STUDY PROTOCOL

Protocol of a feasibility randomised controlled trial of Empowered Conversations: training family carers to enhance their relationships and communication with people living with dementia. [version 1; peer review: awaiting peer review]

Cassie Eastham¹, Warren Mansell²,³, Chris Sutton³, Yeliz Prior⁴, John Keady³, Gemma Shields³, Cathy Riley¹, Gail Bowker⁵, Yvonne Sylvestre³, Lydia Morris³

¹Greater Manchester Mental Health NHS Foundation Trust, Prestwich, England, M25 3BL, UK
²Curtin University, Perth, Western Australia, 6102, Australia
³The University of Manchester, Manchester, England, M13 9PL, UK
⁴University of Salford, Salford, England, M5 4WT, UK
⁵Independent Researcher, Manchester, England, UK

Abstract

Background: Communication difficulties can cause frustration, low mood, and stress for people living with dementia and their carer. Carers should be offered training on adapting their communication skills. However, it is not common for skills-based education to examine emotional aspects of care and the effect of dementia on relationships. The Empowered Conversations (EC) training course was developed in response to a gap in service provision and has been adapted to a virtual format (Zoom). It addresses the specific psychological, relationship, and communication needs of informal and family dementia carers. The primary aim of the study is to investigate the feasibility of conducting a multi-centre randomised controlled evaluation trial of EC. Secondary aims include exploring the acceptability of delivering the intervention online and examining the optimum way of establishing cost-effectiveness.

Methods: The feasibility trial uses a pragmatic data-collector blind parallel two-group RCT design with two arms (EC intervention plus treatment as usual, and treatment as usual waitlist control). There will be a 2:1 allocation in favour of the EC-training intervention arm. 75 participants will complete baseline outcome measures exploring their role as a carer, including their physical and mental health, attitudes to caring, quality of life, and use of health and social care services. These will be repeated after six-months. Participants allocated to the treatment group who complete the course will be invited to participate in a qualitative interview discussing their experience of EC.
Discussion: The study will investigate recruitment pathways (including facilitators and barriers to recruitment), estimate retention levels and response rates to questionnaires, obtain additional evidence regarding proof of concept, and consider the most appropriate primary outcome measures and methods for evaluating cost-effectiveness. The results of the feasibility study will be used to inform the development of a multicentre randomised controlled trial in the United Kingdom.

Registration: [ISRCTN15261686](02/03/2022)

Keywords
Dementia, Carers, Caregivers, Stress, Burden, Psychosocial intervention, Training, Communication

Corresponding author: Lydia Morris (lydia.morris@manchester.ac.uk)

Author roles: Eastham C: Conceptualization, Project Administration, Writing – Original Draft Preparation, Writing – Review & Editing; Mansell W: Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Review & Editing; Sutton C: Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Review & Editing; Prior Y: Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Review & Editing; Keady J: Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Review & Editing; Shields G: Conceptualization, Funding Acquisition, Methodology, Writing – Review & Editing; Riley C: Conceptualization, Writing – Review & Editing; Bowker G: Conceptualization, Writing – Review & Editing; Sylvestre Y: Methodology, Writing – Review & Editing; Morris L: Conceptualization, Funding Acquisition, Methodology, Project Administration, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing

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Plain language summary
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 caused by dementia. This can lead to frustration, low-mood and stress for both people living with dementia and their carers.

The 6-session online Empowered Conversations course is designed to enable carers to maintain and improve 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 made. Feedback from informal carers indicates it is in an optimum form and we are ready to test it further in a large trial. Before this is done, it is necessary to complete a smaller ‘feasibility’ trial to check whether such a larger trial is possible. This article explains how the feasibility trial will be carried out.

Our ‘feasibility’ trial will check several things. We 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. We want to ensure that our design is good enough to identify any improvement in carers’ well-being, relationships and communication. We will also ask carers to take part in a one-to-one interview about their experiences of the course, including their views on the course being delivered on Zoom.

Introduction
Background and rationale
In the UK, around 61% of people who are aged over 60 and have a diagnosis of dementia live at home (Wittenberg et al., 2019a) Informal care, defined as unpaid support given to a family member, partner or friend who could not otherwise cope because of their physical or mental health needs (NHS England, 2014), is therefore an essential component of dementia care with a cost of £13.9bn per year for unpaid care, compared with £15.7bn spent on formal social care (Wittenberg et al., 2019b).

Informal carers in the UK report significantly lower life satisfaction, happiness, and self-worth (Carers UK, 2022), sixty-four percent of informal carers in England say they have limited support for their psychological and social needs (Health and Social Care Information Centre, 2017). It is widely recognised that the availability of dementia post-diagnostic support varies both internationally and across the UK (Alzheimer’s Disease International, 2022; Alzheimer’s Society, 2022; Frost et al., 2021).

It has been identified that caring for a person with dementia is more stressful than caring for someone with a physical health condition (Brodaty & Donkin, 2009) and that about 40% of informal carers of people living with dementia experience significant depression or anxiety (Cooper et al., 2007). The ongoing cognitive, communication, and perceptual changes caused by all types of dementia present significant challenges for informal carers (Clare et al., 2019; Moniz-Cook et al., 2011).

Informal carers of people living with dementia can benefit from support and interventions that address their needs. For example, certain tailored psychosocial interventions can reduce carer depression and anxiety (Morris et al., 2018) and multicomponent psychosocial interventions (combining two or more different approaches, such as counselling and support) for carers can prevent care breakdown and delay care home admission (Elvish et al., 2013; Mittelman et al., 1993; Olazarán et al., 2010).

Difficulties with communication cause frustration, low mood, and stress for both people living with dementia and their carers (Dooley et al., 2015; Holst & Hallberg, 2003; Steeman et al., 2006). Conversely, research has found that improving communication can enhance relationships and support people living with dementia to feel connected and understood (Judge et al., 2013; La Fontaine & Oyebode, 2014).

Communication skills training for carers can improve the well-being and quality of life of the person living with dementia, and result in positive interactions during the delivery of care (Eggenberger et al., 2013; Morris et al., 2018; Perkins et al., 2022). However, although skills-based interventions may improve carers’ knowledge and communication skills, it is not common for communication skills training to include emotional aspects of care and the changing role dynamics within the caring relationship (Morris et al., 2018; Williams et al., 2018). The Empowered Conversations (EC) communication training course for carers was developed in response to the gap in service provision identified through reviewing research literature and carrying out scoping exercises and public engagement work (Innes et al., 2022; Morris et al., 2020; Morris et al., 2021). In addition, a further systematic review of communication training programmes identified that interventions were often based only on basic models of communication, lacked post-intervention follow up and used a variety of non-standardised outcome measures (Perkins et al., 2022).

More recently, acceptability and feasibility work has been published regarding an emotional intelligence focused training workshop for professional and family carers (Heid et al., 2022). Although emotional intelligence skills can be developed through EC, the course also includes relational dynamics and specific communication skills. The course integrates evidence-based models to address the specific psychological, relationship, and communication needs of carers (Morris et al., 2020). Earlier research, using a pre-post-follow-up design, has demonstrated that carer stress was significantly reduced, and communication significantly improved over time following participation in the course (Morris et al., 2021). Twenty-eight of the 159 carers
who participated in the study agreed to be interviewed after the course and twenty-seven described feeling able to better connect with the person they support after attending EC (Innes et al., 2022; Morris et al., 2020).

Currently, EC is only routinely provided in Greater Manchester. The intervention is delivered in a group format and includes multiple components, including both educational and therapeutic components. This is in line with evidence that concludes the most effective interventions for improving carers’ psychological health include these features (Dickinson et al., 2022).

Initially, EC courses were delivered as in person (face-to-face) groups but, following restrictions caused by COVID-19, EC was adapted to an online format delivered using Zoom. A review with meta-analysis of online interventions for family carers indicated that multicomponent interventions achieved the best results as regards reducing depression, anxiety, grief, and burden and increasing quality of life, empathy, and knowledge about dementia; however, online interventions focusing on more specific aspects also contributed to a range of improvements (Etxeberria et al., 2021). In addition, comparisons of support packages delivered in in person and online versions have shown that both formats offer similar effectiveness (Karagiozi et al., 2022; Noel et al., 2022; O’Connor et al., 2023). However, it is possible that online interventions could also exclude certain individuals (Giebel et al., 2021; Wheatley et al., 2022).

The proposed feasibility RCT, with nested qualitative study, will provide data to inform a fully powered multi-centre RCT of an intervention delivered online that could satisfy a currently unmet need for carers in the UK.

Study objectives
The primary aim of the study is to establish the feasibility of examining the EC intervention within a multi-centre RCT.

The study’s key objectives are:

1. To establish recruitment pathways.
2. To identify facilitators and barriers to recruitment, including whether the online format of the intervention presents a barrier to under-served or other groups.
3. To estimate retention levels and response rates to questionnaires.
4. To obtain additional evidence regarding proof of concept.
5. To estimate potential effectiveness on a range of candidate primary outcome measures, and their standard deviations (SDs).
6. To identify the most appropriate primary outcome measure for a multi-centre evaluation trial.
7. To establish the optimum way of evaluating cost-effectiveness in a multi-centre evaluation trial.

Primary outcome(s)
1. Recruitment numbers per month.
2. Retention rate recorded as the number of participants who remain in the study at the 6-month follow-up.
3. Feasibility of an evaluation trial, as indicated by 1 & 2 above, and informed by the qualitative data

Key secondary outcomes
1. Obtain estimates of the standard deviations of measures.
2. Explore ‘proof of concept’, Establish the optimum way of evaluating cost-effectiveness.
3. Identify the most suitable primary outcome measure(s) for a subsequent evaluation trial.
4. Explore acceptability of delivering the intervention online

Candidate primary outcome measure(s) for a subsequent evaluation trial include:
1. Carer anxiety and depression measured using Hospital Anxiety and Depression Scale Total Score (HADS-T), or HADs depression or anxiety subscales
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

Trial design
The trial will use a pragmatic data-collector blind parallel two-group RCT design. The two arms will be the EC training-intervention (plus Treatment as Usual), or Treatment as Usual (TAU) waitlist control.

There will be a 2:1 allocation in favour of the EC training-intervention arm.

The comparator is a Treatment as Usual (TAU) waitlist control. This comparator is helpful in an effectiveness design (and so within a feasibility trial that aims to scale up to an effectiveness trial). Participants in the TAU arm will be offered the EC intervention after completing their 6-month follow up questionnaires.

The trial will also include a nested qualitative study. This will involve interviews with participants who attended at least three sessions of the EC intervention, as well as individual or focus group interviews with participants who declined to take part in the trial or have attended two or fewer sessions of the course.

Protocol
Trial registration: ISRCTN15261686 (registered on February 3rd, 2022)
Protocol version: 2.6 21/11/2023
Methods: Participants, interventions, and outcomes

Study setting

The study will take place across the ten boroughs (Bolton, Bury, Manchester, Oldham, Rochdale, Salford, Stockport, Tameside, Trafford, and Wigan) within Greater Manchester, a metropolitan county in the Northwest of England with varying levels of deprivation (Table 1). The study will be hosted by Greater Manchester Mental Health NHS Foundation Trust with a study site at Pennine Care NHS Foundation Trust. Recruitment will also take place within the third sector and community organisations across Greater Manchester.

EC is an online intervention and participants will take part from their own homes or any other suitable place of their choice. The baseline and six-month follow-up questionnaires will be offered online (using REDCap) or in person with a researcher. Any face-to-face research activities, such as interviews, will take place at the participant’s home or another appropriate venue of their choice.

Eligibility criteria

The trial aims to recruit 75 carers of people living with dementia.

To be included in the main study, participants must:

- Be the current unpaid or informal carer for someone living with dementia (any sub-type or severity)
- Live in Greater Manchester
- Be aged 18 or over.
- Have capacity to give informed consent for the study.
- Have sufficient English language skills to understand and participate in the training and research activities.
- Be interested in taking part in a training course for carers of people living with dementia.

Where appropriate, the Clinical Dementia Rating (CDR) scale will be used to assess the person with dementia’s level of cognitive impairment.

The researcher will ask the carer if it is appropriate to approach the person with dementia about completing the CDR. Carers will be asked to consider significant issues such as the person being unaware of their dementia diagnosis, being distressed by cognitive testing or discussing their memory, or if the person has significant unmanaged behavioural or psychological symptoms of dementia. Such concerns would exclude the person with dementia from participating.

The person living with dementia will need to have capacity to give informed consent to completing the CDR scale. If they appear to lack capacity, they will need to have a personal consultee who can be approached to discuss their involvement in the research.

The carer’s eligibility to participate is not conditional on the person living with dementia being offered or completing the CDR.

Intervention

This version of EC is delivered online using Zoom by two trained facilitators from Age UK Salford. Each group will comprise 6–10 participants.

Facilitators follow a course manual to deliver a structured framework of core topics, discussions, and activities over six-weeks (Table 2). However, they also have flexibility to

<table>
<thead>
<tr>
<th>Borough</th>
<th>Index of Multiple Deprivation Rank of Average Score</th>
<th>Health Deprivation and Disability Rank of average score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolton</td>
<td>27</td>
<td>36</td>
</tr>
<tr>
<td>Bury</td>
<td>69</td>
<td>54</td>
</tr>
<tr>
<td>Manchester</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Oldham</td>
<td>16</td>
<td>31</td>
</tr>
<tr>
<td>Rochdale</td>
<td>14</td>
<td>17</td>
</tr>
<tr>
<td>Salford</td>
<td>15</td>
<td>9</td>
</tr>
<tr>
<td>Stockport</td>
<td>86</td>
<td>52</td>
</tr>
<tr>
<td>Tameside</td>
<td>24</td>
<td>15</td>
</tr>
<tr>
<td>Trafford</td>
<td>118</td>
<td>88</td>
</tr>
<tr>
<td>Wigan</td>
<td>58</td>
<td>33</td>
</tr>
</tbody>
</table>
adapt the material to the different needs of participants, including optional and extra activities that can be used if appropriate. Each session lasts for 2-hours and is held at the same time and day for the duration of the course. Where possible, participants will be offered a choice of morning, afternoon, or evening sessions to accommodate their needs. Participants are sent a workbook before the start of the course and additional (optional) learning materials are sent to participants in a weekly email from the facilitator. The course summary can be found in the Extended data (Morris et al., 2023).

Each session begins with a ‘Pause for Breath’ (a short breathing exercise led by a facilitator) and an opportunity to reflect on both the previous week’s session and the participants’ experiences during the week. This is followed by the week’s activities and each session is closed with a summary, including prompts for reflection or actions that the participants can try during the week.

Facilitators are trained to deliver the course using the manual and will have participated in an EC course before their training begins. New facilitators receive nine hours of one-to-one training provided across the duration of two EC courses. New facilitators begin to deliver aspects of these courses with support from an experienced facilitator, weekly debriefs and supervision.

All course facilitators access weekly supervision with an experienced facilitator and monthly external clinical supervision.

Fidelity and competence of the course facilitators will be monitored using an adapted version of checklist that has been used in two previous studies of a group-based intervention using similar techniques to EC (the Take Control Course) (Morris et al., 2016; Morris et al., 2018).

Adherence of the course to the intervention will be monitored by Age UK Salford. Staff will record attendance at each session. Participants completing three or more sessions will be considered to have completed the intervention.

**Table 2. Session content for EC course.**

<table>
<thead>
<tr>
<th>Theme</th>
<th>Week 1</th>
<th>Introducing Curiosity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Week 2</td>
<td>What Gets in the Way of Our Conversations?</td>
</tr>
<tr>
<td></td>
<td>Week 3</td>
<td>Stop, Listen, Look</td>
</tr>
<tr>
<td></td>
<td>Week 4</td>
<td>Empathy and Memory</td>
</tr>
<tr>
<td></td>
<td>Week 5</td>
<td>Building on Strengths and Resources</td>
</tr>
<tr>
<td></td>
<td>Week 6</td>
<td>Summing Up – Drawing the Course to a Close</td>
</tr>
</tbody>
</table>

**TAU**

TAU will be the medical, psychological, and social support that is available to the care dyad within their local area. This may include, but is not limited to, services such as NHS memory assessment or community mental health teams, dementia cafés, social care, and carers support groups.

There will be no restriction on treatment as usual. This is intended to be a pragmatic trial and preventing carers from accessing services would be unethical.

Any services that carers access will be captured with the Healthcare Service Use questionnaire.

**Outcomes**

The study will measure outcomes in terms of (1) identifying the most appropriate primary clinical outcome measures and (2) the feasibility of conducting a multi-centre study.

Participants will complete ten clinical outcome measures at baseline and at 6-month follow-up to address objectives 4–6. These will be Short Sense of Competence Questionnaire, Dyadic Relationship Scale (Caregiver), Carer Communication Questionnaire, Perceived Stress Scale, Hospital Anxiety & Depression Scale (HADS) (potential primary outcome measures), C-DEMQOL, Caregiving Ambivalence Scale, Bristol Activities of Daily Living Scale, EQ-5D-5L, and Healthcare service use.

A ‘shortlist’ of potential primary outcome measures will be developed using the evidence of proof of concept/proof of efficacy and carers’ views discussed in the qualitative interviews. Participants will also be asked to record key demographic data at baseline and complete a feedback form when they finish the course sessions.

Exploratory analysis of cost-effectiveness measures (objective 7) will be conducted using data from the EQ-5D (a commonly used measure of health status) and healthcare service use questionnaires. The CDR scale will be used as a measure to directly assess the supported person’s level of cognitive impairment. This clinical interview assessment will be conducted at baseline with the care dyad. This will help describe the sample and establish whether using this measure would be feasible within the proposed multi-centre trial.

The feasibility of proceeding to a multi-centre study (objectives 1, 2 and 3) will be judged on the recruitment and retention of participants.

- If an average of 6–10 carers were recruited per month from the proposed Greater Manchester recruitment site, then this would be expected to be at a sufficient level for a multi-centre trial. This would need to be fulfilled in addition to the below stop/go criterion.
• Stop/go criteria for retention (baseline to primary outcome completion at 6-month follow-up out of number randomised) is:
  o Green (progress to full trial): At least 80% retention:
  o Amber (full trial considered feasible if reasons for poor retention identified and can be addressed): 65%–<80% retention.
  o Red (unlikely to progress to full trial): Below 65% retention.

Sample size
The target sample size for the RCT will be 75 (50 EC training-intervention:25 TAU). However, to account for withdrawals and to ensure each course cohort is an appropriate size (6–10 participants), up to 90 participants will be recruited.

This is a typical sample size for feasibility trials and, assuming a minimum of 80% retention (60 participants) will enable the SD to be estimated with satisfactory precision (Sim & Lewis, 2012) and the overall retention rate to be estimated by a 95% confidence interval with width 19.2%. It will also enable estimation of efficacy (Standardised Effect Size [SES]) using an 80% confidence interval width ≤0.4.

Recruitment
The participant timeline is summarised in Figure 1. Potential participants will be identified through NHS memory services, established carer and dementia support groups, health and social care networks, and Join Dementia Research. The study team will attend groups and meetings, both online and in person, to talk about participation in the trial. The study will also be promoted on social media channels (Twitter and Facebook), organisational newsletters/blogs, and via professional and service user/carer networks.

Updates about the trial will be sent by email to community and professional stakeholders to maintain interest in recruitment.

Professionals will give carers a short summary of the trial and ask them to complete a consent to contact form if they are interested in knowing more. Where a physical consent to contact form cannot be used (e.g., telephone appointments), verbal consent will be documented by the professional in their usual records. Alternatively, carers can self-refer by telephone or email, or give consent to contact directly to the study team during promotional activities.

The study team will then provide a detailed participant information sheet and, after a minimum of 24-hours, contact the carer to answer any questions and discuss the trial in more detail.

Recruitment levels will be monitored and reviewed by the study’s trial management group. If targets are not being achieved, the group will discuss strategies to address this.

Methods: Assignment of interventions
This is a feasibility trial using pragmatic data-collector blind parallel two-group RCT design. The two arms will be the EC training-intervention (plus TAU), or TAU waitlist control.

Allocation: Sequence generation
Randomisation will be performed as block randomisation with a 2:1 allocation, in favour of the immediate intervention arm. A computer-generated randomisation schedule with randomly permuted blocks, of randomly-selected block sizes, will be used to ensure allocation concealment.

Unbalanced randomisation is used to provide more information on aspects of the EC intervention, such as barriers to participation and intervention acceptability. In addition, it is anticipated that this design will make the trial more ethically acceptable if used for a subsequent effectiveness trial. Moreover, although imbalance tends to make evaluation trials less efficient (increasing the overall sample size to achieve target power), it is expected that there will be some degree of clustering (by group) in the EC arm which will lessen the impact of the imbalance, meaning that a ratio between 1:1 and 2:1 would provide the optimal design. We would, however, expect to retain a 2:1 allocation ratio for an evaluation trial, should this be found to be feasible.

Randomisation process
A researcher will contact carers who are interested in taking part and screen their eligibility using the defined recruitment criteria. Eligible carers who are agreeable to taking part in the research will then complete the baseline questionnaires in a face-to-face appointment with the researcher or be sent an electronic invitation to complete these online.

On completion of the consent form and baseline measures, the researcher will send the participant’s details to the EC administrator, who will then randomise the participant to the treatment or control group using the online Sealed Envelope application. This ensures concealment from members of the research team completing recruitment.

Blinding
The trial will be data-collector blind. We cannot blind participants or those delivering the intervention to treatment group. Emergency unblinding could occur if the facilitators or researchers identify a high risk of self-harm or suicide, or of harm from others (e.g., safeguarding concerns); in this scenario it would be likely that unblinding would be needed to best support the participants well-being.
Figure 1. Participant timeline.
The research team will be unblinded after the participant completes the 6-month follow up questionnaires. The statistical team will remain blind until the Statistical Analysis Plan has been approved.

**Methods: Data collection, management and analysis**

**Quantitative data collection methods**
Participants will complete the baseline and follow-up questionnaires (Table 3) during a face-to-face appointment with the researcher or online using the REDCap system. Participants completing the questionnaires online will be encouraged to complete the questionnaires in one session.

The CDR scale is completed with the care dyad. If appropriate, this will be completed in a face-to-face appointment or by collecting the carer’s responses by telephone before a face-to-face appointment with the person they support.

**Demographic questionnaire:** This is a non-standardised questionnaire to collect demographic information about the carer and the dementia diagnosis of the person they support.

**Short Sense of Competence Questionnaire:** The 7-item measures the carer’s feeling of being capable to care for the person they support on a 5-point Likert scale (Strongly Disagree [1] to Strongly Agree [5]). Validated with carers of people living in the Netherland; Cronbach’s alpha .79 (Vernooij-Dassen et al., 1996); used with a range of populations, including UK carers (Stansfeld et al., 2019).

**Dyadic Relationship Scale (Caregiver):** The 11-item scale asks carers to consider positive and negative aspects within their relationship with the person they support. Carers complete a four-point scale (Strongly Agree [0] to Strongly Disagree [3]) in response to statements about their relationship during the previous month. Validated with urban and rural populations in the United States; Cronbach’s alpha .84–.89 (Sebern & Whitlatch, 2007).

**Carer Communication Questionnaire:** Carers reflect on a recent, familiar act of communication with the person living with dementia and score eight statements against a 7-point scale (Strongly Disagree [1] to Strongly Agree [7]).

**Perceived Stress Scale:** This is a 10-item scale measuring an individual’s perceived stress levels in situations during the previous month. Carers rate the frequency of their feelings on a 5-point scale (Never [0] to Very Often [4]). This has been

<table>
<thead>
<tr>
<th>Measure</th>
<th>What this measures</th>
<th>Number of items</th>
<th>Baseline</th>
<th>Follow Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic questionnaire</td>
<td>Age, Gender, Ethnicity, Sexual orientation, Relationship to cared for person, Dementia diagnosis, Geographical location, Household composition, income and government assistance, Education history, Employment status, Chronic health conditions</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Short Sense of Competence Questionnaire</td>
<td>Relational competence</td>
<td>7</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Dyadic Relationship Scale (Caregiver)</td>
<td>Relationship strain (e.g., I felt resentful)</td>
<td>11</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Carer Communication Questionnaire</td>
<td>Carer perceptions of communication</td>
<td>10</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Perceived Stress Scale</td>
<td>Stress</td>
<td>10</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Hospital Anxiety &amp; Depression Scale (HADS)</td>
<td>Anxiety and Depression</td>
<td>14</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>C-DEMQOL</td>
<td>Quality of life</td>
<td>30</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Caregiving Ambivalence Scale</td>
<td>Goal conflict</td>
<td>6</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Bristol Activities of Daily Living Scale (BADLS)</td>
<td>Ability of someone with dementia to carry out daily activities such as dressing and preparing food</td>
<td>20</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>EQ-5D-5L</td>
<td>Health-related quality of life</td>
<td>5</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Healthcare service use</td>
<td>Hospital, primary, community and social care use</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Clinical Dementia Rating (CDR) scale</td>
<td>Severity of dementia.</td>
<td>-</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
Ambivalence describes the presence of concurrent positive and negative feelings towards the caring role and cared for person (Losada et al., 2017). Carers use a four-point scale (Never [0] > Always [3]) to rate the frequency of feelings presented in six statements. Validated with family carers in Spain; Cronbach’s alpha .86 (Losada et al., 2017).

