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Participant Information Sheet

Study title: *Exploring whether specific aspects of thinking skills are related to outcomes of Cognitive Behavioural Therapy for anxiety, in adults aged over 65.*

IRAS number: 301704

I would like to invite you to take part in this research project, which forms part of my training. I am a researcher training to become a clinical psychologist. Before you decide, it is important for you to understand what the research is for and what it will involve for you if you take part. Please take the time to read the following information and feel free to talk to others about this. You should only participate if you want to; choosing not to take part will not disadvantage you in any way and will not affect your clinical care within Oxfordshire Talking Therapies. Take your time to decide if you would like to take part and please do get in contact if you have any questions or if anything is unclear, or if you would like more information.

What is this study about?

This study aims to explore whether specific aspects of our thinking skills are important to consider in relation to the outcomes for a specific type of treatment (in this case, cognitive behavioural therapy (CBT) for anxiety). In particular, we are interested in these factors in people aged over 60, as there is little research in this area.

The types of thinking skills that we are interested in are executive functioning (these are 'higher level' thinking skills and include our ability to plan and organise) and short-term memory (our ability to hold information in mind for short periods of time).

These thinking skills can sometimes change as we age. We hope to measure these skills in people aged over 60 before they start CBT to see if this is linked to how well (usually, how much less anxious) those people feel when CBT finishes. This could help us make sure CBT is useful for people aged over 60 in the future.

Do I have to take part?

No. You can ask questions about the research before deciding whether or not to take part. If you do agree to take part, you can stop at any time by telling us. You do not have to tell us why.

What would you need to do if you took part?

If you choose to take part in this study, you will have an online meeting with the researcher prior to your CBT treatment starting. At this meeting, you would complete two questionnaires (one about your general health and background, one about your planning and organising skills) and two quick tasks (one short drawing task and one memory task), with the researcher. This would take around 30-40 minutes. After this appointment, your CBT treatment will continue as usual, and you would not need to see the researcher again. Your scores on these questionnaires and tasks will not impact your treatment at all. Your therapist will not see them.

Typically, in Oxfordshire Talking Therapies, people having CBT treatment complete short questionnaires about their mood and worry each week to see how they are progressing. This is a normal part of the treatment. When your treatment finishes, the researcher would look at your scores from these questionnaires to understand how your mood and worry might have changed from the start to the finish of treatment. Your scores would be pseudonymised for inclusion in the research, so it would not be possible for anyone else to know they were your scores.

It is important to note that the questionnaires and tasks completed with the researcher are not designed to identify if someone has a memory or thinking problem in any way. They will not be able to tell us if you have a thinking or memory problem. If you have concerns about your memory or thinking, you should speak to your GP.

Are there any benefits in taking part?

There are not likely to be any direct benefits to taking part in this study.

Are there any potential risks in taking part?

This study should not cause direct risk to you, though some people may find some of the tasks with the researcher a little anxiety provoking. As mentioned above, the purpose of the tasks is not to identify or diagnose any specific problems with memory or thinking, as it is just measuring a normal ageing process that people can experience.

You will be asked if you have any previous mental health diagnoses (and what these are) but this information will be kept confidential.

What will happen if I don't want to carry on with the study?

You are able to change your mind and withdraw from the study at any point during your involvement, until data analysis begins. If you would like to withdraw from the study during your involvement, you can email the researcher using the contact details below. You do not have to tell us why you no longer want to take part. Deciding to stop taking part will not affect your treatment in any way. If you withdraw, the data we had already collected will be kept but no further data will be collected and your records will not be accessed by the researchers again.

How will we use information about you?

We will need to use information from you for this research project. This information will include your first and last name, and contact details. Contact details may include telephone number, email address, and/or home address. This information will not be stored by the researcher, it will only be entered directly in to the email addresses if you are being contacted by email, or written directly on an envelope if you are being written to. 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.

Your answers to the questionnaires and tasks completed with the researcher will be stored using a special code and will be held securely for three years after the study finishes. The questionnaires that you complete as part of your treatment with Oxfordshire Talking Therapies (about your mood and worries) are stored by the service on their secure clinical system, as is standard with any treatment in the service. When the researcher accesses these scores after your treatment ends, the scores will be pseudonymised and stored securely without any identifying information that could link these scores to you.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. All the pseudonymised data will be stored in a password protected data file, on a password protected laptop. None of the data will be accessed by anyone other than the researcher. Your clinician who is completing CBT treatment with you will be able to see the weekly questionnaires about your mood and anxiety, as that is normal as part of your treatment within Oxfordshire Talking Therapies. .

Your consent form will be stored in a locked cabinet at the Oxfordshire Talking Therapies office. Only the researchers will have access to the consent forms. Your consent form will be stored for 3 years and then destroyed. Non-identifiable data will be stored for 3 years after the study finishes, and then destroyed. We need to manage our 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?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from <https://www.oxfordhealth.nhs.uk/privacy/>

- by asking or contacting one of the research team: Fiona.patrick@oxfordhealth.nhs.uk
- by sending an email to Oxford Health Data Protection Officer at mark.underwood@oxfordhealth.nhs.uk

What if something goes wrong?

If you have any concerns about the way you have been approached or treated during the study, please talk to the trainee, Fiona Patrick, or to her clinical supervisor at Oxfordshire Talking Therapies, Dr Sam Sadler (Samantha.sadler@oxfordhealth.nhs.uk).

If you wish to speak to an independent body about any concerns or complaints about any aspect of the way you have been approached or treated during this study, you can do this through the Patient Advice and Liaison Service (PALS). PALS, Oxford Health NHS Foundation Trust, PALS Office, Warneford Hospital, Warneford Lane, Oxford OX3 7JX. Tel: 0800 3287971. E-mail: PALS@oxfordhealth.nhs.uk

In the event that something does go wrong, and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Further Information and Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact the trainee: Fiona Patrick (Fiona.patrick@oxfordhealth.nhs.uk)

GDPR Data Management Statement

All data collected will be collected in line with the Data Protection Act 2018 and GDPR (General Data Protection Regulations). Data collection will also comply with the Common Law Duty of confidentiality. Oxford Health NHS Foundation Trust is the data controller and is responsible for looking after your information and using it properly. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research. Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' You can find out more about how we use your information at <https://www.oxfordhealth.nhs.uk/privacy/>.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) (www.ico.org or 0303 123 1113).

