Site logo to be added

**Participant Information Sheet - interview**

**A feasibility study of Acceptance and Commitment Therapy for older people with treatment-resistant generalised anxiety disorder (FACTOID)**

**Invitation to participate in a research study**

We would like to invite you to join our research study that is being funded by the National Institute for Health 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 partner, 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 the purpose of the study?**

The purpose of this study is to develop a new form of talking therapy called Acceptance and Commitment Therapy. This will be for older people with generalised anxiety disorder that has not responded well to treatment.

**What is generalised anxiety disorder?**

Generalised anxiety disorder or chronic worrying is the most common anxiety disorder in older people. It has been linked with difficulties with distress, coping, quality of life and disability. Usually, medication and talking therapy are offered to older people experiencing chronic worrying. However, many people do not respond to this treatment, which is an issue that we hope to address with Acceptance and Commitment Therapy.

**What is Acceptance and Commitment Therapy?**

Acceptance and Commitment Therapy is a new form of talking therapy that helps people to learn new ways of coping with distressing thoughts and feelings. It also helps people to develop ways of taking part in more activities that are meaningful to them. Acceptance and Commitment Therapy has been found to be helpful for reducing distress in other conditions including anxiety, depression, life-limiting illness and chronic pain. It may be particularly suited to older people who experience chronic worrying as many experience difficulties with chronic ill health and other problems such as social or family problems. Standard talking therapy such as Cognitive Behavioural Therapy tries to help improve these difficulties, but this is not always possible. Acceptance and Commitment Therapy, with its focus on helping people learn how to best live with such difficulties, may be more helpful.

**Why have I been chosen?**
You have been chosen because you have been experiencing difficulties with chronic worrying. We are asking 15 older people who are experiencing these difficulties to take part in this study. You have been given this information sheet because you expressed an interest in the study.

**Do I have to take part?**
No. It is up to you to decide whether you would like to take part in this study. We will go through this information sheet with you, and you will be able to ask any questions you have about it. If you do decide to take part you will be given this information sheet to keep and you will be asked by the researcher to sign a consent form. If you decide to take part you will be free to withdraw from the study at any time without having to give a reason as to why you want to withdraw. A decision to withdraw at any time or a decision not to take part will not affect the standard of care you receive or your future medical care or legal rights.

**What will the study involve if I take part?**
If you take part in the study, you will meet with a researcher who will discuss the study with you and ask you some questions to find out whether you are suitable to participate in the study. If you are, then you will be invited to take part in two interviews lasting up to 1.5 hours. The first interview will explore your previous experiences of treatment for chronic worrying and how we can adapt Acceptance and Commitment Therapy for those whose chronic worrying has not responded to treatment. The second interview will explore your thoughts about the intervention we have developed, and how we can improve it. Our aim is to see if we can adapt Acceptance and Commitment Therapy for older people whose chronic worrying has not responded to treatment. Any travel expenses incurred by yourself during the course of the study will be reimbursed.

**What are the possible disadvantages or risks of taking part?**
The risks of taking part could be that you may experience some emotional distress during the screening assessment and interviews as these may require you to reflect on your past and current difficulties. Therefore, there is a possibility that your mood may worsen by the end of the study. You will be able to discuss any emotional distress with the member of the research team and we will notify your GP/care coordinator so that you can receive more support, if necessary.

**What are the possible benefits of taking part?**
You may benefit from taking part in this study because you will be given access to a new type of talking therapy that has been shown to benefit people with other conditions including anxiety, depression, life-limiting illness and chronic pain, but is not yet widely available to those with treatment-resistant generalised anxiety disorder in the UK.

**Will my taking part in this study be kept confidential?**
Yes. All of the information we collect about you will be anonymised using a unique identification number so that it will not be possible to identify you from any of your information. Your data will be stored using this unique identification number and not your contact details (i.e. names or addresses) so that you cannot be identified from it. All data will be kept strictly confidential, and will only be seen by members of the research team.

All of the information about yourself (such as your contact details and your responses to screening questions, interview questions and paper questionnaires) will be stored in one of two ways so that we can verify the information at a later date, if necessary. All electronic data will be held on a secure database on a password-protected computer and on University College London's password-protected secure electronic network. All electronic data will be stored at University College London for 10 years, and will be destroyed after this. Personally identifiable data in paper format (e.g. consent forms, completed questionnaires) will be stored securely in locked cabinets at NHS sites or at University College London for 10 years. Data will be securely destroyed after this.

Audio recordings of your interviews will be recorded on encrypted digital voice recorders, and then transferred and stored onto University College London's password-protected secure electronic network. All data on encrypted digital voice recorders will be deleted after the data have been transferred. Transcriptions of your interviews will be completed as soon as possible after we have met with you.

**Will my doctor be informed?**
If you decide to take part in the study, with your permission, we will write to your GP to inform them of this. We will also contact your GP during the study if we become concerned for your safety or another person's safety (e.g. if you express an intention to harm yourself or another person). This is so that you can be referred for more support.

**What will happen if I don't want to carry on with the study?**
If you don't want to carry on with the study, you will be free to withdraw from it at any time, without having to give a reason. Withdrawing from the study will not affect the standard of care you receive or your future medical care or legal rights. If you were to withdraw from the study then we would use any information collected in the study up to the point that you withdrew from the study.

**What will happen to the results of the study?**
At the end of the study, we will analyse all of your information with other participants' information. We will then publish our findings in an academic journal and at relevant conferences. We will also send you a summary of these if you request this. You will not be identified in any publication arising from this study.

**Who is organising and funding the research?**
The research is funded by the National Institute for Health Research, which covers the running costs of the study. The research is being led by Dr Rebecca Gould who is a clinical psychologist and a Senior Research Associate at University College London. The research is sponsored by University College London.

**Who has reviewed the study?**
All NHS research is looked at by an independent group of people called a Research Ethics Committee in order to protect participants' safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by London - Camberwell St Giles Research Ethics Committee (reference number 17/LO/0704).

**Who can I contact for further information?**
You can contact Dr Rebecca Gould, who is the Chief Investigator in the study, if you have any questions or require any further information about this study. Her details are: Dr Rebecca Gould, Department of Psychiatry, University College London, Wing A, 6th floor Maple House, 149 Tottenham Court Rd, London W1T 7NF. Tel: 020 7679 9925. Email: r.gould@ucl.ac.uk.

**What if there is a problem?**
If there is a problem or if you have any concerns about the way you have been approached or treated during this study, then please contact: Dr Rebecca Gould, Department of Psychiatry, University College London, Wing A, 6th floor Maple House, 149 Tottenham Court Rd, London W1T 7NF. Tel: 020 7679 9925. Email: r.gould@ucl.ac.uk.

**What if something goes wrong?**
If something goes wrong or if you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed because of someone's negligence, then you may have grounds for a legal action for compensation against University College London, but you may have to pay for your legal costs.

**What if I have a complaint about this study?**
If you have a complaint about this study or are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution. If you remain unhappy and wish to complain formally about any aspect of the way you have been approached or treated during the course of this study, then please contact the Research Governance Sponsor of this study, which is University College London. Please write to UCLH/UCL, Joint Biomedical Research Unit, R&D Directorate, Rosenheim Wing, Ground Floor, 25 Crafton Way, London, WC1E 5DB quoting study *FACTOID 15.161.05.* You can also make a formal complaint by following the standard NHS Complaints Procedure: you can find more details about this by contacting your local hospital Patient Advice and Liaison Service (PALS).

This study is funded by the NIHR Health Technology Assessment (HTA) Programme (ref: 15/161/05). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.


**Thank you for considering taking part in this research study.**