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

Submission date
11/04/2023

Recruitment status
No longer recruiting

Registration date
12/04/2023

Overall study status
Ongoing

Last Edited
24/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 February 2026

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

Study website
https://iact4carers.com/

Contact information

Type(s)
Principal Investigator

Contact name
Prof Naoko Kishita

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

324157

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55321, IRAS 324157

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

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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)

Overall study start date
01/02/2021

Completion date
01/02/2026

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 496; UK Sample Size: 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
England

United Kingdom

Study participating centre

Norfolk and Suffolk NHS Foundation Trust
The Knowledge Centre
Drayton High Road
Norwich
United Kingdom
NR6 5BE

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Windsor Research Unit
Cambridge Road
Fulbourn
Cambridge
United Kingdom
CB21 5EF

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

Study participating centre
Devon Partnership NHS Trust
Wonford House
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre
North East London NHS Foundation Trust (NELFT)
Research and Development Department
1st Floor
Maggie Lilley Suite
Barley Lane
Ilford
United Kingdom
IG3 8XJ

Study participating centre
Cornwall Partnership NHS Foundation Trust
The Kernow Building
Wilson Way
Pool
Redruth
United Kingdom
TR15 3QE

Study participating centre
Solent NHS Trust
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

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

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

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

Study participating centre
Northamptonshire Healthcare NHS Foundation Trust
77 London Road
Kettering
United Kingdom
NN15 7PW

Study participating centre
Derbyshire Healthcare NHS Foundation Trust
Centre for Research and Development
Kingsway
Derby
United Kingdom
DE22 3LZ

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

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

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

Study participating centre
Oxford Health NHS Foundation Trust
Warneford Lane
Headington
Oxford
United Kingdom
OX3 7JX

Study participating centre
South London and Maudsley NHS Foundation Trust
111 Denmark Hill
London
United Kingdom
SE5 8AZ

Study participating centre
Rotherham Doncaster and South Humber NHS Foundation Trust
2 St Catherines Close
Balby
Doncaster
United Kingdom
DN4 8QN

Study participating centre
Berkshire Healthcare NHS Foundation Trust
Harry Pitt Building
Earley Gate
Whiteknights Road
Berkshire
United Kingdom
RG6 7BE

Study participating centre
Lancashire and South Cumbria NHS Foundation Trust
Lantern Centre
Vicarage Lane
Fulwood
Preston
United Kingdom
PR2 8DW

Sponsor information

Organisation
University of East Anglia

Sponsor details
Norwich Research Park
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United Kingdom
NR4 7TJ
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Sponsor type
University/education

Website
https://www.uea.ac.uk/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/05/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

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?
HRA research summary			20/09/2023	No	No
Protocol file	version 1.0	21/12/2022	01/08/2024	No	No
Protocol article		12/09/2024	16/09/2024	Yes	No
Other files	version 1.1	02/12/2024	24/06/2025	No	No
Statistical Analysis Plan	version 1.0	19/06/2025	24/06/2025	No	No