The clinical and cost effectiveness of internet-delivered self-help Acceptance and Commitment Therapy for family carers of people with dementia (iACT4CARERS): Study protocol for a randomised controlled trial with ethnically diverse family carers

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Abstract

Background: Following the successful completion of feasibility and acceptability studies of internet-delivered self-help Acceptance and Commitment Therapy for family carers of people with dementia (iACT4CARERS), a full-scale randomised controlled trial (RCT) evaluating its clinical and cost effectiveness will be conducted. This paper describes the design and protocol for a multi-site, parallel, single-blind, 2-arm RCT evaluating the clinical and cost effectiveness of iACT4CARERS plus treatment-as-usual (TAU) in comparison to TAU alone for reducing anxiety in family carers of people with dementia.

Methods: 496 family carers aged ≥18 years, who are caring for a person with dementia, will be recruited from national healthcare services, general practices and community groups in England. Participants randomised to the intervention arm will receive iACT4CARERS over 12 weeks. Participants will complete outcome measures at baseline (0 weeks) and at 12-weeks and 24-weeks post-randomisation. The primary outcome and timepoint will be anxiety at 12 weeks. Secondary outcomes will include psychological flexibility, depression, and cost-effectiveness (cost per quality adjusted life years). Primary analyses will be by intention-to-treat and data will be analysed using linear mixed models. Fidelity and quality of implementation will be assessed and contextual factors associated with variation in outcomes identified in a process evaluation.

Conclusion: If iACT4CARERS is found to be effective and affordable, this self-help intervention, including minimal contact with minimally trained therapists, has the potential to be rolled out widely within healthcare services in the UK, reducing inequality in access to psychological services among this population.

Clinical trials registration: ISRCTN registry identifier ISRCTN45995725.

Keywords

caregivers; dementia; acceptance; mindfulness; cognitive behaviour therapy; online therapy

Introduction

Previous systematic reviews demonstrate that the prevalence of anxiety and depressive symptoms in unpaid family carers of people living with dementia is around 32% [1, 2]. Furthermore, some studies report that anxiety symptoms may be more common than depressive symptoms in this population [3]. Despite such high prevalence rates, many family carers currently receive little or no support for their own psychological needs due to barriers such as mobility constraints, lack of respite care and limited availability of skilled therapists [4]. Designing a service that can be delivered remotely and accessed from home at a time convenient for the carer, such as an internet-delivered intervention, may be one solution to challenges of treatment accessibility and therapist availability.

Current evidence suggests that interventions that include psychotherapeutic components demonstrate the largest effects on reduction of depressive symptoms in family carers of people living with dementia [5]. Manualised psychological therapies researched so far are mainly based on cognitive behaviour therapy (CBT) delivered in person. A previous meta-analysis of in-person CBT for dementia family carers delivered face-to-face or via telephone demonstrated a small overall effect of CBT on depression (Cohen's effect measure, d=0.34), while no significant overall effect was observed for anxiety [6]. A meta-analysis focusing solely on internet- or DVD-delivered self-help CBT for dementia family carers demonstrated that an overall effect of CBT on depression is likely to be reduced (d=0.27) when a self-help format is used [7]. The effect on carer anxiety was not reported. A recent meta-analysis, which examined the effectiveness of broader online support for dementia family carers, such as CBT and psychoeducation, also demonstrated no significant overall effect of online support on anxiety, while a small overall effect was found for depression (g=0.21) [8]. These figures suggest a need for improvement, particularly in terms

of the effective provision of self-help psychological therapies that can lead to reduced anxiety symptoms among this population.

Acceptance and Commitment Therapy (ACT) is an evidence-based psychotherapy, which aims to increase psychological flexibility through three sets of skills: stepping back from restricting thoughts and approaching or allowing painful emotions; focusing on the present, connecting with what is happening in the moment; and clarifying and acting on what is most important to do and building larger patterns of effective values-based action [9].

A recent systematic review of ACT for family carers of people living with long-term conditions included 10 studies that targeted dementia family carers [10]. Of these, seven were feasibility and pilot studies, which demonstrated that ACT was deemed to be feasible and acceptable among this population. Three remaining randomised controlled trials (RCTs) showed some evidence supporting the effectiveness of in-person ACT for reducing anxiety and depressive symptoms. Beyond the carer population, evidence for internet-delivered self-help ACT has been growing rapidly in recent years. Systematic reviews of RCTs of internet-delivered guided or non-guided self-help ACT, which mainly targeted general or student populations, have demonstrated that internet-delivered self-help ACT can reduce anxiety and depressive symptoms, suggesting that ACT skills can be learnt online [11, 12].

Based on the current evidence, we conducted feasibility and acceptability studies of internet-delivered self-help ACT for family carers of people with dementia (iACT4CARERS) [13-15] in which pre-defined criteria for progression from the feasibility study to a full-scale RCT were successfully met. In the feasibility study, more than 100 carers were referred across three research sites over six months and 33 eligible carers were recruited, with ≥70% completing seven or all eight online sessions [13]. There was preliminary evidence of

improvements in anxiety, depression and psychological flexibility. This was particularly so for anxiety, which demonstrated an average reduction of 26% on the General Anxiety Disorder-7 (a reduction of 20% on this scale is considered to be a minimum clinically important difference [16]). Thus, a full-scale RCT to evaluate the clinical and cost effectiveness of iACT4CARERS was deemed to be warranted.

Objectives

This full-scale RCT aims to evaluate the clinical and cost effectiveness of iACT4CARERS plus treatment-as-usual (TAU) compared to TAU alone in family carers of people living with dementia who present with anxiety symptoms. This study also aims to assess fidelity and quality of implementation, establish causal mechanisms, and identify contextual factors associated with variation in outcomes using the process evaluation approach.

Materials and Methods

1. Trial Design

This is a multi-site, single-blind, parallel, 2-arm RCT comparing iACT4CARERS plus TAU to TAU alone in family carers of people with dementia presenting anxiety symptoms (ISRCTN: 45995725). The RCT will contain a 10-month internal pilot (see Appendix 1 for progression criteria for the internal pilot)[1]. This protocol is reported in accordance with the SPIRIT guidance [17] and refers to study protocol version 1.0 (dated December 2022), which has

[1] An internal pilot phase is essential for assessing whether the trial can be completed within the proposed timeline and budget. This phase typically addresses major uncertainties or risks, such as recruitment, intervention delivery and adherence, which could impact the trial's success. Establishing this phase is a requirement set by the funder (National Institute for Health and Care Research) for this trial.

undergone full external peer review by the funding body and approved by the NHS Research Ethics Committee.

2. Eligibility Criteria

2.1 Participants (Family Carers)

Eligibility criteria for participants are shown in Table 1. Participants with insufficient understanding of English will not be excluded. An informal interpreter (family member or friend) or a professional interpreter can support the participant throughout the study. This approach was recommended by this study's Patient and Public Involvement (PPI) panel of dementia family carers from ethnic minority groups.

Table 1
Inclusion and Exclusion Criteria

Inclusion criteria
• Aged 18 years and over. • Caring for a family member diagnosed with dementia: Any family members including in-laws and unmarried partners will be eligible. • Presenting anxiety symptoms: Participants scoring in the clinical range of 5 or above on the GAD7 at screening will be eligible. • Help-seeking: Participants will be asked if they would like to receive help with their anxiety through iACT4CARERS at screening. • Having access to internet: Participants will need to have access to a computer, tablet, or smartphone connected to the internet.
Exclusion criteria
• Lacking capacity to provide fully informed written consent. • Currently receiving ongoing formal psychological therapy such as CBT, psychodynamic psychotherapy, systemic therapy and counselling. • Experiencing disabling medical or mental health problems making participation inappropriate or impractical. • Expressing active suicidal intent [1)].

Note. CBT = Cognitive Behaviour Therapy; GAD7 = General Anxiety Disorder-7. 1) The risk of suicide will be assessed using a suicide risk assessment protocol co-developed with the study team and the local NHS mental health service during the screening session. This protocol

includes specific questions addressing various aspects of the risk associated with active suicidality. Specifically, it includes questions to distinguish between active and passive suicidal ideation, assess the presence of a plan, inquire about past suicide attempts, and estimate the likelihood of a future attempt.

2.2 Therapists

A maximum of 20 trial sites will take part: organisations within the National Health Services (NHS) of England. Therapists will be recruited from these trial sites. Therapists will be mainly NHS support workers (e.g., social care support workers) and assistant practitioners (e.g., assistant psychologists, occupational therapy assistants). NHS clinicians (e.g., occupational therapists) will be eligible if they do not hold a formal qualification in clinical psychology or CBT, such as Clinical Psychologists, CBT therapists and counselling therapists.

3. Intervention

3.1 iACT4CARERS

iACT4CARERS consists of the online programme, iACT4CARERS, which has been tested in the previous feasibility and acceptability studies [13-15], and two one-to-one sessions via telephone or video call with the therapist, each lasting 30 minutes. The online programme consists of eight sessions: Table 2 describes each session. Each session will be made available to participants five days after the completion of the previous session. Each session takes about 30-50 minutes to complete, depending on the number of self-learning activities included in each session. Participants will be informed that access to the online programme will cease after 12 weeks.

In each online session, participants are asked to engage in self-learning activities, such as watching videos and listening to audio exercises that illustrate ACT skills. At the end of each session, participants are encouraged to reflect on what was helpful in the session and identify a small step they could take that reflect their values. Therapists will provide

individually tailored feedback to facilitate participants' self-learning on ACT skills and to encourage them to practice ACT skills they found helpful after each session.

In addition to the online programme, participants are given the option to book two 30-minute one-to-one sessions with their therapist. Participants can book these sessions anytime during the 12-week intervention phase. These sessions will be focused on encouraging the participants to: (a) express their feelings and emotional needs; (b) share their challenges and concerns regarding the use of a technology-based intervention; and (c) discuss their expectations for weekly reflection and online feedback from their therapist to best tailor support. These one-to-one sessions are optional and not signing up for these will not result in withdrawal from the intervention.

All therapists will be required to attend a 2-day training on ACT and online feedback provision for this study. They will also be trained to use the manual for one-to-one sessions, which details the structure of sessions and provides a topic guide with example scripts. Drop-in group supervision sessions via video call will also be available every two weeks for the duration of the study.

Table 2
Content of Each Session of iACT4CARERS

Session number	Main focus of the session
1	Learning what ACT is. Learning to let go of the need to control painful emotions. Learning to embrace and allow painful emotions.
2	Leaning to clarify values (what is truly important in life) and identify committed actions (actions that reflect chosen values).
3	Learning to overcome external barriers (e.g., limited free time) using a three-step problem-solving approach.
4	Learning to overcome internal barriers (e.g., distressing thoughts) using cognitive fusion techniques (stepping back from internal struggles).
5	Learning to overcome internal barriers (e.g., worries about future or past) using present moment awareness techniques (focusing on the present).
6	Learning to treat oneself with kindness using self-compassion techniques.
7	Learning to break down an action into small steps to build a pattern of effective action that reflects values.
8	Revisiting all skills learned and preparing for the future.

Note. ACT = Acceptance and Commitment Therapy

3.2 Treatment-as-usual (TAU)

Participants in either arm will continue to receive routine support, such as Admiral Nurse appointments, during the trial. Participants will not be discouraged from seeking treatment outside of the study for ethical reasons. According to UK national clinical guidelines [18], TAU for dementia family carers normally consists of information, brief education, practical advice, local carer support groups and/or respite care provided by health and social care services, or relevant charities based on the needs in the UK. TAU will be described using a modified Client Service Receipt Inventory (CSRI) [19]. Participants will

not be withdrawn from the study if they start receiving formal psychological therapy such as CBT during the trial, but this information will be collected using the modified CSRI.

3.3 Treatment fidelity

All written feedback provided online by therapists will be digitally recorded and randomly selected scripts will be reviewed and rated by independent ACT experts using an adapted form of the ACT Fidelity Measure (ACT-FM) [20] to check for intervention fidelity. Therapist response time (the time gap between the participant leaving a comment and their therapist providing a response) will also be recorded for each session.

4. Outcomes

A summary of study outcomes is shown in Table 3 and schedules of outcome measures for participants are provided in Table 4. The primary outcome measure is anxiety symptoms as assessed by the General Anxiety Disorder-7 (GAD7) [21]. Secondary outcomes include measures of depressive symptoms [22], psychological flexibility [23, 24] and satisfaction with therapy and therapist [25]. Data on quality of life [26, 27] and health and social care service utilisation [19] will be collected for health economic evaluation. Expectations about treatment and participants' intervention arm preference are potential sources of bias that can affect treatment outcomes and these measures will be collected before randomisation.

Table 3
Summary of Study Outcomes

Primary outcome	**Assessment tools**
Anxiety symptoms	Generalized Anxiety Disorder-7 (GAD7)
Secondary outcomes	**Assessment tools**
Depressive symptoms	Patient Health Questionnaire-9 (PHQ9)
Psychological flexibility (openness to experience, behavioural awareness, valued action)	Comprehensive Assessment of Acceptance and Commitment Therapy processes (CompACT)
Experiential avoidance (one component of psychological flexibility) in the caregiving context	Experiential Avoidance in Caregiving Questionnaire (EACQ)
Satisfaction with therapy and therapist	Satisfaction With Therapy and Therapist Scale-Revised (STTS-R)
Health economic measures	**Assessment tools**
Health-related quality of life	EQ-5D-5L
Capability in older adults	ICEpop CAPability measure for Older people (ICECAP-O)
Health and social care service utilisation	Modified Client Service Receipt Inventory (modified CSRI)
Measure of bias	**Assessment tools**
Expectations about treatment	Two 5-point Likert-scale items asking how much participants expect their symptoms and life to improve if they receive iACT4CARERS
Intervention arm preference	Two 5-point Likert-scale items asking how much participants hope to receive iACT4CARERS and TAU alone without iACT4CARERS

Table 4

The Schedule of Enrolment, Intervention and Assessments

Events/Measures	**Screening Baseline (-1 week)**	**Allocation (0 week)**	**Intervention (-)**	**12-week follow up (12 weeks)**	**24-week follow up (24 weeks)**
Eligibility screen	X				
Informed consent	X				
Randomisation		X			
iACT4CARERS intervention (treatment arm only)			X		
GAD7	X			X	X
PHQ9	X			X	X
CompACT	X			X	X
EACQ	X			X	X
STTS-R (treatment arm only)				X	
EQ-5D-5L	X			X	X
ICECAP-O	X			X	X
Modified CSRI	X			X	X
Expectancy questionnaire	X				
Treatment preference	X				
Qualitative interview (treatment arm only)				X	

Note. Follow-up assessments will be completed within two weeks of the scheduled date.

5. Process Evaluation

The process evaluation aims to assess fidelity and quality of implementation, establish causal mechanisms, and identify contextual factors associated with variation in outcomes.

5.1 Evaluation of implementation

Table 5 summarises data which will be gathered as part of the trial to understand the process through which training and the intervention are delivered.

5.2 Evaluation of Mechanisms of Impact and Context

Individual interviews will be conducted with participants allocated to the intervention arm to understand the mediating factors and context that may influence implementation or outcomes. Subgroups of carer participants (completers, non-completers) from white and non-white ethnic groups will be purposefully sampled to achieve an approximate sample size of n=40, informed by the concept of Information Power [28]. Therapists who participate in the trial and referrers (clinicians involved in identifying and referring participants) will also be invited to be interviewed to explore factors which may influence implementation. Table 6 summarises topics included in the interview guide for each group.

Table 5

Process Evaluation - Data for Evaluation of Implementation

Domain	Data
Fidelity (Was the intervention delivery as intended?)	• Trial therapist attendance at training and drop-in supervision sessions. • Scores for the therapist fidelity checklist completed by independent experts. • Participants' time spent for each online session. • Completion of goal setting each week by participants. • Achievement of a goal each week by participants. • Questions completed at the beginning of each online session assessing how much participants have used learnt skills between the sessions.
Adaptation (Were there any adaptations required to deliver the intervention as intended?)	• Adaptations made to the format of training to respond to the needs of therapists with different backgrounds.
Dose (Did participants receive the right amount of the intervention?)	• Number of online sessions completed. • Number of weeks required to complete the whole online programme. • Number of optional one-to-one sessions signed up by participants. • Number of sessions where participants completed the reflective comments and home practice.
Reach (To what extent did the intervention reach its intended service users?)	• Diversity of participants in terms of age, gender, geographical location and ethnicity.

Table 6

Process Evaluation – Interview Topics for Carer Participants, Therapists and Referrers

Participants (family carers)
• Perceptions of signing up for the intervention • Perceptions of intervention and methods of delivery • Perceived benefits/limitations • Barriers and facilitators for completing the intervention • Availability and competency of the therapist • Facilitators for implementation • Impact of an interpreter (only if the interpreter was used during the study)
Therapists
• Perceptions of delivering the intervention • Perceptions of methods of delivery (ease of supporting family carers online) • Barriers and facilitators for delivering the intervention • Treatment fidelity • Perceptions of training and support • Perceived benefits to the participants • Barriers for implementation
Referrers
• Background of referrer (roles in the service and the study, previous experiencing in approaching and referring carers) • Process of referrals • Perceptions on supporting materials for recruitment activity • Barriers and facilitators for implementation • Barriers for reaching out to carers from ethnic minority groups

6. Procedure

6.1 Recruitment

Multiple recruitment strategies will be used to reach out to potential participants, and both clinician- and self-referrals will be accepted.

Trial Sites. Clinicians will approach potentially eligible participants at participating trial sites and will seek verbal consent for the central study team based at the University of East Anglia (UEA) to contact the participant with further information about the study if they

express interest. Trial sites will share the contact details of participants with the central study team via the central database managed by the Norwich Clinical Trials Unit (NCTU). Carer-focused publicity materials, such as study flyers and animations describing the study, will also be made available in waiting areas of the services and on their social media platforms for those who may wish to self-refer.

Participant Identification Centres (PICs). Ten PICs, which are most likely to be primary carer services (GPs), will be set up for only identifying potential participants. An invitation letter with an expression of interest card will be sent to potential participants from PICs. If interested, participants will be asked to return the expression of interest card directly to the central study team using a pre-paid return envelope or email.

Recruitment within the Community. Various methods will be used in the community to reach potential participants. This includes advertisements through local newspapers and on a national recruitment website (Join Dementia Research). The study will also be advertised through relevant charities (e.g., Dementia UK, Alzheimer's Society) and local community services (e.g., carer support groups). Carer-focused publicity materials will be made available through relevant resources such as newsletters and social media platforms. These approaches will allow potential participants to self-refer to the trial via telephone, email, or the project website (https://iact4carers.com). Multiple strategies recommended by our PPI panel will also be used to maximise the recruitment of participants from ethnic minority groups, including the development of a video-recorded study advertisement in different languages and visiting groups for these communities with support from our collaborating partner, the Centre for Ethnic Health Research.

