

# A clinical trial of internet-delivered acceptance and commitment therapy for family carers of people with dementia

<b>Submission date</b> 11/04/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/04/2023	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 04/02/2026	<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

Family carers are at higher risk of anxiety and depression. Offering treatments online improves availability for people who have mobility problems, live remotely or cannot leave home. This makes it more accessible to everyone and easier to provide, so could be rolled out nationally, reducing inequalities in access to care.

This large study aims to find out if internet-delivered self-help Acceptance and Commitment Therapy for family carers of people with dementia (iACT4CARERS) is helpful in reducing anxiety and affordable; and how iACT4CARERS can be successfully delivered to diverse carer populations and in different healthcare settings.

### Who can participate?

Family carers may be eligible if they are aged 18 years or over and currently providing support to a family member living with dementia. The criteria for participating in the study include a family carer who is presenting with anxiety symptoms and be willing to receive online support for this. They also need to have access to a tablet, computer, or smartphone and have internet access.

### What does the study involve?

We will recruit 496 family carers presenting with anxiety symptoms, as that is the number we need to be sure that iACT4CARERS is adequately tested. Recruitment will target community groups, GPs and NHS mental health services with a specific focus on underrepresented people from ethnic minority groups. A computer allocates half the people to iACT4CARERS intervention and half to the control group (standard care). People in the iACT4CARERS group will be asked to complete the intervention at their own pace with feedback from the therapist for each completed session. Participants in both groups will be asked to complete questionnaires assessing anxiety, depression and other relevant outcomes before and after the intervention and 3 months after that. The researchers will also interview participants, therapists and clinicians involved in recruitment to gain in-depth insights into their views on the intervention and its implementation.

What are the possible benefits and risks of participating?

There may be no direct benefit to participants if they are not allocated to receive iACT4CARERS. If participants are allocated to receive iACT4CARERS, they may see some improvements in their mood after completing the online programme. It is hope that this study will help us find out if iACT4CARERS works and should be widely rolled out in healthcare (NHS) services. Some people may experience some upsetting feelings during online sessions. If this happens during the study and participants feel that they can no longer commit themselves to the process, they can withdraw from the study at any time without giving a reason.

Where is the study run from?

The University of East Anglia with support from the Norwich Clinical Trials Unit (CTU) (UK)

When is the study starting and how long is it expected to run for?

February 2021 to July 2025

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?

Associate Professor Naoko Kishita, n.kishita@uea.ac.uk

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Naoko Kishita

### ORCID ID

<https://orcid.org/0000-0001-8453-2714>

### Contact details

University of East Anglia

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Norwich

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

324157

### Protocol serial number

## Study information

### Scientific Title

The clinical and cost-effectiveness of internet-delivered self-help acceptance and commitment therapy for family carers of people with dementia (iACT4CARERS): a randomized controlled trial with ethnically diverse family carers

### Acronym

iACT4CARERS

### Study objectives

Primary hypothesis:

1. iACT4CARERS plus treatment-as-usual (TAU) will be superior to TAU alone in improving anxiety symptoms in family carers of people with dementia at 12 weeks post-randomisation

Secondary hypotheses:

1. iACT4CARERS plus TAU will be superior to TAU alone in improving anxiety symptoms over a 24-week follow-up period

2. iACT4CARERS plus TAU will be superior to TAU alone in improving other mental health outcomes (e.g. psychological flexibility, depression) over 12-week and 24-week follow-up periods

3. iACT4CARERS plus TAU will be superior to TAU alone in terms of cost-effectiveness (cost per QALY)

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 05/04/2023, London - Queen Square Research Ethics Committee (HRA NRES Centre Bristol, 3rd floor, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)2071048225; queensquare.rec@hra.nhs.uk), ref: 23/LO/0188

### Study design

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

Potential participants will be recruited through various methods including self-referrals responding to study advertisements and referrals from Participant Identification Centres and participating trial sites. In all cases, all potential participants will be first referred to the University of East Anglia.

### STEP 1: Initial contact

Upon receipt of referrals, the research team member based at the University of East Anglia (UEA) will describe the study to potential participants and send an information pack consisting of an information sheet, eligibility checklist and consent form via email if they express an interest. The information pack can also be sent via post if preferred. The research team member will give a follow-up phone call to see if they have any questions.

### STEP 2: Informed consent and screening assessment (50 minutes)

Participants who opt to take part in the study will be asked to attend the screening session via telephone or video call. At the beginning of the session, potential participants will be asked to provide fully informed written consent electronically. Once online written consent has been obtained, participants will be asked to complete the online screening assessment. The screening assessment includes an eligibility checklist (a series of statements asking that they meet the eligibility criteria), demographic questions and the measure of anxiety (Generalised Anxiety Scale; GAD7). Participants meeting eligibility criteria and scoring five or above on the GAD7 will be asked to continue completing all baseline measures online.

If the postal information pack option is selected, participants will be asked to return the signed consent form and the completed eligibility checklist, the GAD7, socio-demographic questions and baseline measures using a prepaid envelope.

### STEP 3: iACT4CARERS intervention (40-60 minutes x 8 sessions)

Eligible participants will be randomised to iACT4CARERS plus treatment as usual (TAU) or TAU alone. Participants randomised to iACT4CARERS plus TAU will receive a link to the iACT4CARERS website and login details via email (and post if requested). Unauthorised access to the intervention will be prevented by providing participants with unique login details. Participants will be instructed to complete eight online sessions within 12 weeks from this. Each session has three phases: self-learning, reflection and practice. The self-learning phase will guide carers through core Acceptance and Commitment Therapy (ACT) skills. Interactive exercises to illustrate ACT skills will be presented using multiple modes (video/audio/text). The reflection phase encourages participants to reflect on exercises, which they found helpful and ask questions. Individually tailored written feedback will be provided by a trial therapist via the online programme to encourage continued practice each week. The practice phase allows participants to set a goal and practice ACT skills offline between online sessions. Participants will be offered two brief (30-minute) one-to-one sessions with a therapist via telephone or video call in addition to the online programme (iACT4CARERS). These one-to-one sessions will be provided at the beginning and middle of the intervention.

### STEP 4: 12-week and 24-week follow-ups (50 minutes each)

At 12 and 24 weeks after randomisation, participants will receive an email asking them to complete the follow-up measure online. The email will include a reminder, which reiterates the reasons why this follow-up data is important. If the follow-up measure is not completed within a week, the research team member based at the University of East Anglia will give a follow-up phone call to check if the participant needs additional support for completing the online assessments. Participants, who have indicated that they wish to receive the follow-up measure via post, will receive the follow-up assessments via post and will be asked to return them using a prepaid envelope.

Purposely sampled participants will be invited to an individual interview at a 12-week follow-up as part of the process evaluation. The interview part is optional, and participants will receive a separate Participant Information Sheet (PIS) and consent form for this part of the study if invited. All interviews will be audio-recorded with their permission. Handwritten field notes will

also be used to record additional comments and observations during the session. The research team member (interviewer) will use a blended approach during the interview, which consists of passive interviewing (allowing the participant space and time to share their narrative) and more active approaches by using questions and prompts listed in the interview guide.

Trial therapists and referrers will also be invited to individual interviews separately.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Anxiety is measured using the General Anxiety Disorder-7 (GAD7) at baseline and 12- and 24-week post-randomisation

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

1. Depression is measured using the Patient Health Questionnaire-9 (PHQ9) at baseline and 12- and 24-week post-randomisation
2. Psychological flexibility is measured using the Comprehensive Assessment of Acceptance and Commitment Therapy processes (CompACT) and the Experiential Avoidance in Caregiving Questionnaire (EACQ) at baseline and 12- and 24-week post-randomisation
3. Quality of life is measured using the Health-related quality of life (EQ-5D-5L) and the ICEpop CAPability measure for Older people (ICECAP-O) at baseline and 12- and 24-week post-randomisation
4. Health and social care service utilisation is assessed using the Modified Client Service Receipt Inventory (modified CSRI) at baseline and 12- and 24-week post-randomisation
5. Satisfaction with therapy is measured using the Satisfaction With Therapy and Therapist Scale-Revised (STTS-R) at 12-week post-randomisation (only applicable to the intervention group)

## **Completion date**

14/07/2025

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 years and over
2. Caring for a family member diagnosed with dementia
3. Presenting anxiety symptoms (this will be assessed using a standardised measure GAD7 at screening)
4. Help-seeking (carers who want to receive online support)
5. Having access to the internet

