

# Talking Therapies Research Resource

## Participant Information Sheet

### Overview

You are invited to take part in the Talking Therapies Research Resource project. Talking therapies help many people but they don't work for everyone. We want to identify factors that predict response to talking therapies in order to help identify which treatments might work best for different people. Our project is a collaboration between IAPT services and the Centre for Affective Disorders. The Talking Therapies Research Resource (TTRR) is one branch of the SLaM NIHR BioResource, and is a way for those who have received a talking therapy within IAPT to join the BioResource for Mental Health.

Signing up to the Talking Therapies Research Resource project will involve providing access to your medical records (so we can find out, for example, whether you are better after your treatment through the Talking Therapies Service), completing some questionnaires, and giving a saliva sample if you are happy to do so.

On the website you can see information about a number of research studies that are being carried out, investigating predictors of treatment response and exploring what might work for those who did not get better following treatment. If you decide to sign up to this project you will be able to take part in these studies should you wish to. You can stop taking part at any time.

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### 1. What are the Talking Therapies Research Resource and the BioResource?

The Talking Therapies Research Resource is a website that anyone who has been referred to an NHS talking therapies service can become a member of. Members are asked to provide access to their medical records, complete a questionnaire and, if they are happy to do so, provide a saliva sample. The researchers running the study will combine these three sources of data in order to identify why some treatments work well for some people, and not for others. We also hope the Research Resource will work as a recruitment platform for studies investigating similar questions. Members will be able to see information about and sign up for other relevant research projects if they wish to.

The Talking Therapies Research Resource is part of a project called the BioResource for Mental Health. This is part of a National NIHR BioResource, which is an NHS project to build up a central bank of people who agree that they can be re-contacted for future studies and that their information and samples can be used for health research. In this case, your data will be used in scientific/medical research to help us better understand why different mental illnesses happen and how we can develop better treatments for them. We aim to collect:

- Biological samples – specifically saliva for genetic testing.

- Clinical data - Examinations by doctors, family information, your response to treatment etc. This data will only be kept locally. Some securely anonymised information and samples from this resource may also be made available to approved scientists working in biomedical and healthcare research, for universities, hospitals and industry.

By becoming a member of the Talking Therapies Research Resource, you will become part of the BioResource for Mental Health. The BioResource team will look after your data and saliva sample and supervise any research projects that use data or samples.

## **2. What is the purpose of the resource?**

Talking therapies work differently for different people, and sometimes people don't feel better when their therapy ends. We would like to find out why this might be happening. At the moment, there is quite a lot of research looking at responses to medication for people with anxiety and/or depression. However, there is much less research which looks at treatment responses to psychological therapy and the common factors amongst people who are not responding to therapy. The purpose of this project is to support research into areas of difficulty such as anxiety and depression, particularly what treatments work best for whom and why. By signing up for the resource, you will be invited to take part in research studies that are attempting to answer this, or a related, question.

### **The Research Resource aims to:**

1. Collect psychological data (questionnaire responses) and biological (saliva) samples for use in (a) predicting treatment outcomes, (b) improving our understanding of difficulties such as anxiety and depression, and (c) screening for recruitment to specific studies.
2. Link patients' psychological and biological data with their medical records.

We also hope the Research Resource will work as a recruitment platform for studies investigating similar questions. Aims related to this element are to:

3. Create an online resource of members interested in taking part in research.
4. Provide members with information about research projects that they can get involved in.
5. Regularly update members on the progress of the research and the contribution that they have made.

Ultimately, this research will hopefully allow us to direct patients towards treatments that are more effectively suited to their personal circumstances.

## **3. Why am I being asked to take part?**

You are eligible to take part if you have recently been referred to a talking therapies service within the NHS.

## **4. Will my participation be kept confidential?**

Yes. All information about you will be kept confidential and only the research team running the resource will have access to your personal and contact details. We will send you information via email about ongoing research projects and you can decide whether you want to take part in them or not.

A participant ID number will be used to identify data about you, and we will keep the list that links ID numbers to people's identities locked separately from the data.

**All data use is strictly within the terms of the Data Protection Act (DPA 1998).**

## **5. What will I need to do if I sign up?**

There are **three steps** to signing up to the Research Resource.

### **Step 1: Give your consent to take part, including allowing us to access to your clinical records**

- The consent form includes a description of each of the types of activity you might be invited to take part in. It is up to you which ones you consent to.
- As part of this process we will request access to relevant information from your medical records. This access has been approved by a committee, which reviews and monitors access to clinical records, and would only be provided to the TTTR team and, having been anonymised, to researchers approved by our advisory board.
- For example, we will request information on the details of your treatment within the talking therapies service or your GP. This allows us to enable studies of anxiety, depression and response to treatment and to better identify which studies you might be eligible to take part in.
- We will combine this data with other data you provide us with so that we can begin to look at the factors that predict how well people respond to psychological treatment.

### **Step 2: Questionnaire data**

- We will ask you to complete some questions which will ask about your demographics (e.g. age, gender, and employment situation), emotional wellbeing, personality and experiences of treatment. This will take around 20-30 minutes to complete.
- All of your responses will be stored against a unique participant ID number so that your answers remain anonymous.

### **Step 3: Saliva sample**

- If you are happy to do so, we will ask you to provide a saliva sample by spitting into a specially designed collection tube. This will be sent to you at home and you can send it back to us using a freepost envelope which we will provide.
- We will extract DNA (i.e. genetic material) from this sample, and use this in analyses to identify whether genetic factors influence the development and treatment of anxiety and/or depression.
- Your saliva sample and the extracted DNA will be labelled using your unique ID number so that they remain anonymous but can be linked to your other data.
- In all instances, the list that links ID numbers from one source of data (e.g. DNA) to another (e.g. medical records) will be kept locked separately from the data.