6.2 Screening and Baseline

Upon receipt of clinician- and self-referrals, the central study team will send the Participant Information Sheet (PIS) to potential participants via email or post. Participants who opt to take part in the study will be asked to attend the screening (baseline assessment) session via video call or phone call. Participants will be asked to provide fully informed written consent using an online consent form, unless the paper version is preferred. Once online written consent has been obtained, participants will be asked to complete the online screening assessment, which includes an eligibility checklist (a series of statements asking that they meet the eligibility criteria), demographic questions and the measure of anxiety (GAD7), hosted by the central database managed by NCTU. Participants meeting eligibility criteria will be asked to complete all baseline measures. If participants request to use a paper version of the consent form and questionnaires, all documents will be posted to participants before the session, signed and completed by them, and returned using a prepaid envelope. The central study team will manually enter the data into the central database upon the receipt of documents at which point eligibility will be confirmed.

6.3 Randomisation and Blinding

Eligible participants will be randomised on a 1:1 basis between iACT4CARERS plus TAU or TAU alone with minimisation for ethnicity (Asian, Black, White, Mixed or Other ethnicity groups) and the baseline score of GAD7 (mild, moderate or severe anxiety) within a week from the screening session. Allocation will be computer-generated by a centralised system managed by NCTU to ensure concealment prior to randomisation. The sequence will be hidden from users of the system.

The unblinded trial manager based at NCTU will implement the allocation. Participants randomised to iACT4CARERS plus TAU will receive an automated email, which includes a link to the iACT4CARERS website and login details, from the centralised system.

Participants recruited at trial sites will be randomly assigned to a trial therapist from the same site. Self-referred participants recruited from other resources, including PICs, will be randomly assigned to one of the therapists across trial sites. The allocated therapist will receive an automated notification. Research staff within the central study team collecting baseline and follow-up data will be blinded to group allocation.

6.4 12-week and 24-week Follow-Ups

Twelve and 24 weeks after randomisation, participants will receive an email automatically from the central database asking them to complete the follow-up questionnaires online. If the follow-up measure is not completed within a week, research staff within the central study team will give a follow-up phone call. Participants will be asked not to reveal their group allocation during follow-up calls. Participants, who have elected to receive the follow-up questionnaires via post at screening, will receive the documents via post from the trial manager and will be asked to return them using a prepaid envelope. The trial manager will give a follow-up phone call a week after the documents have been posted to ensure that participants have received them.

Selected participants from the intervention arm will be invited to an individual interview around 12-week follow-up stage as part of the process evaluation. The interview will be optional, and participants will receive a separate PIS and consent form for this part of the study, if invited. Interviews with participants will be conducted by the unblinded delegate based at NCTU via video call or telephone. Trial therapists and referrers will also be invited to interviews at the end of the trial and will also receive a PIS and consent form in relation to this. All interviews will be audio recorded, transcribed, and anonymised.

7. Sample size

Participants in our feasibility study of iACT4CARERS had an average reduction of 26% on GAD7 [13]. A reduction of 20% on GAD7 is considered to be a minimum clinically important difference [16]. Based on a 20% reduction from the mean baseline GAD-7 score and the variability estimated from our feasibility study, a clinically meaningful effect size is estimated at d=0.55. Systematic reviews of RCTs of self-help ACT and mindfulness-based interventions (mainly for individuals with a mental or physical health condition) have demonstrated a pooled effect size of *d*=0.35 for anxiety [29, 30]. To ensure adequate statistical power, we have decided to take the most conservative approach possible and have used an effect size of *d*=0.35 in our sample size calculation. To detect the effect size of *d*=0.35 between the two trial arms at a two-tailed significance level of 5% with 90% statistical power, each arm requires 173 participants. Twenty-seven percent of participants were lost to follow-up in our feasibility study of iACT4CARERS. Assuming a dropout rate of 30%, a total of 496 carers will be recruited over 20 months for this trial.

8. Data management

Data will be entered under the participants' ID number onto the central database managed by NCTU (REDCap). Access to the database will be via unique, individually assigned usernames and passwords, and only accessible to the relevant members of the study team. Blinded central study team members will have restricted access and will not be able to view treatment allocation. The servers are protected by firewalls and are patched and maintained according to UK best practice. The physical location of the servers is protected physically and environmentally in accordance with UEA's General Information Security Policy.

9. Statistical analysis[2]

In the primary analysis, which will be by intention to treat, linear mixed models with random intercepts for site and therapist will be used to estimate group differences in total score on GAD7. Scores at 12- and 24-week follow-ups will each be used as dependent variables in separate models. The treatment group will be used as the independent variable. Baseline outcome score, the trial site and ethnicity will be used as the covariates. Sensitivity analyses will be used to identify any variations or methods (e.g., the number of sessions completed) that may influence the findings. Secondary outcome measures will be analysed similarly to the primary outcome measure. The impact of contamination due to non-compliance as well as participants receiving treatments that are not part of the trial (e.g., psychological and pharmacological therapies) will be assessed by using complier average causal effect (CACE) analysis where information on any extra-trial treatments will be incorporated as covariates in the CACE approach.

If more than 5% of data is missing, we will adopt appropriate techniques for handling missing data depending on the mechanism of missingness. Specifically, if the mechanism of missing data is found to be missing at random, i.e., missingness is predicted by observed covariates, we will employ multiple imputation to handle missing data [31], where the imputation model will include observed predictors of missing data. The estimates obtained from the analysis of imputed datasets will be combined using Rubin's rule [32].

[2] The comprehensive data analysis plans, including the Statistical Analysis Plan and the Health Economic Analysis Plan, will be developed and subsequently made available to the public in accordance with their respective objectives and the funder's requirements before data analysis begins in the latter half of 2025. These documents will undergo review by two independent committees: the Data Monitoring and Ethics Committee and the Trial Steering Committee.

10. Economic analysis

The main outcome measure used for the economic evaluation will be quality adjusted life years (QALYs), measured using the EQ-5D-5L at baseline, 12 weeks, and 24 weeks. This will constitute a 'within trial' cost-utility analysis. As the timeframe is 24 weeks neither costs nor benefits will be discounted. The perspective of the analysis will be that of the NHS and social care. The EQ-5D-5L will be scored using the recommended scoring algorithm at the time of analysis: currently, the UK's National Institute for Health and Care Excellence recommends the use of the algorithm developed by Hernandez-Alava [33]. Sensitivity analyses will include using the ICECAP-O to generate an alternative preference-based outcome measure and also conducting a cost-effectiveness analysis using the primary outcome measure (cost per point change in GAD7). A variety of resource use will be estimated as part of this analysis, including resources required to provide the intervention and therapist support. These will be recorded on the study database. Additionally, the use of health and social care by the participant will be obtained using a modified CSRI. All resources identified will be costed using appropriate unit cost data [34].

As part of the analysis process, the degree of missingness of the data will be assessed. If there are low levels of missing data, then a complete case analysis may be appropriate. If, however, missingness is deemed to be a potential problem then appropriate methods for dealing with these will be employed [35]. A priori, we would expect that this would involve multiple imputation techniques. We would expect to use regression-based methods to analyse costs and effects to allow for differences in baseline characteristics between groups. Non-parametric bootstrapping will be employed to allow for uncertainty. We will estimate cost-effectiveness acceptability curves to estimate the probability that the intervention is cost-effective at different willingness to pay thresholds for a unit of the

outcome measure. As part of the analysis process, we will also conduct appropriate sensitivity analysis to estimate the effects of any key assumptions made.

11. Process Evaluation Analysis

Data gathered for evaluation of implementation will be analysed descriptively by calculating total numbers, percentages and means and standard deviations as appropriate. Carer participant, therapist and referrer interview transcripts will be analysed separately using a focused thematic analysis [36]. Three coders will independently read through an initial subsample (a minimum of 10%) of transcripts, separate the data into meaningful fragments and label emerging themes with codes. Coding strategies will be compared with instances of disagreement discussed until a provisional conceptual framework is developed around internal and external factors influencing the outcomes and implementation. The analytical framework will be applied to the remaining transcripts, with themes and subthemes refined as necessary.