### **Participant type(s)**

Carer

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

496

**Key exclusion criteria**

1. Lacking the capacity to provide fully informed written consent
2. Currently receiving ongoing formal psychological therapy (e.g. CBT, psychodynamic psychotherapy, systemic therapy and counselling)
3. Experiencing disabling medical or mental health problems making participation inappropriate or impractical
4. Expressing active suicidal intent

**Date of first enrolment**

25/10/2023

**Date of final enrolment**

14/01/2025

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Norfolk and Suffolk NHS Foundation Trust**

The Knowledge Centre

Drayton High Road

Norwich

England

NR6 5BE

**Study participating centre****Cambridgeshire and Peterborough NHS Foundation Trust**

Windsor Research Unit

Cambridge Road

Fulbourn

Cambridge

England  
CB21 5EF

**Study participating centre**

**Hertfordshire Partnership University NHS Foundation Trust**

The Colonnades  
Beaconsfield Road  
Hatfield  
England  
AL10 8YE

**Study participating centre**

**Devon Partnership NHS Trust**

Wonford House  
Dryden Road  
Exeter  
England  
EX2 5AF

**Study participating centre**

**North East London NHS Foundation Trust (NELFT)**

Research and Development Department  
1st Floor  
Maggie Lilley Suite  
Barley Lane  
Ilford  
England  
IG3 8XJ

**Study participating centre**

**Cornwall Partnership NHS Foundation Trust**

The Kernow Building  
Wilson Way  
Pool  
Redruth  
England  
TR15 3QE

**Study participating centre**

**Solent NHS Trust**

Highpoint Venue

Bursledon Road  
Southampton  
England  
SO19 8BR

**Study participating centre**  
**Southern Health NHS Foundation Trust**  
Memory Assessment and Research Centre (MARC)  
Botley Road  
West End  
Southampton  
England  
SO30 3JB

**Study participating centre**  
**Dorset HealthCare University NHS Foundation Trust**  
Research & Development  
11 Shelley Road  
Boscombe  
Bournemouth  
England  
BH1 4JQ

**Study participating centre**  
**South West London and St Georges Mental Health NHS Trust**  
Trinity Building  
15 Springfield Drive  
London  
England  
SW17 0YF

**Study participating centre**  
**Northamptonshire Healthcare NHS Foundation Trust**  
77 London Road  
Kettering  
England  
NN15 7PW

**Study participating centre**  
**Derbyshire Healthcare NHS Foundation Trust**  
Centre for Research and Development

Kingsway  
Derby  
England  
DE22 3LZ

**Study participating centre**  
**Surrey and Borders Partnership NHS Foundation Trust**  
Two Bridges  
Guildford Street  
Chertsey  
England  
KT16 9AU

**Study participating centre**  
**South West Yorkshire Partnership NHS Foundation Trust**  
Research & Development  
Room 311, Block 9  
Ouchthorpe Lane  
Wakefield  
England  
WF1 3SP

**Study participating centre**  
**Avon and Wiltshire Mental Health Partnership NHS Trust**  
Victoria Centre  
Downs Way  
The Great Western Site  
Swindon  
England  
SN3 6BW

**Study participating centre**  
**Oxford Health NHS Foundation Trust**  
Warneford Lane  
Headington  
Oxford  
England  
OX3 7JX

**Study participating centre**

**South London and Maudsley NHS Foundation Trust**

111 Denmark Hill  
London  
England  
SE5 8AZ

**Study participating centre****Rotherham Doncaster and South Humber NHS Foundation Trust**

2 St Catherines Close  
Balby  
Doncaster  
England  
DN4 8QN

**Study participating centre****Berkshire Healthcare NHS Foundation Trust**

Harry Pitt Building  
Earley Gate  
Whiteknights Road  
Berkshire  
England  
RG6 7BE

**Study participating centre****Lancashire and South Cumbria NHS Foundation Trust**

Lantern Centre  
Vicarage Lane  
Fulwood  
Preston  
England  
PR2 8DW

**Sponsor information****Organisation**

University of East Anglia

**ROR**

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

# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme; Grant Codes: NIHR150071

## 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

### IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		12/09/2024	16/09/2024	Yes	No
<a href="#">HRA research summary</a>			20/09/2023	No	No
<a href="#">Other files</a>	version 1.1	02/12/2024	24/06/2025	No	No
<a href="#">Protocol file</a>	version 1.0	21/12/2022	01/08/2024	No	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	19/06/2025	24/06/2025	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes