Participant Information Sheet

Study Title: Adapting primary care services to meet the needs of people with unusual experiences: a feasibility study.
Researcher:
ERGO number: 64425

You are being invited to take part in this research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide whether to take part. You may like to discuss this with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

The aim of this study is to investigate the feasibility of adapting primary care services to meet the needs of people with unusual experiences who have been referred to NHS 'Improving Access to Psychological Therapies' (IAPT) services. This study is being run by the University of Southampton and NHS Trusts in the South of England.

Why have I been asked to participate?

You are being asked to take part in this study because you are receiving input from an IAPT service, and you have indicated that you may have (or have had) unusual experiences.

What will happen to me if I take part?

Your treatment will be undertaken by a qualified CBT therapist who has received additional training to support people who have unusual experiences. You will receive CBT for anxiety / depression that has been adapted to take account of your unusual experiences. You will be offered up to 16 individual therapy sessions and complete outcome measures over this time. After therapy, you will be asked to take part in an interview to discuss your experience of the adapted CBT. If you give your consent, you will also be contacted at 3, 6 and 12 months after therapy has ended to complete follow-up questionnaires.

Are there any benefits in my taking part?

Your participation will help us understand if it is possible to offer adapted CBT to people with unusual experiences who seek help from primary care IAPT services. You may also benefit from having an intervention that takes account of your unusual experiences as well as your feelings of anxiety or depression.

Are there any risks involved?

We will ask you to complete questionnaires at regular intervals. These questionnaires touch on sensitive topics but most are used in routine clinical practice and so we do not expect that these will cause you any distress. However, if you do experience any discomfort and require support, please let your CBT therapist know. You can also contact your GP or the Samaritans (116 123).

What data will be collected?

You will be asked to complete the standard questionnaires used in the IAPT service, along with four additional measures, at regular intervals. Personal information such as age, gender and ethnicity will be collected but not be shared with anyone outside the research

team. After therapy, you will be asked to take part in an interview to discuss your experience of the adapted CBT. We will also ask you to complete questionnaires at 3, 6 and 12 months after therapy has ended.

Will my participation be confidential?
Yes. Your participation and the information we collect about you during the research will be kept strictly confidential. Questionnaire data held by the research team will not include identifiable information about you and will be kept separately to your consent form. Questionnaire data will be recorded on a secure password protected computer. Consent forms will be scanned and kept separately on a secure password protected computer. Your personal medical notes will not be accessed by the research team.

Confidentiality will only be broken if you disclose information that suggests you or someone else is at risk of harm. In such instances, this information will be shared with the appropriate agencies (e.g. your GP, social services, police, as necessary). If this is necessary, we will involve you as much as possible in this process. This is important to safeguard both you and the people around you.

Do I have to take part?
No, it is entirely up to you to decide whether or not to take part. If you decide you do want to take part, you will need to sign a consent form to show you have agreed to participate.

What happens if I change my mind?
You have the right to change your mind and withdraw at any time (up until your data has been anonymised and added to the secure database). You do not need to give any reason. Your participant rights and access to routine care as a patient will not be affected. If you decide not to take part, this will not affect your access to CBT for anxiety and depression or any other healthcare.

What will happen to the results of the research?
Your personal details will remain strictly confidential. Research data and findings made available in any reports, publications or research repositories will not include information that can directly identify you. If you would like to receive the results of the study, please let us know and we will send you a summary when the research has been completed.

Where can I get more information?
If you have any further questions, please contact Dr Katherine Newman-Taylor at knt@soton.ac.uk or Dr Tess Maguire at T.L.Maguire@soton.ac.uk. *Please note: these email addresses should not be used in the case of emergency. If you are worried about immediate risk of harm to yourself or others, please contact your local crisis team or call 999.*

What happens if there is a problem?
If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk). Alternatively, the normal NHS complaints processes are available to you through your GP practice or Mental Health Trust. Your local Patient Advice and Liaison Service can be contacted for advice or if you wish to make a complaint <contact details for local PALS to be added here>.

Who has reviewed this study?
Ethical approval will be received from the University of Southampton Ethics Committee prior to submitting to the Research Ethics Committee and Health Research Authority. It is a requirement that your records in this research be made available for scrutiny by monitors from University of Southampton whose role is to check that research is properly conducted and the interests of those taking part are adequately protected. These people have a duty to keep your information strictly confidential.

Data Protection Privacy Notice
The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you (consent forms) for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Thank you for taking the time to read the information sheet and considering taking part in the research.