

# Online acceptance and commitment therapy for family carers

<b>Submission date</b> 13/07/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/07/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/04/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Caring for someone with dementia can be hard and family carers are much more likely to be depressed or anxious than non-carers and therefore need support with their mental health. Unfortunately, family carers are currently under-provided for by NHS psychological services. This is because some carers are unable to travel, and for others finding somebody else to look after the person with dementia while they attend psychological services is an issue. An online therapy could address this. This study will convert face-to-face delivered "Acceptance and Commitment Therapy" (ACT) for family carers of people with dementia to an online mode of delivery combined with three peer support group sessions. The researchers will then find out what works and does not work when using ACT in this new way so that they can carry out a full research trial in the future.

### Who can participate?

Unpaid carers aged 18 and over who are currently providing care to a relative with a clinical diagnosis of dementia. To be eligible for the study, participants will need to be presenting mild-to-moderate anxiety or depressive symptoms.

### What does the study involve?

First, participants will be asked to attend the initial assessment session. This initial session can be done face-to-face or remotely via telephone or video call. If eligible, they will be invited to the intervention phase. During the intervention phase, participants will be asked to take part in online ACT, which can be completed remotely. Online ACT consists of eight sessions, which need to be completed weekly. Participants will receive feedback from their dedicated therapist online each week. Participants will have an option to attend three peer support groups while completing online ACT. Peer support groups will be delivered face-to-face or remotely via video call. After the completion of online ACT, participants will be asked to complete the follow-up assessment pack online or via post. Following this, participants will be invited to an individual interview to provide feedback on the programme.

### What are the possible benefits and risks of participating?

Participants may see some improvements in their mood and/or the number of activities that they do each day. This is not guaranteed, but the research team hopes that the study will

provide information on how to support family members who experience emotional difficulties. Some carers may find it upsetting to talk about their thoughts and feelings in relation to their caregiving experiences. If this happens during the study sessions and participants feel that they can no longer commit themselves, the research team will do their best to help. Participants can withdraw from the study at any time without giving a reason.

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

When is the study starting and how long is it expected to run for?  
July 2018 to April 2021

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

Who is the main contact?  
Dr Naoko Kishita  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
256357

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

CPMS 44167, IRAS 256357

## Study information

**Scientific Title**

Online acceptance and commitment therapy for family carers of people with dementia: a feasibility study of a new mode of delivery (iACT4CARERS)

**Acronym**

iACT4CARERS

**Study objectives**

The key objectives of this study are:

1. To undertake an uncontrolled feasibility study to examine the feasibility and acceptability of online Acceptance and Commitment Therapy with family carers of people with dementia
2. To estimate study parameters for a future effectiveness randomised controlled trial

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 18/03/2020, NHS Health Research Authority London - Queen Square Research Ethics Committee (HRA NRES Centre Bristol, 3rd floor, block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8061; queensquare.rec@hra.nhs.uk), REC ref: 20/LO/0025

**Study design**

Non-randomized; Interventional; Design type: Treatment, Psychological & Behavioural

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Family carers of people with dementia

**Interventions**

First, the study team member will approach the participant (either clinician-referred or self-referred) to check eligibility and will send the Participant Information Sheet. The participant will be given at least 48 hours to read the Participant Information Sheet before being re-contacted by the study team. If the participant requires more time and then they can take as much as they need to read the Information Sheet and ask questions.

Initial assessment session (60 minutes x 1 session)

If the eligible participant is interested in taking part, the research team will arrange the initial assessment session. The participant can attend the initial session in person. If the participant

decides to attend the session in person, this usually will take place at the location convenient for them such as their own home, the university, or local NHS premise. The participant also can attend the session via videoconference or telephone if these are more convenient for them. This option aims to accommodate flexibility with regard to their preferences and maximise the opportunity for participation which is critical for this particular population. If this happens, the study team member will send the initial assessment package with a return envelope to the participant prior to the appointment date.

At the beginning of the initial assessment session, the participant will be asked to sign the written consent. Then the participant will be asked to complete questionnaires about their thoughts and feelings regarding their caregiving role and the level of disability of the person they are caring for. Those participants attending the assessment session via videoconferencing or over the telephone will be asked to return all the documents using a return envelope. No data will be collected via videoconferencing or over the telephone (i.e., the research team will only see the completed questionnaires when the questionnaire package arrives in the research team's post at UEA with written consent).

The research team will use the information gathered during the assessment session to see whether the participant meets the study criteria. If the participant does not meet the criteria, the study team will not be able to include them in the study. If this happens, the research team member will explain this to the participant and make sure that they have the opportunity to ask questions.

Eight online psychological training sessions + three peer support groups (optional)

If the participant can be included in the study, the research team member will check if the participant wishes to join three peer support groups in addition to the online programme. The participant can attend peer support groups which will be held at the university or local NHS premise in person or access peer support groups from their own home via videoconference if the participant is unable to travel.

If the participant wishes to join three peer support groups in addition to the online programme, they will be placed on a waiting list until three or more participants have signed up for groups. If there are not enough attendees to form peer support groups after four weeks from the date the participant signed up for the study, the research team can give the participant an option for them to start the online programme without attending groups. If this happens, the research team will let the participant know when the study team is ready to run new peer support groups so that the participant can join groups at later dates. All peer support groups will be audio recorded on a digital voice recorder. These recordings will be used only to check if the therapist (facilitator) follows the appropriate guidelines during groups.

