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

Phase 1 Study Protocol

Phase 1 protocol 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
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1. Context of the project

This study is part of a broader research project funded by the NIHR. In 2019, We received funding from the NIHR Research for Patient Benefit Programme (PB-PG-0418-20001) to (1) develop internet-delivered self-help Acceptance and Commitment Therapy (ACT) for family carers of people with dementia (iACT4CARERS), (2) explore whether iACT4CARERS is acceptable in this population, and (3) test whether it is feasible to deliver iACT4CARERS within NHS services. This feasibility study was successful, meeting all pre-defined criteria for progression from the feasibility study to a full-scale trial.

Following this, we received funding from the NIHR Health Technology Assessment (NIHR150071) to conduct a full-scale trial and evaluate the clinical- and cost-effectiveness of this new intervention, iACT4CARERS. This recently funded project (iACT4CARERS trial) consists of two phases (Phase 1 and 2) and has three key objectives.

1. To finalise iACT4CARERS based on recommendations from our feasibility study and Patient and Public Involvement (PPI) work (Phase 1).
2. To establish the clinical- and cost-effectiveness of iACT4CARERS plus TAU compared to TAU alone in an RCT with an internal pilot phase (Phase 2).
3. To assess fidelity and quality of implementation, establish causal mechanisms and identify contextual factors associated with variation in outcomes using the process evaluation approach (Phase 2).

This study protocol (ethics application) covers Phase 1 of the iACT4CARERS trial. The study protocol (ethics application) for Phase 2 of the project will be submitted separately in collaboration with the Norwich Critical Trials Unit at a later stage.

2. Background

2.1 What is the problem?

Previous systematic reviews led by the lead investigator (Kishita)[1, 2] demonstrated that the prevalence of anxiety and depression in family carers of people with dementia is around 32%. These estimates are substantially higher than reported prevalence rates in the general population in the UK[3] indicating a clear need for support with their mental health.

The current standard care pathway for mental health conditions in family carers of people with dementia includes self or GP referral to NHS psychological services[4]. However, many carers are not able to access timely psychological support due to various barriers such as mobility issues, lack of respite care and a shortage of skilled therapists leading to long waiting lists[5]. One way to address the clear need for improved access, and also scalability, is to design a service that can be delivered remotely, accessed independently at home, and at times chosen by the participant. Online treatments can do this.

Psychological treatments for carers of people with dementia, which have been previously tested such as the STrAtegies for RelaTives (START) intervention[6], are mainly delivered face-to-face and are based on conventional cognitive behaviour therapy (CBT). A recent review of in-person CBT for carers of people with dementia demonstrated a small to medium overall effect on depression (d=0.34)[7]. A meta-analysis focusing solely on technology-based self-help CBT for family carers of people with dementia demonstrated a small overall effect on depression (d=0.27)[8]. No significant overall effect was observed for anxiety in either review, suggesting that conventional CBT may have a limited effect on carer anxiety. These results suggest a need for improvement in psychological therapies among this population. We particularly need to identify the intervention that can (1) be delivered in a self-help format so that it is accessible by all for the reasons noted above and (2) effectively target anxiety to overcome challenges observed in previous studies.

2.2 Evidence explaining why this research is needed now

Acceptance and Commitment Therapy (ACT) is a form of psychotherapy with a strong evidence base for improving outcomes such as mood and quality of life in various populations, including people with anxiety, depression, chronic pain and somatic health problems[9-11]. ACT does not aim to change thoughts and feelings but rather to reduce avoidance and enhance personally meaningful behaviour. ACT achieves this by promoting psychological flexibility through three sets of skills, including the ability to (1) “step back” from restricting thoughts and allow painful emotions (i.e. OPEN); (2) focus on the present, connected with what is going on around us in the moment (i.e. AWARE); and (3) clarify and act on what is most important to do and build increasing patterns of effective values-based actions (i.e. ENGAGED)[12].

This strategic focus is highly practical because it is easier to change what we do, and how we do it, than to stop or change what we think[12]. As such, it has been argued that ACT is particularly useful for those living with immutable and chronic conditions[13]. Since many carers also face uncontrollable circumstances, ACT may be well suited to this population. Indeed, a recent systematic review on carer interventions, led by the lead investigator (Kishita)[14], demonstrated strong empirical support for face-to-face ACT in treating carer anxiety and depression.

Recent systematic reviews also suggest that ACT skills can be learnt online[15-17]. In the UK, co-investigator McCracken was successful in converting manualised ACT for people with complex chronic pain to an online mode of delivery[18, 19]. This feasibility study led to numerous enhancements of the treatment; the upgraded treatment was approved and implemented in the NHS just four years after the research began.

iACT4CARERS feasibility study

We received funding from the NIHR Research for Patient Benefit Programme (PB-PG-0418-20001) to (1) develop online self-help ACT for carers of people with dementia (iACT4CARERS; https://iact4carers.com), (2) explore whether iACT4CARERS is acceptable in this population, and (3) test whether it is feasible to deliver iACT4CARERS within NHS services. iACT4CARERS was offered on a self-learning basis, with minimal contact with a non-expert, minimally trained therapist.

Pre-defined criteria for progression from the feasibility study to a full-scale trial required iACT4CARERS to be deemed acceptable to carers as indicated by uptake and initial engagement (recruitment of 30 eligible carers over 6 months, with ≥70% completing at least two online sessions). These criteria were successfully met. Participant recruitment took place from August 2020 and January 2021 during the pandemic with 108 carers referred across three sites over six months. Thirty-three eligible carers were recruited, with ≥91% completing more than two sessions, suggesting excellent acceptability[20]. There was preliminary evidence of improvements in anxiety, depression and psychological flexibility, particularly in anxiety, which demonstrated an average reduction of 26% on the GAD7 anxiety scale (a reduction of 20% on GAD7 is considered to be a Minimum Clinically Important Difference[21]). Therefore, randomised controlled trial (RCT) evidence on clinical- and cost-effectiveness of this new intervention is warranted.

It is important to highlight that 76% (n=25/33) of eligible carers who received iACT4CARERS had self-referred from the community, and 24% of carers were referred from NHS services[20]. This suggests a substantial unmet need in the community, a desire to engage with interventions such as these, and perhaps a lack of carer identification (and/or carer support need identification) by formal healthcare services.

NHS and social care need

Currently, carers of people with dementia who receive the least support are those from ethnic minority groups. A recent systematic review of studies that included UK South Asian patients with dementia could not identify a single clinical trial of an intervention in this population, either for patients or carers[22]. Another recent systematic review suggested that female family members are often the main source of care in the South Asian communities, and since caregiving is seen as familial obligation within their culture, they are often reluctant to openly share their challenges and seek support[23]. An online approach such as iACT4CARERS has the potential to improve the psychological well-being of carers, cost effectiveness to NHS services, and importantly equity of access to care. Thus, a full-scale RCT to evaluate the effectiveness of iACT4CARERS in a diverse carer population is warranted.

This project is also timely and ethically justified from the perspective of the NHS and social care need. The NHS Long Term Plan (2019) sets the development of Integrated Care Systems to increasingly focus on population health as one of the top priorities[24]. This policy emphasises the need for preventative services, which individuals can access at a time and place that is convenient for them[25]. iACT4CARERS does not require highly trained expert therapists, and our feasibility study was successfully delivered within GP and NHS psychological services entirely remotely during the pandemic. This flexibility in delivery can address practical challenges currently faced by the NHS.

ACT with people from minority groups

A previous review, which explored cultural competence in ACT, suggested that ACT has been implemented across many countries including low-/middle-income countries such as

India and South Africa[26]. A recent study, which demonstrated the effectiveness of guided self-help ACT among South Sudanese refugees in a large RCT (n=694)[27], led to the development of non-guided self-help ACT for coping with adversity during the pandemic, and has been available on the website of the World Health Organisation in 11 different languages. A recent large trial (N=2,415), which involved 868 ethnic minority participants, also demonstrated that smartphone-delivered ACT was effective for smoking cessation[28]. These suggest that there is a strong potential for iACT4CARERS to be used with a diverse group of carers including those from ethnic minority groups.