Once you are a member of the resource, you will be able to see information about a number of research studies that you are eligible to take part in. If you choose to do so, you can sign up to be a participant in any number of these studies.

## **6. What are the possible benefits?**

There may be no immediate benefit to you in terms of treatment but you will contribute to knowledge about which factors influence how likely someone is to respond to psychological therapy. This knowledge may lead to better treatment guidelines and improve future care for patients.

The Talking Therapies Research Resource is an information resource for members as well as researchers. With this in mind, you will have access to pages dedicated to providing useful information to members. This will include:

- Links to information sources
- Details of local and online support networks
- Links to online forums
- Updates about relevant research

By becoming part of the Talking Therapies Research Resource, you will be involved in a community of members and researchers dedicated to investigating which treatments might work best for different people, and striving to give back to the participants that have made their research possible.

### **7. What are the possible disadvantages and risks of taking part?**

Some of the questionnaires ask about topics which some people might find sensitive, and about experiences of anxiety and/or depression. Most of the questions will be very similar to those you complete during your treatment. You do not have to complete any questions that you do not wish to. Providing a saliva sample is a very low risk procedure but some people find it unpleasant.

Your participation is strictly confidential and the risk of identifiable information being accidentally disclosed is extremely low.

### **8. What should I do if I want to be part of the resource?**

- If you decide to take part in the resource, you will need to fill in an online consent form.
- You will then be asked to provide questionnaire data and, if you are happy to do so, a saliva sample before being able to sign up for any of the research studies available.

### **9. What is consent and how does it work?**

It is essential that all participants in the Talking Therapies Research Resource agree to take part of their own volition, and indicate that they fully understand what signing up will mean. There is no obligation to sign up. Once you have provided consent you can unsubscribe at any time.

Signing up to the resource means you are consenting to the following:

- Overall consent to collect and store data about your personal circumstances (according to the information you provided) and access to your medical records
- Consent to be contacted about other research studies
- If you are happy to do so, overall consent to collect and store your genetic data (via a saliva sample)

## **10. Supporting Information**

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### **What will happen to my saliva sample?**

It will be analysed and then stored in a secure laboratory at King's College London. Access to your anonymised sample may be made available to other scientists under strict and confidential legal data-sharing agreements.

We want to know how genes influence response to psychological treatment. Genes are made out of DNA. We will isolate and analyse and store a sample of your DNA from your donated tissue sample and using advanced laboratory techniques we will determine your genetic makeup. This may include determining the sequence of all or part of your genetic code.

Data will not be passed on to unapproved third parties including your doctor, your insurance company or your employer. Your stored samples can only be linked to you by authorised individuals and only when we intend to invite you to participate in follow-up studies.

Your DNA sample will be stored for use in this and future ethically approved research aimed at better understanding the development and treatment of a range of health conditions.

### **Clinically relevant genetic findings**

You will usually not be given any individual feedback on risk for medical conditions from these

analyses. The results are general for research purposes only and not for clinical diagnosis or treatment. **In the extremely rare instance that we do find something that is of known clinical importance, we will write to your GP recommending further investigation.**

### **Will my information be kept confidential?**

Yes, all of your data will be stored in linked anonymised format using a unique participant ID number.

The link between your name and your data will be held by the core research team and will only be broken in exceptional circumstances e.g. where you tell us you wish to withdraw your data from the resource. The results from any study you take part in may be published, but your name will not appear in any publications or reports.

Medical records, questionnaire data, and genetic data will be kept in electronic format and saved on encrypted King's College London file servers. Access will be restricted to the core research team.

Your medical records will not contain any of the results from this research. Participation is strictly confidential.

King's College London will act as data controller for this project and will be legally responsible for the security of any information held under the Data Protection Act. Prof. Thalia Eley and Dr Gerome Breen will act as data custodians for the electronic data and as custodians of all biological samples.

### **What will happen if I change my mind about being part of the resource?**

Taking part is entirely voluntary and you can change your mind at a later stage. You do not need to give a reason.

If you decide to withdraw from the resource, then we will, if you request it, remove your data from our electronic databases and destroy your DNA sample. You may also request to be removed from the BioResource part of the project.

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### **What if something goes wrong?**

We do not anticipate that anything will go wrong but if you have any concern about any aspect of this project, please call on 0800 995 1999 and ask for the Talking Therapies Research Resource team who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this by contacting The South London and Maudsley NHS Foundation Trust Complaints office (0203228 2444/2499).

In the unlikely event that something does go wrong and you are harmed during the research due to someone's negligence then you may have grounds for a legal action for compensation against King's College London but you may have to pay your legal costs.

### **How have patients and the public been involved in this project?**

During the design of the Talking Therapies Research Resource we consulted several service user panels. We have taken into account patient opinions on the tests we will carry out, remuneration and how best to approach patients about participation.

### **Who is organising and funding this project?**

- This project is led by Prof Thalia Eley, Dr Gerome Breen and Prof Anthony Cleare at King's College London and Dr Janet Wingrove, head of Southwark IAPT and is sponsored by the South London and Maudsley NHS Trust.
  - This project is funded by the NIHR BRC for Mental Health.
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### **Who has reviewed this project?**

- All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. They make sure that people who take part in research are treated ethically.
- This project has been reviewed and given favourable opinion by South Central – Oxford C Research Ethics Committee.