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Views and experiences of ethnic minority family carers on internet-delivered guided self-help Acceptance and Commitment Therapy for family carers of people with dementia (iACT4CARERS)

Submission date 18/08/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered
		[ ] Protocol
Registration date 19/08/2022	**Overall study status** Completed	[ ] Statistical analysis plan
		[X] Results
Last Edited 26/03/2024	**Condition category** Mental and Behavioural Disorders	[ ] Individual participant data

Plain English summary of protocol
Background and study aims
Family carers of people with dementia are at higher risk of anxiety, but they currently have limited access to psychological services due to various barriers. Offering psychological 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.

We conducted a first study to explore if we could deliver Acceptance and Commitment Therapy (ACT) for family carers of people with dementia online within GPs and NHS mental health services, and family carer views of it (acceptability). This initial study was successful and more than 100 potential participants were referred to the study in just six months. Thirty-three eligible participants received online ACT, more than originally planned. We now need a larger trial involving enough carers to establish whether online ACT can reduce carer anxiety and is affordable and whether it should be widely rolled out in the NHS.

The first step in preparing for the next large trial will be to investigate the acceptability of online ACT among family carers from ethnic minority groups as we did not fully explore the views of this population in our first study. Family carers from ethnic minority groups currently have the least access to formal support services. Ensuring that online ACT is acceptable and accessible to culturally diverse family carers will be critical for a successful wider rollout.

Who can participate?
Family carers of people with dementia from ethnic minority groups

What does the study involve?
Carers will be asked to complete eight online sessions on a self-learning basis with weekly

feedback from their therapist. Individual interviews will be conducted with carers and therapists to assess the acceptability and identify areas for further improvement.

What are the possible benefits and risks of participating?
By completing the online programme, participants may see some improvements in their mood and/or the number of activities that they do each day. Some participants may find it upsetting to reflect on their distressing thoughts and feelings during online therapy sessions. 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?
June 2022 to November 2023

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme (UK).

Who is the main contact?
Dr Naoko Kishita, N.Kishita@uea.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Naoko Kishita

ORCID ID
https://orcid.org/0000-0001-8453-2714

Contact details
School of Health Sciences
University of East Anglia
Norwich Research Park
Norwich
United Kingdom
NR4 7TJ
-
N.Kishita@uea.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 53137, NIHR150071, IRAS 316137

Study information

Scientific Title
Views and experiences of ethnic minority family carers on internet-delivered guided self-help Acceptance and Commitment Therapy for family carers of people with dementia (iACT4CARERS): A qualitative study

Acronym
iACT4CARERS

Study objectives
This study aims to pilot the refined version of iACT4CARERS (internet-delivered self-help Acceptance and Commitment Therapy for family carers of people with dementia), which incorporates additional one-to-one sessions via telephone or video call, among family carers of people with dementia from ethnic minority groups.

Research questions:
1. What are the perceptions and experiences of iACT4CARERS, with a particular focus on newly introduced additional one-to-one sessions, among family carers of people with dementia from ethnic minority groups?
2. What are the perceptions and experiences of iACT4CARERS, with a particular focus on newly introduced additional one-to-one sessions, among therapists?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/08/2022, NHS London - Queens Square Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 2071048225; queensquare.rec@hra.nhs.uk), ref: 22/PR/0743

Study design
Interventional non randomized

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Once written consent has been obtained, potential participants will be asked to complete self-reported measures using an online or postal survey pack. These will include a demographic questionnaire, the Generalized Anxiety Disorder-7 (GAD7) and the Patient Health Questionnaire-

9 (PHQ9). These variables will be used to characterise the sample. The risk of suicide will also be assessed by the trained researcher (i.e. Chief Investigator, research associates) during the initial assessment session.

Eligible participants will receive a link to the iACT4CARERS website and login details immediately after the initial assessment session 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. 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 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 (20-30 minutes) 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.

After the completion of iACT4CARERS, participants will be asked to attend an individual interview session via telephone or video call. Interviews will examine attitudes towards one-to-one sessions, suitability of their content, any impact they had on engagement with iACT4CARERS and any suggestions for improvement. First, participants will be asked to complete the Satisfaction with Therapy and Therapist Scale-Revised, either electronically or via post. Following this, the researcher will conduct the individual interview. The volume and quality of the audio recording will be checked at this point to ensure a clear recording. All interviews will be audio-recorded with the participant’s permission. Handwritten field notes will also be used to record additional comments and observations during the session. The researcher 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 (attached to this ethics application). To end the interview, the researcher will allow a final opportunity for the participant to add or expand upon anything else that may have not yet been discussed. Closing remarks will be made, whereafter the interview will be concluded.

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

Intervention Type
Behavioural

Primary outcome(s)
Themes identified from transcripts of interviews conducted after completion of the intervention that identify views and experiences of family carers from ethnic minority groups and trial therapists on iACT4CARERS.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/11/2023

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Identifying oneself as a carer from ethnic minority groups
3. Caring for a family member diagnosed with dementia
4. Willing to complete iACT4CARERS
5. Having access to the internet

Purposeful sampling will be used to recruit ten family carers of people with dementia from ethnic minority groups. Ethnic minorities refer to all ethnic groups except the white British group. A recent study on the dementia diagnosis in UK primary care demonstrated that dementia patients from the Asian ethnic group were the second largest group followed by the white British patient group. Therefore, we aim to recruit at least five family carers from the Asian ethnic group.

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
13

Key exclusion criteria
1. Lacking capacity to provide fully informed written consent.
2. Experiencing disabling medical or mental health problems making participation inappropriate or impractical.
3. Expressing active suicidal intent.

Date of first enrolment
01/11/2022

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
United Kingdom

England

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

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

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

Sponsor information

Organisation
University of East Anglia

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

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 due to the data being qualitative, and not having relevant consent.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/03/2024	26/03/2024	Yes	No
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes