundation Trust
Drayton High Rd
Norwich
England
NR6 5BE

Study participating centre
Black Country Healthcare NHS Foundation Trust
2nd Floor, Trafalgar House, 47-49 King St
Dudley
England
DY2 8PS

Study participating centre
Central and North West London NHS Foundation Trust
Trust Headquarters
350 Euston Road
Regents PLACE
London
England
NW1 3AX

Study participating centre
Lincolnshire Partnership NHS Foundation Trust
St George's
Long Leys Road
Lincoln
England
LN1 1FS

Study participating centre
Cheshire and Wirral Partnership NHS Foundation Trust
Trust Headquarters Redesmere
The Countess of Chester Health Park
Liverpool Road
Chester
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CH2 1BQ

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
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EX2 5AF

Sponsor information

Organisation
North East London NHS Foundation Trust

ROR

https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Professor Aimee Spector (aimee.spector@nelft.nhs.uk). The data will be pseudonymised and uploaded into a repository. Professor Spector will consult with NELFT as the sponsor on a case-by-case basis regarding each data request received.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/12/2024	04/12/2024	Yes	No
Participant information sheet	version 2.0	08/08/2023	17/08/2023	No	Yes
Participant information sheet	version 3.0	04/10/2023	05/09/2024	No	Yes
Participant information sheet	version 1.0	02/02/2026	26/03/2026	No	Yes
Participant information sheet	version 1.0	02/02/2026	26/03/2026	No	Yes
Protocol file	version 2.0	09/08/2023	21/08/2023	No	No
Protocol file	version 7.0	27/08/2024	05/09/2024	No	No
Protocol file	version 12	21/01/2026	26/03/2026	No	No