

# Trial of Empowered Conversations dementia carer training

<b>Submission date</b> 25/02/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/03/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/10/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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

### Type(s)

Public

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Principal Investigator

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

301042

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Community

## **Study type(s)**

Quality of life

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

## **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 measure**

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)

### **Secondary outcome measures**

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

### **Overall study start date**

01/10/2021

### **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

### **Age group**

Mixed

### **Sex**

Both

### **Target number of participants**

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

England

United Kingdom

## Study participating centre

**Greater Manchester Mental Health NHS Foundation Trust**

Prestwich Hospital

Bury New Road

Prestwich

Manchester

United Kingdom

M25 3BL

## Study participating centre

**Pennine Care NHS Foundation Trust**

225 Old Street

Ashton-under-lyne

United Kingdom

OL6 7SR

# Sponsor information

## Organisation

University of Manchester

## Sponsor details

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## Sponsor type

University/education

## Website

<http://www.manchester.ac.uk/>

**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**

### **Publication and dissemination plan**

The researchers plan to publish their research in key peer-reviewed journals in this area, such as Aging and Mental Health, and Dementia. The papers will include a co-authored paper produced with members of the PPI advisory group.

The dissemination strategy will involve collaboration with, and the active involvement of, carers of people living with dementia. Whenever possible, presentations will be made jointly by carers and researchers (the researchers have budgeted for this). The key conferences that they plan to present at are the annual UK Alzheimer's Society Conference and the UK Dementia Congress.

The researchers will also participate in other relevant events and workshops where ongoing findings from the study can be brought to a more general audience (e.g. during the annual Dementia Awareness Week). Findings will be presented to carers, who will receive tailored feedback regarding the study.

### **Intention to publish date**

31/05/2024

### **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?
<a href="#">HRA research summary</a>	Participant experiences	10/07/2023	28/06/2023	No	No
<a href="#">Protocol article</a>			26/10/2023	Yes	No
<a href="#">Other publications</a>		09/10/2024	10/10/2024	Yes	No