**BADLS:** The BADLS is an informant rated scale measuring the person with dementia’s ability to complete personal and domestic activities of daily living. Carers rate the person’s ability to complete twenty individual tasks on a four-point scale (or scoring zero if the person has never completed the activity). The tool was developed and evaluated specifically for use with people living with dementia (Bucks & Haworth, 2002).

**EQ-5D-5L:** This health status measure asks participants to rate the presence of problems across five domains (Mobility, Self-care, Usual Activities, Pain or Discomfort, Anxiety or Depression) on a five-point scale (No problems to extreme presence). In addition, a visual analogue scale is provided for the informant to rate their current health on a scale from 0–100 (where 100 represents the best health possible).

**Healthcare Service Use:** This is a questionnaire designed to capture the carer’s use of health and social care services in the previous 6-months, adapted from similar questionnaires used in other trials with economic evaluation components (Lovell et al., 2019; Morrison et al., 2019). This includes recording inpatient admissions, hospital outpatient or day appointments, accident and emergency (A&E) visits, and use of primary, community and social care services.

**CDR:** Following a structured interview with the carer and person living with dementia, the interviewer’s clinical judgement and interpretation of the responses is used to score the person’s level of impairment across five domains (Memory, Orientation, Judgment & Problem Solving, Community Affairs, Home & Hobbies, and Personal Care). This can be rated on a 5-point scale of impairment (0=none, 0.5=questionable, 1=mild, 2=moderate, 3=severe) across the individual domains, or a global score can be produced using the tool’s scoring algorithm (0=Normal, 0.5=Very Mild Dementia, 1=Mild Dementia, 2=Moderate Dementia, 3=Severe Dementia). The CDR has good psychometric properties and has been validated in a range of populations (Olde Rikkert et al., 2011).

Following the initial invitation to complete their follow up questionnaires, participants will be prompted to complete these after 14 days (email and text), 28 days (phone call) and 6-weeks (email and text).

**Qualitative data collection methods**

Qualitative data will be collected from two groups: (1) participants who completed three or more sessions of EC as part of the treatment arm, and (2) participants who completed two or fewer sessions of the course and people who declined to take part in the study.

After unblinding, participants in the treatment group will be invited to complete the appropriate qualitative interview (based on the number of sessions attended).

1) Semi-structured interviews will be used to ask participants who complete three or more sessions about life before the course, deciding to take part in the study, their experience of the course, life now, and taking part in a research study. This includes their feelings of engagement with the research, the timing of being offered the course in relation to their dementia ‘journey’, and their feelings about the relative importance of the study’s outcome measures.

2) These interviews will focus on identifying any barriers to attending the course (including the online format) or taking part in the study, and ideas for ways to facilitate access to the course and research activities. This aspect of the project will be conducted by a trainee clinical psychologist and form part of a wider project to explore barriers to attending an online psychosocial training intervention for carers.

Participants who attended two or fewer sessions will be asked to complete an individual interview about their experiences.

Participants who were allocated to the treatment arm but did not attend any sessions will be asked for brief feedback about their reasons in a telephone call with a researcher. During this conversation, they will be asked if they would like to take part in a more detailed, individual interview.

People who declined to take part in the trial itself will be given the option to take part in an individual interview or focus group.
**Data management**

Personal information will be pseudonymised and all procedures for handling, processing, storing, and destroying the data will be compliant with the Data Protection Act 2018. Personal data, such as names and addresses, and recorded interviews will be stored on secure servers within the University of Manchester.

Participants will be allocated a unique, 6-character participant identifier e.g., ZABC01 that will be used on case report forms (CRF), the REDCap system, and local and central portfolio management systems. A modified identifier (Unique ID+A, e.g., ZABC01A) will be used on the CDR scale documentation and to record participation on local and central portfolio management systems.

Data will be fully anonymised after the data has been analysed and is ready to be archived.

Outcome measures completed in a face-to-face interview will be recorded by a researcher on the CRF and entered on to the REDCap system by the researcher. Data, including consent, will be automatically entered, and recorded on the REDCap system by participants who choose to use it.

Access to REDCap will be restricted to essential members of the research team who will have individual login and passwords. Physical copies of consent forms will be kept separately in locked cabinets in personal offices within the University of Manchester. All consent forms will be kept for 10 years in line with University policy.

Any other paper documentation e.g., CDR, CRF, interview transcripts, will be stored in locked cabinets at the University of Manchester.

Encrypted University of Manchester devices will be used to record interviews. Recordings will be transferred directly to a (password protected) university computer and securely transferred for transcription. Transcription of audio-recordings will be carried out by a member of the research team, University of Manchester employee or an external supplier, who is one of the approved suppliers for the University of Manchester, where there is a confidentiality agreement in place. Audio recordings will be deleted once checked for validity after transcription.

Research data generated by the study will be kept for 10 years in line with the policies and guidelines from the University of Manchester.

**Data quality processes**

Data quality-checking processes will be used to verify data entered via hard-copy questionnaires. For We will obtain a 20% sample of each set of questionnaires (i.e. all the baseline and follow-up measures for 20% of the sample) and record the number of errors. Any errors will then be corrected, and if there are more than a small percentage (1–2%) of fields with errors detected, then we will repeat this data checking process for all the questionnaires.

**Statistical methods**

Overall recruitment and retention data will be presented in a CONSORT diagram. Monthly recruitment data will be presented, both overall and by borough. Retention will be presented as number (%), both overall and by treatment group, and will be accompanied by 95%CIs. Summaries of baseline characteristics and outcome measures at baseline and follow-up will be presented (mean, SD; frequency %, as appropriate).

Statistical analysis of outcome data will be ‘as randomised’ and include available data from all participants regardless of protocol adherence. No imputation of missing outcome data will be performed; however, if there are any missing baseline values of the corresponding outcome data, we will use simple mean imputation (across the groups) to avoid exclusion of such participants in the proposed complete-case analysis. Mixed-effects regression analysis will be used to analyse the candidate primary outcome measures (at follow-up), and for the three pathways targeted by EC (ambivalence [goal conflict], relational stress and communication). In each case, models will include the treatment factor (fixed effect), the baseline value of the corresponding outcome measure (fixed effect) and ‘course’ (random effect [or fixed effect if convergence is not achieved] in a partially-nested model).

For the pathways targeted by EC, this analysis will be used to provide further evidence of proof of concept. For the candidate primary outcome measures, these analyses will be used to consider evidence as to potential proof of efficacy/effectiveness and will also provide estimates of their SD to assist with the estimation of the required sample size for a full effectiveness trial, should that measure be retained for consideration as primary.

The correlations between candidate outcomes to help interpret potential efficacy on the different potential primary outcome measures (well-being, relational distress, communication, and competency) will be explored to help inform our proposed primary outcome for a potential main trial.

Potential proof of concept / proof of efficacy will be examined using adjusted point estimates and confidence intervals (CIs), ranging from 75% to 95% confidence (steps of 5%, following the approach proposed by Lee et al., 2014), for the between-groups differences in means for the candidate primary outcomes measures at the end of treatment, and the same measures at follow-up obtained from the analyses described above (Lee et al., 2014). This approach is based on a minimally important difference (MID) between trial arms and is therefore more appropriate than formal hypothesis testing when a study is underpowered. A clinically meaningful difference between arms is generally around an effect size of 0.3–0.4 (Rothwell et al., 2018); however, analysis will consider
the confidence intervals in relation to MIDs documented in the literature and, if necessary, will explore the perceived size of MID during this study.

Exploratory analysis will be conducted to inform a cost-effectiveness analysis within a definitive trial, including: an analysis of the range of services used and ability of participants to report complete service use data; the ability of the quality-adjusted life-year (QALY) (informed by the EQ-5D-5L) to discriminate between groups based on changes in clinical outcomes; factors likely to influence the incremental cost per QALY ratio.

Full details of the quantitative analyses will be included in a Statistical and Health Economic Analysis Plan (SHEAP) which will be written by the Trial Statistician, with input from the other members of the Trial Management Group. It will then be discussed and, following any agreed revisions, approved by the Trial Steering Committee prior to database ‘lock’. The approved version of the SHEAP will be made available on the University of Manchester repository (Figshare) in advance of commencing the statistical analysis.

Qualitative analysis
The qualitative data from participants completing three or more sessions will be analysed using thematic analysis (Guest, 2012). Computer-assisted qualitative data analysis software (NVivo) will be used for the analysis. Themes identified will be reviewed by a qualitative methods expert independent of the study (peer verification).

Member checking will be used to verify the trustworthiness and potentially to refine key themes. A key informants approach to member checking (Onwuegbuzie & Leech, 2007) will be used so that feedback could be obtained from participants who gave both positive and critical feedback.

The themes and rationale for these (relevant quotes and description) will be fed back to participants to establish whether the themes reflect their experiences and perspectives.

Qualitative data from people who decline to participate in the research or complete two or fewer sessions will be analysed using framework analysis.

Methods: monitoring
Data monitoring
This is a very low risk trial and, as such, it has been deemed unnecessary to form an independent data monitoring (and ethics) committee. No formal interim analysis will be conducted.

A Trial Management Group will meet regularly to monitor the delivery of the trial. A Trial Steering Committee comprising an independent Chair, four other independent members (including PPI and Statistician) and the Chief Investigator and Research Associate will have overall supervision of the trial and will meet three times a year, or more if indicated. The trial will also have ongoing feedback from its public involvement and engagement group who meet on a quarterly basis.

Harms
The primary participants in this trial will be community-based informal carers caring for people living with dementia. Although this is a group that does not have a particular elevated risk for Adverse Event (AE) or Serious Adverse Event (SAE), we will follow the host NHS organisation’s guidance for recording and reporting adverse events for non-CTIMPs.

Auditing
There are no planned audits from external organisations. However, data from the project may be audited by relevant agencies from the project sponsor. We have made this clear to all participants before they agree to take part in the study. The chief investigator and trial management team monitors study protocol adherence. The TSC and sponsor will also be able to request audits.

Ethics and dissemination
Research ethics
The study has been reviewed by the Wales Research Ethics Committee 2 and received approval in February 2022 (REC: 22/WA/0010).

Protocol amendments
Protocol amendments will be submitted in the first instance to the University of Manchester as the project Sponsor. Following authorisation by the Sponsor, protocol amendments will be submitted to the REC for review. Approved modifications to the amended protocol will be shared with trial sites, research team, and members of the TMG and TSC.

Consent - Carers
All participants will provide informed, written consent for their research activities.

Carers will be given a detailed participant information sheet and can discuss this with a member of the research team, and ask questions, before giving consent. Consent will be completed at the time of the baseline outcome measures. If these are completed in a face-to-face appointment with a researcher, the consent form will be completed with the carer and a copy given to the participant prior to commencement of data collection.

Participants using the REDCap system must complete an electronic consent form before they can access the online measures.

An additional consent form will be completed by participants who take part in the qualitative interviews.

Consent – person with dementia
In line with the Mental Capacity Act (MCA; 2005) the research team will assume capacity of the person living with dementia unless it is established otherwise. All practicable steps will be taken to help the person make the decision to take part in the study. This will include creating information and consent resources in an easy-to-read format, presenting explanations...
in various ways, and ensuring that the time and location of the appointment optimises the person’s participation.

The researcher will refer to the study’s standard operating procedure for assessing capacity. If the researcher feels that the person living with dementia lacks capacity to consent to participate, this will be documented and discussed with the person and the carer. The researcher will check whether the carer is suitable and willing to act as a personal consultee. If they are not suitable or willing, another friend/relative will be sought to act as a personal consultee.

The researcher will discuss the person’s participation with the personal consultee. Following the capacity assessment and best interest forms, the researcher will seek the consultee’s views on whether it is in the person’s best interest to take part in the research. This decision will also be documented.

Confidentiality
After consent to contact has been obtained, the research team will have access to the participant’s name and contact details. These will only be used to arrange for their participation in the research activities and intervention and will only be available to key members of the research team.

A confidentiality agreement is in place with the University’s approved transcription services.

All potential personal identifiers (e.g., location) within qualitative interviews will be removed as part of the transcription process.

During the consent process, participants will be made aware that study data and material may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, for monitoring and auditing purposes, and this may include access to personal information.

Participants will also be informed that members of the research team have a professional responsibility to break confidentiality if there are concerns the participant or anyone else might be at risk of serious harm.

Declaration of interests
The authors and trial team report no conflict of interest.

Access to data
In line with NIHR guidelines, fully anonymised data will be deposited in a public repository (Figshare). 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.

Patient and Public Involvement and Engagement (PPIE)
A PPIE advisory group was set up during the development of the trial and its protocol and will continue to meet quarterly for the length of the study. A PPIE representative (a former carer of a person living with dementia) will also contribute trial management group and trial steering committee meetings.

The PPIE group’s responsibilities will include monitoring study progress (following research team updates), giving carer perspectives on potential outcome measures, advising on recruitment methods and materials, reviewing public-facing documents, exploring and commenting on emerging analyses of interviews, and involvement with dissemination activities, including conference presentations and writing for publication.

All PPIE activities will follow INVOLVE guidance.

Dissemination policy
The results of the trial will be disseminated to key audiences including feasibility study participants, potential future trial participants (carers of people living with dementia within and outside Greater Manchester), health and social care professionals, MPs and other regional government representatives, organisational leadership in the NHS, social care and the third sector, and academic audiences.

The results of the trial will be disseminated using methods that are appropriate for the intended audience. These will include peer reviewed scientific journals, conference presentations, internal reports, plain English summaries, presentations, social media, digital media (podcasts and webinars) and press releases.

Participants will be given the option of providing their contact details to receive a summary of the study results.

Authorship eligibility will be in accordance with University of Manchester guidelines, which conforms to the International Committee of Medical Journal Editors guidance.

The trial has been registered on the ISRCTN registry (ISRCTN15261686) which gives public access to key details of the study.

Study status
Closed to recruitment.

Data availability
Underlying data
No data are associated with this article.

Extended data
Figshare at The University of Manchester: Course Summary- Empowered Conversations (6 session; family care partners). https://doi.org/10.48420/23592378.v1 (Morris et al., 2023)

Reporting guidelines
Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

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We would like to thank Emma Smith (Project Manager) and the Empowered Conversations team at Age UK Salford for their contribution to delivering the study, the Research and Innovation teams at Greater Manchester Mental Health NHS Foundation Trust and Pennine Care NHS Foundation Trust for their support in recruitment and delivery of the study, and members of the Trial Steering Committee for their advice and guidance.

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Witternberg R, Hu B, Barraza-Araiza L, et al.: CPEC Working Paper S The projections were produced using an updated version of a model developed by CPEC at LSE for the Modelling Outcome and Cost Impacts of Interventions for Dementia (MODEM) study (www.modem-dementia.org.uk). The authors would like to thank members of the MODEM study team for their contributions in developing the MODEM models. DISCLAIMER. 2019a.

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