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Trial of Empowered Conversations dementia carer training

Submission date
25/02/2022

Recruitment status
No longer recruiting

Registration date
02/03/2022

Overall study status
Completed

Last Edited
07/04/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There are 700,000 family and informal carers for people living with dementia in the UK alone. Sixty-four percent of informal carers 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 six-session online Empowered Conversations 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.
The course has been tried out over the last 4 years and changes have been made. Feedback from informal carers indicates it is in an optimum form and the researchers are ready to test it further in a large trial. Before they do this, they need to do a smaller 'feasibility' trial to check whether such a larger trial is possible. This is important because a big trial will help identify if the course works, but trials are expensive and unhelpful if they go wrong. This 'feasibility' trial will check several things. The researchers want to make sure that carers would be willing to have an only 66% chance of receiving the course straight away, because it is essential to have a comparison group. The remaining 33% of carers would be offered the course 6 months later. The researchers want to ensure that the design is good enough to identify any improvement in carers' well-being,
relationships and communication. They will also ask carers to take part in a one-to-one interview about their experiences of the course.

Who can participate?
Carer participants will be included if they live within the Greater Manchester area and are informally caring for someone living with dementia

What does the study involve?
Participants are randomly allocated to the Empowered Conversations training intervention (plus treatment as usual), or the treatment as usual (TAU) waitlist control group. Empowered Conversations is a six-session online course and a psychosocial intervention. Carer self-report measures will be analysed at the start of the study and at a 6-month follow-up. Cost-

effectiveness data will also be collected. Those in the TAU group will receive the Empowered Conversations training intervention at the end of their follow-up, assuming they still wish to receive it.

What are the possible benefits and risks of participating?
Participants will attend the Empowered Conversations course with other people in a caring relationship with a person living with dementia. These courses have been found to be supportive and enjoyable. However, talking about caring experiences could be upsetting. The research and facilitator team will support participants if they feel distressed. There are no expected risks to taking part in the research activities (questionnaires and interviews). Potential benefits to carers are through attending the course. Initial evidence indicates that Empowered Conversations can improve stress levels and communication of care partners and this in turn may help the person living with dementia that you are supporting. It is hoped that the findings of the overall study will be useful in evaluating and improving access to Empowered Conversations.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
October 2021 to August 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
301042

Protocol serial number
IRAS 301042, CPMS 51659

Study information

Scientific Title
Evaluation of the feasibility of a randomized controlled trial of Empowered Conversations: a training to enhance relationships and communication between family carers and people living with dementia

Study objectives
The primary aim is to establish the feasibility of examining Empowered Conversations (EC) within a multi-centre randomized controlled trial (RCT). The study has the following key objectives to:
1. Establish recruitment pathways
2. Identify facilitators/barriers to recruitment. This will include specifically examine whether the online format presents any barriers to under-served, or other, groups accessing the trial.
3. Estimate retention levels and response rates to questionnaires
4. Obtain additional evidence regarding proof of concept
5. Estimate potential effectiveness on a range of candidate primary outcome measures, and their standard deviations (SDs)
6. Identify the most appropriate primary outcome measure for a multi-centre effectiveness trial
7. Establish the optimum way of evaluating the cost-effectiveness
8. Involve carers and people living with dementia in key decisions about the study and explore opportunities for Patient and Public Involvement and Engagement (PPIE) in the multi-site RCT

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/02/2022, Welsh Research Ethics Committee 2 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 230457, +44 (0) 7787 371748, +44 (0)1686 252101; Wales.REC2@wales.nhs.uk), REC ref: 22/WA/0010

Study design
Single-centre interventional single-blind randomized controlled feasibility trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Carers of people living with dementia; some of whom will be experiencing anxiety and/or depression

Interventions
The two arms will be the Empowered Conversations training intervention (plus Treatment as Usual), or Treatment as Usual (TAU) waitlist control. Empowered Conversations is a six-session online course and a psychosocial intervention. Randomisation will be performed as block randomisation with a 2:1 allocation, in favour of the immediate intervention arm. Carer self-report measures will be analysed at baseline and 6-month follow up in order to estimate the SD of outcome measures and examine recruitment and retention. Cost-effectiveness feasibility data will also be collected as part of this work package. Those in the TAU arm will receive EC at the end of their follow-up, assuming they still wish to receive it.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment numbers achieved per month, i.e. per month an average of 6-10 carers
2. Retention rate recorded as the number of participants who remain in the study at the 6-month follow-up
3. Estimates of the standard deviations of candidate primary outcome measures will be examined to establish whether they could detect a minimally important difference and to assist with the estimation of the required sample size for a full effectiveness trial (see secondary outcome measures)

Key secondary outcome(s))
The candidate primary outcome measures (all measured at 6 months) are:
1. Carer anxiety and depression measured using Hospital Anxiety and Depression Scale Total Score (HADS-T)
2. Carer stress measured using Perceived Stress Scale
3. Carer relationship stress using the Dyadic relationship scale
4. Carer sense of competence in their caring role measured using Short Sense of Competence

Completion date
31/08/2023

Eligibility

Key inclusion criteria
1. Carer participants will be included if they live within the Greater Manchester area and are informally caring for someone living with dementia
2. Able to give informed consent
3. Have sufficient English language skills to understand the training (i.e. verbal and written language abilities required to understand verbal presentations and complete simple exercises)
4. Carer ability to participate will not be conditional on carers' agreement to approach the person living with dementia or being able to consent the person living with dementia to be interviewed

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
75

Key exclusion criteria
Unable to give informed consent to the trial

Date of first enrolment
07/03/2022

Date of final enrolment
31/01/2023

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

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

Fully anonymised data will be deposited in a public repository (Figshare), which 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?
Results article		02/04/2026	07/04/2026	Yes	No
Protocol article		10/07/2023	26/10/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Participant experiences	09/10/2024	10/10/2024	Yes	No