ISRCTN10087117 https://doi.org/10.1186/ISRCTN10087117

Trial of Empowered Conversations dementia carer training

Submission date
12/03/2026

Recruitment status
Recruiting

Registration date
30/03/2026

Overall study status
Ongoing

Last Edited
30/03/2026

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
There are 700,000 family carers for people living with dementia in the UK. Sixty-four percent of carers who are unpaid in England say they have limited support for the range of psychological and social needs they experience. It can be difficult to keep communicating well due to thinking and memory changes that arise when someone is living with dementia. This can lead to frustration, low-mood and stress for both people living with dementia and their carers. The 6-session Empowered Conversations (EC) course is designed to enable carers to establish and maintain good communication and relationships with those they support. Course facilitators are trained to provide specific communication techniques, ways of managing conflicts and working with difficult emotions. EC can be delivered in person or online.

The main goal of the study is to find out if EC, a group-based support program for people who care for someone with dementia, helps and is worth the cost. The study aims to: (1) see how well EC works; (2) find out if it provides good value for money.

Who can participate?
Current unpaid or family carer for someone living with dementia (any subtype or severity) in the community. Participants should provide emotional or practical support at least weekly, be aged 18 or over, and have the capacity to give informed consent for the study. Either the carer or the person living with dementia that they are supporting should live within the boundaries of the recruiting Trusts.

What does the study involve?
During the first appointment, participants will be asked to complete some brief demographic questionnaires that should take about 15-20 minutes. Participants will be able to complete these online, over the phone, or at home. During the second appointment, participants will be asked to complete several questionnaires that should take about 45- 60 minutes. Participants will be able to complete these online, over the phone, or at home.

Participants will then be randomised to either receive the six-week EC course during the study's duration or continue as usual. Participants who are selected to continue as usual will be offered to receive the online EC course after the study has finished.

Approximately 4 and 6 months after the first appointment, participants will be invited to complete further questionnaires. Participants will be able to complete these online, over the phone, or at home.

What are the possible benefits and risks of participating?
The anticipated benefits for carer trial participants are improvements in carer psychological well-being, communication and quality of life. Outcomes from our feasibility trial indicate that carers experience significant reductions in stress and improvements in communication following the EC course. Qualitative data suggests that these improvements in carer stress and communication have an impact on the well-being of the person living with dementia that they are supporting.

It is not anticipated that there are any significant risks or burdens for trial participants. Although talking about the problems of being a carer could be upsetting, in our experience, carers do not find it distressing and usually find it helpful. Some participants may find completion of questionnaire measures burdensome; the researchers will provide practical (splitting sessions up) and emotional support (distress management) if required.

Where is the study run from?
Lancashire Clinical Trials Unit, University of Lancashire (UK)

When is the study starting and how long is it expected to run for?
April 2026 to June 2028

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

Who is the main contact?
Dr Lydia Morris lydia.morris@manchester.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

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Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
346849

Central Portfolio Management System (CPMS)
63791

National Institute for Health and Care Research (NIHR)
208874

Study information

Scientific Title
A multi-centre effectiveness and cost-effectiveness superiority randomised controlled trial of a group-based intervention for family carers of people living with dementia, called Empowered Conversations, compared to treatment as usual

Study objectives
Primary objectives are:
(1) Assess the effectiveness of EC in reducing carer stress ([Perceived Stress Scale [PSS] at 26-weeks post-randomisation) compared to a TAU Control;
(2) determine the cost-effectiveness of EC.

Secondary objectives are:
(3) Assess the effectiveness of EC on secondary outcomes: anxiety and depression [Hospital Anxiety and Depression Scale (HADs)]; relationship strain [Dyadic Relational Scale]; quality of Life [Carer QOL and carer perceived rating for person living with dementia)]; Carer goals [Goal-based outcome measure]; Activities of daily living; Peer Support; Communication at 16 and 26 weeks post-randomisation
(4) Assess the effectiveness of EC in reducing carer stress (PSS) at 16 weeks,
(5) Assess fidelity to the intervention protocol using a fidelity checklist that is observer and facilitator rated,
(6) Provide the first examination of whether effectiveness is different in the in-person version compared to the online version of EC,
(7) Explore whether effectiveness varies according to key carer status factors (e.g. providing ‘full-time’ vs ‘part-time’ support; and an estimate of symptom severity of the person living with

dementia),
(8) Provide initial psychometric properties and analysis of the Peer Support measure,
(9) Provide the first full evaluation of safety indices in a definitive clinical trial of EC,
(10) Provide initial acceptability data on the adaptations made to EC, and additional training for facilitators, to make EC more accessible to minoritised (global majority) communities.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/03/2026, East of England - Cambridge South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 0207 104 8084; cambridgesouth.rec@hra.nhs.uk), ref: 26/EE/0022