Once the participant enrolls to the online programme they will be asked to complete eight online sessions on a weekly basis in general, but the participant can take a break from the course when necessary (e.g., Christmas holidays). However, all sessions need to be completed within 3 months. The dedicated therapist will provide the feedback and answer questions online throughout the course. The online programme requires about one hour of self-study time a week.

Follow up assessment (60 minutes x 1 session)

Upon the completion of the online programme, the participant will be asked to complete questionnaires and return them to the research team using a return envelope. The research team member will give the participant a phone call to check if they have any questions regarding the study or questionnaires.

The participant will also be invited to take part in an individual interview lasting approximately 1 hour. The interview can be done face-to-face in person or via videoconference or telephone. The research team member (interviewer) will ask the participant about their experience of completing the online programme and how the research team can improve it. The interview will be audio recorded on a digital voice recorder to make sure that the research team does not miss anything that the participant say and to help the research team summarises the results of the interviews.

All therapists will also be invited to an individual interview to provide feedback.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

The feasibility and acceptability of conducting a future effectiveness RCT, assessed during the trial recruitment phase, the intervention phase and the post-assessment phase (August 2020 – June 2021):

1. Recruitment, eligibility, and attrition: number of referrals over 6 months at each participating NHS site, rates and reasons for refusal, numbers ineligible, reasons for ineligibility, attrition rate, and reasons for withdrawing throughout the study. Timepoint: During the trial recruitment phase
2. Resulting sample characteristics: descriptive demographic data including carers' age, gender, relationship to the care recipient, and the number of hours devoted to caregiving. Timepoint: During the intervention phase
3. Resources needed to complete online ACT: length of time required for carers to complete each online ACT session, length of time required for therapists to provide online feedback per participant, and the amount and nature of supervision required
4. Carer adherence to online ACT: records of access and engagement with online ACT (number of videos/audios accessed, self-reflection sent to a therapist, and practices completed). Timepoint: During the post-intervention phase
5. Carer acceptability: aspects of online ACT that carers found helpful and unhelpful, uptake rate of face-to-face groups in person and via videoconferencing, satisfaction with the intervention and therapists, and reasons for withdrawing from online ACT
6. Therapist acceptability: satisfaction with training and supervision, therapist competence in integrating ACT training into online ACT, and intervention fidelity

## **Key secondary outcome(s)**

The following measures will be completed at baseline (0 weeks) and post-intervention (12 weeks):

1. Depression and anxiety assessed using the Patient Health Questionnaire-9, the Revised Centre for Epidemiologic Studies Depression Scale and the Generalised Anxiety Disorder Scale-7
2. Carer burden assessed using the Zarit Burden Interview Short version
3. Psychological process measures: The Acceptance and Action Questionnaire-II, the Cognitive Fusion Questionnaire, the Experiential Avoidance in Caregiving Questionnaire and the Caregiving Ambivalence Scale
4. Quality of life assessed using the ICEpop CAPability measure for Older people
5. Behaviour symptoms of dementia assessed using the Revised Memory and Behavior Problems Checklist

## **Completion date**

12/04/2021

## Eligibility

### Key inclusion criteria

1. Aged 18 and over
2. An unpaid carer for a relative with a clinical diagnosis of dementia
3. Identifying oneself as a 'primary' or 'co-primary' carer in their family
4. Scoring 6-15 on the Generalised Anxiety Disorder Assessment or scoring 6-15 on the Patient Health Questionnaire (i.e., the study will recruit family carers with mild-to-moderate anxiety or depressive symptoms and those with severe mental health problems will be excluded)

### Participant type(s)

Carer

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Total final enrolment

33

### Key exclusion criteria

1. Receiving psychological treatment such as counselling and CBT
2. Experiencing current difficulties with a severe and poorly controlled psychiatric disorder (e.g., schizophrenia) or other conditions expected to impair treatment engagement (e.g., cognitive impairment)
3. Having no access to the internet in either their own home or at that of a friend/relative

### Date of first enrolment

01/08/2020

### Date of final enrolment

31/01/2021

## Locations

### Countries of recruitment

United Kingdom

England

**Study participating centre**  
**Norfolk and Suffolk NHS Foundation Trust**  
Hellesdon Hospital  
Drayton High Road  
Norwich  
United Kingdom  
NR6 5BE

**Study participating centre**  
**Hertfordshire Partnership University NHS Foundation Trust**  
The Colonnades  
Beaconsfield Road  
Hatfield  
United Kingdom  
AL10 8YE

**Study participating centre**  
**Octagon Medical Practice**  
Nene Valley Medical Practice  
Clayton Orton Goldhay  
Peterborough  
United Kingdom  
PE2 5GP

## **Sponsor information**

**Organisation**  
University of East Anglia

**ROR**  
<https://ror.org/026k5mg93>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**

National Institute for Health Research, Research for Patient Benefit Programme; Grant Reference: PB-PG-0418-20001

### 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 are not expected to be made available as this is a feasibility study, which does not aim to evaluate the efficacy of the intervention.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Feasibility results	07/10/2021	18/10/2021	Yes	No
<a href="#">Results article</a>	Therapists' perceptions and acceptability	15/12/2021	21/12/2021	Yes	No
<a href="#">Results article</a>	Carers' views and acceptability	17/04/2022	19/04/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes