



PARTICIPANT INFORMATION SHEET

The clinical and cost effectiveness of internet-delivered self-help Acceptance and Commitment Therapy for family carers of people with dementia (iACT4CARERS)

We would like to invite you to join our research study that is being funded by the National Institute for Health and Care Research (NIHR), the nation's largest funder of health and social care research.

Before you make a decision, it is important for you to understand why the study is being carried out and what it will involve. Please take your time to read the following information carefully and discuss it with your relatives or friends if you wish. Please feel free to ask us if there is anything that is not clear or if you would like more information.

What is internet-delivered self-help Acceptance and Commitment Therapy for family carers of people with dementia (iACT4CARERS)?

iACT4CARERS is an online programme tailored for family carers of people with dementia. This programme is based on *Acceptance and Commitment Therapy*. This new therapy is not about accepting the diagnosis or situations you are currently facing. This therapy helps people to learn how to live with difficult or distressing thoughts and feelings, while still trying to do things that really matter to them or being the type of person they want to be.

This therapy may be particularly suited to family carers due to its focus on helping people learn how to best live their lives, whilst coping with the difficulties they may be experiencing that are out of their control such as caring responsibilities.

iACT4CARERS can be accessed from your own home using your tablet, computer, or smartphone. The programme has eight online sessions, and you will be asked to complete self-learning activities, such as watching videos for learning new psychological skills, in each session in your own time. Your dedicated therapist will respond to your questions to support your self-learning each week. In addition, you will have the opportunity to directly talk to your therapist at the start and the middle of the programme via telephone or video call.

What is the study about and why have I been approached?

Our aim is to make our online programme 'iACT4CARERS' available to family members supporting a person with dementia across the UK. To make this happen, we first need to find out if iACT4CARERS works. You have been approached because you are currently supporting a family member with dementia. We think that you could make a valuable contribution to this study, helping us understand how helpful iACT4CARERS is for increasing the well-being of family carers.

Am I eligible to take part?

We are looking for family carers of people with dementia living in England to take part in this study. Participants must be aged 18 years or over and be providing support to a family member living with dementia (for example, partner, parent, parent-in-law or sibling). Participants need to be experiencing some worries or anxiety and be willing to receive online support for this. Participants also need to have access to a tablet, computer, or smartphone connected to the internet. Participating in this study is up to you. You do not have to take part if you don't want to.

If you are *currently* receiving psychological support, such as counselling or psychotherapy sessions, unfortunately we cannot invite you to the study. If you are currently on a waiting list for psychological support but unlikely to be starting counselling or psychotherapy sessions anytime soon, you are still eligible to take part. We will not ask you to withdraw from the study if those sessions start while you are taking part in the study. Instead, we will ask you to provide the information so that we can record additional support you may be receiving.

Our online programme is available only in English. If you need support with the English language, you are more than welcome to invite your family member or friend who can support you throughout the study. We can also arrange a professional interpreter if you wish.

What will I be asked to do? How much time will the study take?

If you decide to take part, you will first be asked to consent to take part and answer some questions to check you are eligible for the study. You can do this online using an online form or via post using a paper version. We will also ask you to give us multiple forms of contact, such as email, mobile, landline and postal address so that we can contact you for follow-up assessments.

You will then be asked to complete some questionnaires about yourself and your thoughts and feelings regarding your caregiving role. You can do this online using an online form or via post using a paper version. We will provide support via telephone or video call as needed. This part should not take more than 50 minutes to complete.

It is very important to make sure that we collect all the information required to test if iACT4CARERS works. Thus, we will ask you to fill out all questions if the online survey form is used. You can still choose to use a paper version if you prefer.

If you are eligible, you will be *randomly* allocated by computer to receive **either** iACT4CARERS plus your current treatment **OR** your current treatment alone (no iACT4CARERS). You will have an equal chance of being allocated to either of the groups. Your current treatment refers to any type of support you are currently receiving from health and social care services. You can continue to access support you are currently receiving during the study.

Participants allocated to receive iACT4CARERS will be given a link to the iACT4CARERS website and login details to access the programme. You will be asked to complete eight online sessions in 12 weeks from this. You will lose access to iACT4CARERS after 12 weeks if you have not completed all eight sessions.

Each session will take 40-60 minutes of self-study time. If you need to stop during the session, you can always come back to it at any time and start from where you left off last time. Your dedicated therapist will provide feedback and answer your questions online every week. You will also be invited to book a one-to-one session with your therapist at the start of the programme, and another one-to-one session a few weeks after this.

In order to examine how helpful iACT4CARERS is for family carers, we will ask you to complete the same questionnaires about yourself and your thoughts and feelings regarding your caregiving role that you completed at the beginning at 12 and 24 weeks after you start the study. Each follow-up assessment should not take more than 50 minutes to complete.

It is really important that you try to complete all follow-up assessments, regardless of whether you are allocated to receive iACT4CARERS or not, and even if you stop completing the online programme. This ensures we have all the

information we need to properly test how well iACT4CARERS works in improving the well-being of family carers. You will be entered into a prize draw to win one of 50 £20 gift vouchers for completing follow-up assessments, regardless of whether you are allocated to receive iACT4CARERS or not.

Some participants from the group allocated to receive iACT4CARERS will also be invited to take part in an individual interview at the end of the study. This interview part is optional, and you will receive further detail and be asked to consent to take part in the interview session separately if invited.

Who will find out that I am taking part in this study?

Only you, the research team and your GP (your own GP and not GP for the person you care for) will know that you are participating in this study. The only circumstance in which we may need to break confidentiality is if you tell us anything which may put yourself, the person you care for, or others at risk of harm. If this happens, we will explain why we will need to break confidentiality and whom we will inform.

Can I withdraw from the study?

Being in this study is completely voluntary - you are not under any obligation to consent. If you do consent, but change your mind at a later stage, your legal rights and access to NHS medical care won't be affected at all.

How will you use information about me?

We will need to use information from you for this study. This information will include your name and contact details. The research team will use this information to do this study or to check your records to make sure that the study is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. All information associated with this research is confidential and will be stored securely in

compliance with the UK Data Protection Act (2018) and the EU General Data Protection Regulation (GDPR).

Hard copy data will be stored under secure conditions within the School of Health Science at the University of East Anglia. Electronic data will be stored on secure servers and managed using databases encrypted with industry standard methods and protected by passwords. Data will be stored for 10 years and destroyed thereafter.

Anonymised information may also be shared with researchers, such as our international collaborators, to support other research in the future. No identifiable data will be shared on those occasions.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

The sponsor of this study is the University of East Anglia. You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team members or
- by contacting the sponsor's Data Protection Officer at dataprotection@uea.ac.uk.

Will the study benefit me?

There may be no direct benefit to you if you are not allocated to receive iACT4CARERS. If you are allocated to receive iACT4CARERS, you may see some improvements in your mood after completing the online programme. We hope that this study will help us find out if iACT4CARERS works and should be widely rolled out in the NHS.

What are the risks and disadvantages of taking part?

Some people may experience some upsetting feelings during online sessions. If this happens during the study and you feel that you can no longer commit yourself to the process, please let the research team know. We will do our best to help. As explained earlier, you can withdraw from the study at any time without giving a reason.

This study requires 40-60 minutes of self-study time per week over eight weeks if you are allocated to receive iACT4CARERS. If you are allocated to receive iACT4CARERS, we will also be asking you to use your internet connection. Please note that if you do not have WiFi at home and need to use mobile data to access the internet, we can reimburse the cost by sending a top-up voucher for mobile data (up to £20).

What happens at the end of the study?

At the end of the study, we will analyse your information along with that of other participants. We will publish our findings in an academic journal and at relevant conferences. Individual cases will not be identified in any publication arising from this study. We will also send you a summary of our findings if you wish.

Who is organising and funding the research?

This study is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme (ref: NIHR150071). The research is being led by Dr Naoko Kishita who is a clinical psychologist and an Associate Professor in Dementia and Complexity in Later Life at the University of East Anglia. The research is sponsored by the University of East Anglia and is being run in conjunction with Norwich Clinical Trials Unit.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by NHS HRA London - Queen Square Research Ethics Committee (reference 23/LO/0188).

What if I have a complaint or any concerns?

It is unlikely that you will be harmed by participating in this study. However, if you wish to raise concerns or make a complaint about any aspect of this study, please contact the Chief Investigator:

Dr Naoko Kishita

Associate Professor in Dementia and Complexity in Later Life

School of Health Sciences

University of East Anglia

Norwich Research Park

Norwich, NR4 7TJ

Email: N.Kishita@uea.ac.uk

If you would prefer to speak to someone outside of the research team, then please contact the Dean of School of Health Sciences at the University of East Anglia:

Professor Kenda Crozier

Dean of School of Health Sciences

Email: K.Crozier@uea.ac.uk

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact the study team:

Phone: 07887 582928 / 07586 645780

Email: iact4carers.study@uea.ac.uk

Thank you for considering taking part in this research study.

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.



Resources in the event of distress

NHS emergency services: Call 999 (UK)

NHS for non-emergencies: Call 111 (England)

Samaritans: Call 116 123 (UK)

Alzheimer's society dementia support line:

Call 0333 150 3456

Admiral Nurse dementia helpline:

Call 0800 888 6678