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Social Care, Primary sub-specialty: Social Care; Health Category: Neurological; Disease /Condition: Organic, including symptomatic, mental disorders

Interventions
The trial will recruit 336 participants to compare two approaches to treatment. Two-thirds of the participants (224 people) will receive both a course called 'Empowered Conversations' and the standard care they usually get (called Treatment-As-Usual, or TAU). The other third will receive just the standard care. This selection is chosen at random by a computer program, with the research team having no input on what someone receives.

Empowered Conversations (EC): EC is group-based and delivered across six weeks. It is designed to enable carers to establish and maintain good communication and relationships with those they support. Course facilitators are trained to provide specific communication techniques, ways of managing conflicts and working with difficult emotions. EC can be delivered in person or online.

Treatment-As-Usual (TAU): EC will be compared with TAU, which is likely to be limited in terms of support, but can include support from services (e.g. Age UK or Alzheimer's Society) in some cases. Given that there is rarely a specific carer service or pathway offered within the NHS, the nature of this support will vary. Participants allocated to TAU will be offered the EC course following completion of their participation in the trial.

Intervention Type
Behavioural

Primary outcome(s)
1. Stress measured using the Perceived Stress Scale at baseline, 16 weeks and 26 weeks

Key secondary outcome(s)
1. Perceived support from other group members measured using the Peer Support Questionnaire at baseline, 16 weeks and 26 week

2. Relationship strain measured using the Dyadic Relationship Scale (Caregiver) at baseline, 16 weeks and 26 week

3. Specific goals that the carer has for the course measured using the Goal-Based Outcome Measure at baseline, 16 weeks and 26 week

4. Carer perceptions of communication measured using the Carer Communication Questionnaire at baseline, 16 weeks and 26 week

5. Quality of life (carer) measured using the C-DEMQOL questionnaire at baseline, 16 weeks and 26 week

6. Quality of life (person living with dementia) measured using the DEMQOL-Proxy questionnaire at baseline, 16 weeks and 26 week

7. Anxiety and depression measured using the Hospital Anxiety & Depression Scale (HADS) at baseline, 16 weeks and 26 week

8. Ability of someone with dementia to carry out daily activities, such as dressing and preparing food measured using the Bristol Activities of Daily Living Scale (BADLS) at baseline

9. Demographics measured using the Demographic questionnaire at baseline

10. Health-related quality of life measured using EQ-5D-5L tool at baseline, 16 weeks and 26 weeks

11. Hospital, primary, community and social care use measured using the Healthcare Service Use questionnaire at baseline, 16 weeks and 26 weeks

12. Harms and adverse effects measured using adverse event reports throughout the study and Adapted Adverse Effects of Therapy Checklist at 16 weeks and 26 weeks

Completion date
30/06/2028

Eligibility

Key inclusion criteria
1. Current unpaid or family carer for someone living with dementia (any subtype or severity) in the community
2. Provide emotional or practical support at least weekly
3. Aged 18 or over
4. Have the capacity to give informed consent for the study
5. Either the carer or the person living with dementia that they are supporting, and live within the boundaries of recruiting Trusts

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. Unable to provide informed consent
2. Currently enrolled in a concurrent non-pharmacological (psychosocial intervention) carer research study
3. Caring for someone living with dementia in a Nursing or residential care home
4. The person living with dementia being cared for is receiving palliative care or considered to be in the last six months of their life

Date of first enrolment
15/04/2026

Date of final enrolment
31/07/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
England
M25 3BL

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
England
OL6 7SR

Study participating centre
Lancashire & South Cumbria NHS Foundation Trust Hq
Sceptre Point
Sceptre Way
Bamber Bridge
Preston
England
PR5 6AW

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

Sponsor information

Organisation
University of Manchester

ROR

https://ror.org/027m9bs27

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
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. In line with NIHR guidelines, fully anonymised quantitative data will be deposited in a public repository (https://figshare.com/). This is a publicly available and searchable platform where it will be permanently stored. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check the analysis and results.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	23/02/2026	26/03/2026	No	No