PPI work we have undertaken

In collaboration with the Centre for Ethnic Health Research, we discussed iACT4CARERS with six PPI members who are carers of a family member with dementia from ethnic minority groups. All PPI members reported that they currently do not receive psychological support and expressed positive feelings about iACT4CARERS. However, some barriers were also identified.

The original version of iACT4CARERS had the option for carers to attend three peer support groups via video call. PPI members from ethnic minority groups expressed that (1) mental health issues are not openly discussed in some ethnic minority communities, particularly among male carers and (2) some female carers do not feel comfortable sharing personal issues with male carers. Therefore, it was suggested to include two brief (20-30 minutes) one-to-one sessions with the non-expert therapist via telephone or video call, where carers are encouraged to express their feelings and needs privately, rather than offering peer support groups.

3. Aims and objectives of the iACT4CARERS project

What is the clinical and cost effectiveness of iACT4CARERS in comparison to treatment-as-usual (TAU) for reducing anxiety in carers of people with dementia?

Phase 1

- To finalise internet-delivered ACT for carers of people with dementia (iACT4CARERS) based on recommendations from our feasibility study and PPI work.

Phase 2

- To establish the clinical and cost effectiveness of iACT4CARERS plus TAU compared to TAU alone in a RCT with an internal pilot phase.
- To assess fidelity and quality of implementation, establish causal mechanisms and identify contextual factors associated with variation in outcomes using the process evaluation approach.

This study protocol (ethics application) covers Phase 1 of the iACT4CARERS trial. The study protocol (ethics application) for Phase 2 of the project will be submitted separately in collaboration with the Norwich Critical Trials Unit at a later stage.

4. Methods (Phase 1)

In Phase 1, we will follow a framework for the co-production of public health interventions[29] to finalise iACT4CARERS. Based on completed PPI work, optional online peer support groups will be removed. They will be replaced with two brief (20-30 minutes) one-to-one sessions with a therapist via telephone or video call. To gain preliminary feedback on acceptability and feasibility of this additional element (i.e. one-to-one sessions) of iAC4CARERS, the revised programme will be piloted with 10 carers from ethnic minority groups. Following this, iACT4CARERS will be finalised.

4.1 Research questions

1. What are the perceptions and experiences of additional one-to-one sessions embedded in iACT4CARERS among family carers of people with dementia from ethnic minority groups?

2. What are the perceptions and experiences of additional one-to-one sessions embedded in iACT4CARERS among therapists?

4.2 Sample

Purposeful sampling will be used. Ten family carers of people with dementia from ethnic minority groups will be selectively sampled for this study (sample size informed by the concept of Information Power[30]). Ethnic minorities refer to all ethnic groups except the white British group. A study on the incidence of dementia diagnosis in UK primary care demonstrated that 55% of those who received a diagnosis of dementia between 2007 and 2015 did not report their ethnicity[31]. Of those reported, 2% were from the Asian ethnic group. This patient group was the second largest group followed by the white British patient group. The steepest increase is expected particularly in South Asian communities in the coming years. Therefore, we aim to recruit at least five family carers from the Asian ethnic group.

Inclusion and exclusion criteria

The inclusion criteria are as follows:

1) **Aged 18 and over:** The content of iACT4CARERS is written for adults as the majority of family carers are in their 50s to 70s in the UK.

2) **Identifying oneself as a carer from ethnic minority groups:** Potential participants will be asked to confirm their ethnicity.

3) **Caring for a family member diagnosed with dementia:** Any family members including in-laws, such as daughters-in-law, will be eligible. The diagnosis of dementia will be based on the clinical information provided by the participant (carer). Potential participants will be asked to confirm whether the care recipient has received a formal diagnosis of dementia from a relevant healthcare professional. Potential participants will also be asked to confirm whether they provide regular care (self-defined) to the care recipient. No criteria will be set for frequency of care they provide, such as hours of caring per week, as the psychological impact of caring is related to multiple factors such as the relationship they have with the person with dementia. We will collect background and demographic data such as frequency of care they provide and their relationship to the care recipient.

4) **Willing to complete iACT4CARERS:** A brief description of the intervention will be included in the information sheet. Potential participants will be asked if they are willing to complete iACT4CARERS within 12 weeks and attend the interview session to provide feedback. Only those who are interested will be eligible.

5) **Having access to the internet:** Participants will need to have access to a computer, tablet, or smartphone connected to the internet. iACT4CARERS is accessible from any platform on any device, except for those devices that use an old operating system no longer supported as we cannot ensure the security of data. If participants do not have access to the internet through WiFi and need to use mobile data to access the internet, the relevant charge can be reimbursed (a maximum of £20 per participant).

The exclusion criteria are as follows:

1) **Lacking capacity to provide fully informed written consent:** Participants will be asked to provide consent in accordance with the Mental Capacity Act (2005). Participants will not be included in the study if they are unable to provide this.

2) **Experiencing disabling medical or mental health problems making participation inappropriate or impractical:** Potential participants will be asked to report any ongoing untreated condition during the screening session. The participant's GP will be informed of their involvement in the study, and any concerns raised by their GP regarding their involvement will be followed by a full discussion with the participant.

3) **Expressing active suicidal intent:** The risk of suicide will be assessed by a trained researcher during the initial assessment session. Those presenting suicidal ideation with active intent will be excluded.

Potential participants with insufficient understanding of English to complete screening measures and engage in the intervention will be encouraged to bring a family member who can support the participant and act as an interpreter. This approach was recommended by our Patient and Public Involvement (PPI) members from ethnic minority groups. If this option is not available, a professional interpreter can be arranged through the third company, which the University of East Anglia already has a contract in place.

4.3 Recruitment

Participants will be recruited through our collaborating partner, the Centre for Ethnic Health Research. The Centre for Ethnic Health Research is a research active organisation supported by the NIHR that aims to support research to reduce ethnic health inequalities. In order to reach a breadth of participants, the team from the Centre for Ethnic Health Research will use diverse channels of engagement to suit a variety of ethnic minority groups and accessibility needs. This will include the use of face-to-face, online and remote platforms for recruitment.

Potential recruitment strategies to be used by the Centre for Ethnic Health Research include:
1. The Centre for Ethnic Health Research Community Engagement Officers contacting their existing members (face to face -in accordance with Covid-19 rules; telephone, email, WhatsApp groups, etc.).
2. Advertising the study through the Centre for Ethnic Health Research's existing community networks and forums and partners, such as the voluntary sector and faith organisations.
3. Advertising the study through media (local, community radio stations, the Centre for Ethnic Health Research's social media channels).

Since this study only requires 10 participants, the first strategy (i.e. contact through Community Engagement Officers) will be prioritised. If the target is not met, wider recruitment such as community networks and media will be used. When potential participants express interest, the Centre for Ethnic Health Research will obtain consent for their contact detail to be shared with the researchers based at the University of East Anglia.

4.4 Participant timeline

Initial contact: Upon receipt of referrals, the researcher 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 researcher will give a follow-up phone call to see if they have any questions.

Informed consent and initial assessment: Participants who opt to take part in the study will be asked to attend the initial assessment session via telephone or video call. During this session, potential participants will be asked to provide fully informed written consent either electronically or via post first. The consent form will include a series of statements asking that they have read the information sheet and meet the eligibility criteria (eligibility checklist). 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[32]) and the Patient Health Questionnaire-9 (PHQ9[33]). These variables will be used to characterise the sample. The risk of suicide will also be assessed by the trained researcher during the initial assessment session (further detailed in the ethical and regulatory considerations section).

iACT4CARERS intervention: 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.

Participant interview: 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 (STTS-R[34]), a 12-item self-report questionnaire assessing satisfaction with therapy and satisfaction with the therapist, 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.

4.5 Intervention

The iACT4CARERS intervention (https://iact4carers.com), which has been tested in our previous feasibility study funded by the NIHR will be used. Participants will be asked 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 ACT skills (OPEN, AWARE, and ENGAGED) that together constitute psychological flexibility. 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. Based on our previous feasibility study[35, 36] and completed PPI work, these brief one-to-one sessions will focus on encouraging family carers to: (1) express their feelings and emotional needs;

(2) share their challenges and concerns regarding the use of technology; and (3) discuss the expectation for weekly reflection and online feedback from their therapist so that support can be tailored.

Before the start of the therapist training, an intervention development group consisting of researchers (including PPI) and key stakeholders (including intended recipients/therapists) will co-produce the manual for these additional one-to-one sessions to ensure that all three topics listed above are covered during the sessions. This will involve presentation of the draft manual to all group members. Feedback will be sought, refinements made, and the manual presented again until final content is agreed.

4.6 Therapists

A maximum of three NHS sites will be recruited with support from the NIHR Clinical Research Network (CRN). We have discussed the iACT4CARERS project with the local CRN before the submission of the NIHR HTA grant application (Grant number: NIHR150071), and they have agreed to support the project when funded. A maximum of five therapists will be recruited across these sites. Therapists will be mainly Band 4 assistant practitioners (e.g. assistant psychologist/OT) subject to staff availability. Therapists will attend a 2-day online training workshop, which has been tested in our previous feasibility study, prior to the start of the study. Fortnightly drop-in supervision sessions led by a clinical psychologist trained in ACT will be available via video call throughout the study.

Therapists will also be invited to attend an individual interview session via telephone or video call to share their experiences and provide feedback at the end of the study. All interviews will be audio-recorded with the therapist's permission and will be conducted in a similar way to the participant interviews. The interview guide for therapists is attached to this ethics application.

4.7 Data management

Data collection

The remote data collection approach tested in our previous feasibility study (an online or postal survey pack with telephone or video call support, online interview via telephone or video call) will be used to maximise the opportunity for reaching out to diverse potential participants. This approach was successful in our feasibility study as it negated excluding potential participants by geographical location or those unable to leave the house. All study procedures, including recruitment, intervention delivery and training, can be completed remotely and so the study will be able to continue in the event of future COVID-19 pandemic waves and restrictions.

Data management

The research team will follow NHS/University policies to ensure confidentiality of electronic and hard copy data, in keeping with the UK Data Protection Act (2018) and the EU General Data Protection Regulation (GDPR). Participants' and therapists' identifiable data will be stored under secure conditions in a separate location to the questionnaire data to ensure anonymity. Once consent has been gained, participants and therapists will be assigned an identification number, to be used in place of names on all response sheets to record data anonymously.

Hard copy data will be stored in a locked cabinet in a locked room at the University of East Anglia (UEA). Anonymised electronic data will be stored and managed using databases encrypted with industry standard cryptographic methods, protected by passwords, and held on the data servers at UEA. An audio file of interview recorded on a digital voice recorder will be uploaded to a password-protected secure server at UEA immediately after the interview, and the original recording will be completely deleted from the voice recorder. The recording will be transcribed as soon as possible using software approved by UEA (EDCaption or the transcribing function of Microsoft Teams) or the external transcribing company. The audio files uploaded to the secure server at UEA will be deleted as soon as the accuracy of the transcripts has been confirmed. These anonymised transcripts will be stored and managed using databases encrypted with industry standard cryptographic methods, protected by passwords, and held on the data servers at UEA. In line with the University's Data Protection Policy, study documentation and anonymous data will be securely kept for a period of 10 years following completion of the study.

4.8 Data analysis

Descriptive analysis will be used for demographic and questionnaire data to characterise the sample. Participant interviews will be transcribed verbatim, checked, anonymised and analysed using a focused thematic analysis[37]. Three analysts will independently read through initial transcripts, separate the data into meaningful fragments and label emerging themes with codes. Coding strategies will be compared, and instances of disagreement discussed until a provisional conceptual framework is developed around the acceptability and feasibility of one-to-one sessions. The analytical framework will be applied to the remaining transcripts, with themes and subthemes refined as necessary. The computer programme NVivo will be used to facilitate analysis. Therapist interviews will be analysed in a similar fashion. The findings will be shared with the intervention development group and the manual for the additional one-to-one sessions will be finalised.

5. Ethical and regulatory considerations

Research ethics approval
Health Research Authority (HRA) approval, including ethical approval from the NHS research ethics committee (REC), will be obtained. Recruitment will not commence until full ethical and research governance approvals have been obtained.

Protocol amendments
If any changes to the study procedures are required, we will discuss this with the sponsor in the first instance. If any changes require variation(s) to the contract with the funder, we will inform the funder and will complete a variation to contract request form. Following this, the Notice of Amendment form will be submitted to HRA (and REC if the amendment is substantial).

Consent
Participant information sheets will make it clear that participation is voluntary, and participants can withdraw at any time without their subsequent care being affected. Participants will be given ample time to discuss the study, ask questions and request further information as needed before being asked to provide written consent. Participants will be asked to provide consent in accordance with the Mental Capacity Act (2005). Participants will not be included in the study if they are unable to provide this. Capacity to provide consent will be determined by the researcher at the initial assessment. Capacity to consent will be treated as an ongoing process throughout the duration of the study and will be reviewed at each contact point. If an individual who has given informed consent loses capacity during the study, the participant would be withdrawn from the study. Data already collected with consent will be retained and used in the study.

Confidentiality
The research team will follow NHS/University policies to ensure confidentiality of electronic and hard copy data, in keeping with the UK Data Protection Act (2018) and the EU General

Data Protection Regulation (GDPR). Participants will be assured that confidentiality will be maintained unless there is evidence of risk of harm to self or others.

6. Assessment and management of risk

Procedures for recording and reporting adverse events are in place, with an adverse event (AE) being classified as any compromise of patient safety, and a serious adverse event (SAE) being defined as a compromise of patient safety that results in death; is life-threatening; requires hospitalisation or prolongation of existing hospitalisation; or results in persistent/significant disability/incapacity.

Participants will not be discouraged from attending routine appointments (e.g. GP, admiral nurse) for the duration of their involvement in the study. The risk of harm to self or others will be monitored at every point of contact by the researcher. The participant's GP will also be kept informed of their involvement in the study. The risk of suicide will be assessed by the trained researcher during the initial assessment session. The assessment will be conducted using the suicide risk assessment protocol developed by the Chief Investigator and reviewed by the Norfolk and Suffolk NHS Foundation Trust (NSFT). This protocol has been used across multiple studies run by our team. When suicidal ideation with active intent is present, the researcher will share and explain the emergency numbers for help in a crisis and will co-develop a plan for the participant to contact these emergency numbers immediately. The participant's GP will also be contacted for the participant to be referred for urgent psychiatric assessment and the participant will not be invited to the study. In the eventuality that additional risks are noted, which fall beyond the scope of the study intervention (e.g. safeguarding or environmental issues), the team will exercise a professional duty of care and will make onward referrals to appropriate services for further input.

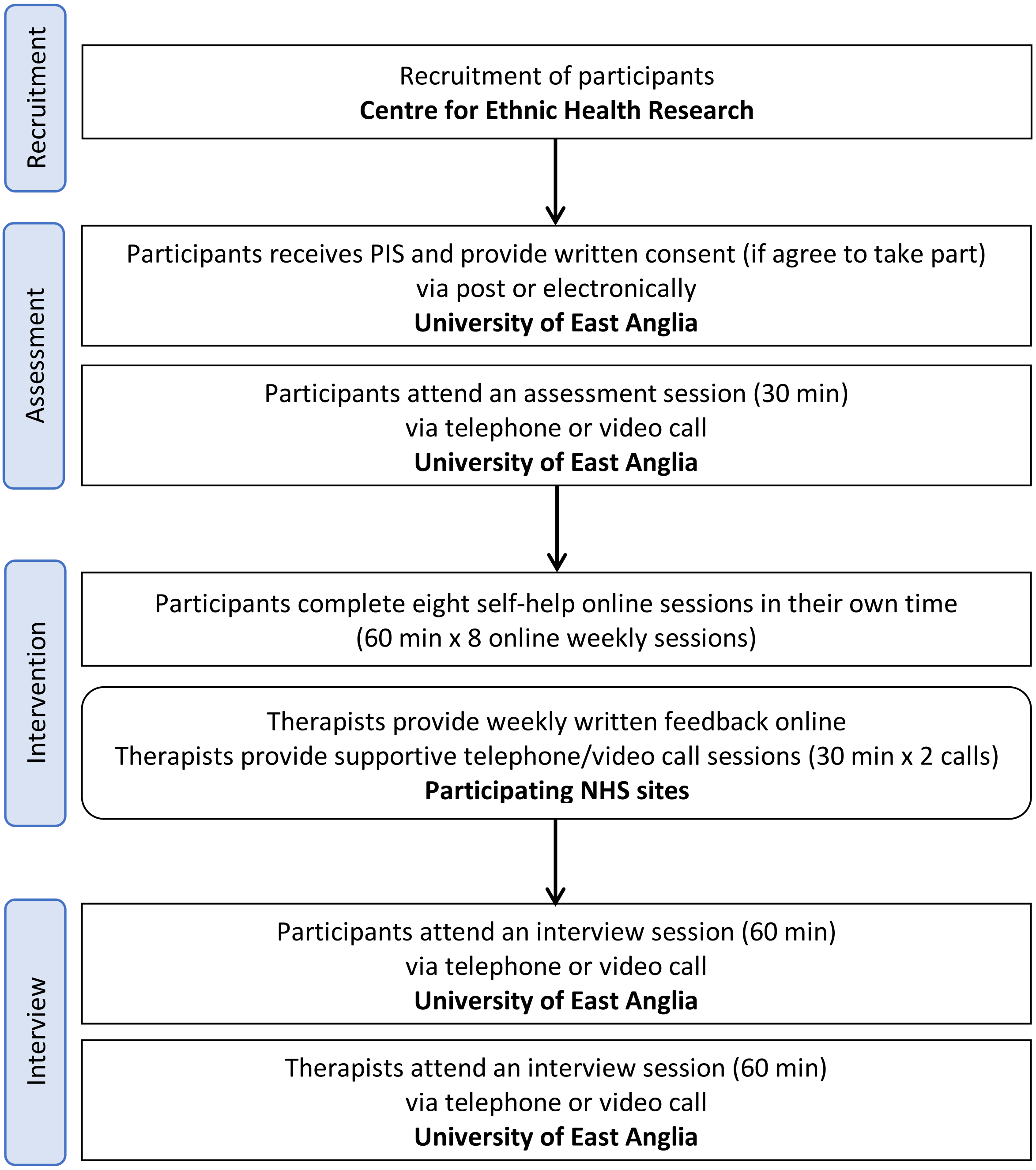
It will be made clear to participants that the online reflective section of iACT4CARERS should not be used for urgent crisis support. In the unlikely event that the participant posts something in the online reflective section that causes the therapist concern for the participant's safety, the therapist will immediately inform the principal investigator and will signpost the participant to contacts for crisis support (e.g. NHS/police emergency services, crisis helplines such as Samaritans as appropriate).

7. Dissemination

The findings of the iACT4CARERS trial, including this study (Phase 1), will be disseminated through multiple methods.

- Publication of findings in open-access, peer-reviewed journals and funder reports.
- Presentations at scientific conferences and meetings within health and social care services.
- Talks to service user groups such as dementia cafes and at the regular dementia public event held at the University of East Anglia, and offer a written piece for newsletter/website published by charities.
- University media press releases and social media.
- Costed-in interactive dissemination event where all key stakeholders listed above will be invited.
- Publication of annual newsletters to share the progress and findings of the project with study participants.

Study Flowchart (Phase 1)



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