12. Ethics and Safety Monitoring

This trial is being conducted in accordance with the principles stated in the Declaration of Helsinki and has received full ethical approval from the NHS London-Queen Square Research Ethics Committee (23/LO/0188). iACT4CARERS is a low-risk intervention. No specific risks or adverse events were reported during feasibility testing of the intervention [13]. Any non-serious untoward incidents occurring during this trial (e.g., clear evidence of high levels of distress making participants difficult to continue with the study) will be recorded in an incident report form. Serious adverse events (SAEs) will be collected using an SAE form. Potential SAEs in this study will include new reports of active suicidal ideation with active suicidal behaviours/plans and imminent intent. However, this is unlikely as the risk of

suicide will be assessed with every participant during the screening session and those presenting a high risk will be excluded and referred to other services (see Table 1).

Discussion

At the time of the submission of this paper, we have 182 participants enrolled. This number was achieved in less than five months of the initial recruitment phase, and we have not identified any difficulties in recruiting family carers, mainly from the White British group. One main challenge that has emerged is recruiting carers from ethnic minority communities through NHS trial sites. We will overcome this barrier by using inclusive community-based recruitment strategies recommended by our PPI panel, with support from the Centre for Ethnic Health Research.

If iACT4CARERS is found to be effective and affordable, this intervention, which uses a self-help format with minimal contact with a non-expert, minimally trained therapist, has the potential to be rolled out widely within healthcare services in the UK. Furthermore, the process evaluation component of this RCT will help us understand how iACT4CARERS can be successfully implemented to diverse carer populations within healthcare services and what factors hamper the implementation and achievement of outcomes. If effective, our final goal is to produce the procedural manual for implementation, which will be a crucial step for translating the knowledge into the real world.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data availability

No data were used for the research described in the article.

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Appendix 1. Progression Criteria for the 10-month Internal Pilot

The randomised control trial will contain a 10-month internal pilot to assess the feasibility of referral rates and acceptability of randomisation. At the end of the 10-month internal pilot phase, progress will be reviewed based on the pre-determined criteria (see Appendix Table 1 below) with the independent Trial Steering Committee (TSC). Green light will indicate support for the progression as planned. In the case of amber light, we will develop a mitigation plan to deliver the study as originally proposed. The plan will be reviewed by the TSC and the funding body, the National Institute for Health and Care Research Health Technology Assessment (NIHR HTA). They will determine whether it is considered feasible and acceptable to the NIHR HTA and whether the trial should continue with amendments. In the case of red light, we will consider with the TSC and the NIHR HTA whether the trial should be terminated.

We will also assess treatment adherence as part of the internal pilot. Participants allocated to the intervention arm will be given access to the online programme for 12 weeks. We will evaluate treatment adherence data for those who have reached the end of the 12-week intervention phase during the internal pilot. Participants completing six or more online sessions during this 12-week intervention phase will be considered treatment completers. The denominator for the treatment adherence calculation is the number of participants who have reached the end of the 12-week intervention phase in the intervention group regardless of the number of sessions completed. The numerator is the number of completers. As per Appendix Table 1, more than 70% of participants need to be identified as treatment completers to achieve Green (50-69% of participants will indicate Amber).

Appendix Table 1
Red/amber/green progression criteria

Progression criteria	Red	Amber	Green
% against the final recruitment target	<25%	25-49%	50%
% against the recruitment target for pilot	<50%	50-99%	100%
Recruitment rate/site/month	<1.2	1.20-1.69	1.7
Number of sites opened	<7	7-14	15
Total number of participants recruited	<124	124-247	248
Treatment adherence (% of completers)	<50%	50-69%	70%