

# Talking Therapies Research Resource

## Participant Information Sheet

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

The Talking Therapies Research Resource (TTRR) is a project set up to explore factors that predict response to talking therapies for difficulties such as anxiety and depression, in order to help identify which treatments might work best for different people. The project is led by the National Institute for Health Research (NIHR) BioResource Centre Maudsley, part of the NIHR BioResource, and is collaboration between NHS Improving Access to Psychological Therapies (IAPT) services, the NIHR BioResource, and researchers at King's College London. The TTRR offers you the chance to take part in ground-breaking research aimed at improving the lives of future patients.

The researchers running the project will collect psychological (questionnaire) data and biological (saliva) samples, so that we can learn more about the factors that may influence difficulties such as anxiety and depression and how well people feel following treatment. We also hope that the TTRR will work as a recruitment platform for studies investigating similar questions. Members will be able to see information about and sign up for other related research projects if they wish to.

The Talking Therapies Research Resource is part of a project called the NIHR BioResource Centre Maudsley. This is a branch of the NIHR BioResource, which is a national 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. The NIHR BioResource is a federation of thirteen individual local BioResources that together are establishing a resource of thousands of patients interested in supporting research. The NIHR BioResource headquarters are based in Cambridge. Local BioResources such as the NIHR BioResource Centre Maudsley have been established around Biomedical Research Centres and are based in Birmingham, Cambridge, Exeter, Leeds, Leicester, London, Manchester, Newcastle and Southampton. If you decide to join the TTRR, you will be recruited by the NIHR BioResource Centre Maudsley, but your information and part of your sample will be shared (securely) with the NIHR BioResource.

We aim to collect:

- Questionnaire data – about your current/past feelings and situation
- 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 on secure firewalled computers in encrypted databases. Some securely anonymised information and samples from the TTRR 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 TTRR, you will become part of the NIHR BioResource Centre Maudsley and the NIHR BioResource. The NIHR BioResource Centre Maudsley and NIHR BioResource teams will look after your data and saliva sample and supervise any research projects that use your 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 similar questions.

### **The TTRR aims to conduct research on mental health and treatment. We will:**

- Collect psychological (questionnaire) data and biological (saliva) samples, so that we can learn more about the factors that may influence difficulties such as anxiety and depression and how well people feel following treatment.
- Link members' psychological and biological data with their medical records.

### **The TTRR also aims to create an online community of IAPT service users. We will:**

- Create an online resource of members interested in taking part in research.
- Provide members with information about research projects that they can get involved in.
- Regularly update members on the progress of the research and the contribution that they have made.
- Provide links to pages that provide detailed information on mental health difficulties, the treatments available and where to seek help if it is needed.

Ultimately, this research will hopefully allow us to direct future 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 are aged 16 or over and have recently been referred to a talking therapies (IAPT) service within the NHS.

**All data use is strictly within the terms of the General Data Protection Regulations (GDPR, 2018).**

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

It is essential that all participants in the TTRR agree to take part by choice, 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.

There are **three steps** to signing up to the TTRR.

### **Step 1: Giving consent to take part**

- 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.
- We will request access to your medical records. 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. This access has been approved by a committee which reviews and monitors access to clinical records. Your data would only be provided to the TTRR and NIHR BioResource team and, having been anonymised, to researchers approved by our steering committee.
- 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.
- We will also ask for your consent to be contacted in the future about other ongoing research studies. We may assess your eligibility for these studies based on information you have provided (i.e. questionnaires, genetic information), or information we have accessed from your medical records (i.e. diagnosis, treatment outcome). You will only be contacted up to 4 times in any one year.

## **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), and your emotional wellbeing, personality and past experiences. This will take around 30-60 minutes to complete. You can leave out any questions you do not wish to answer.
- All of your responses will be stored against a unique participant ID number so that your answers remain anonymous but can be linked to your other data.
- You may be contacted once per year by the TTRR team to ask if you would complete repeat or additional questionnaires. You will not have to complete any of these questionnaires if you do not wish to.

## **Step 3: Saliva sample**

- 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.

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

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

The link between your name and your data will be held by the core research and NIHR BioResource teams. 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 file servers behind secure firewalls at King's College London and on NIHR BioResource file servers at University of Cambridge. Access will be restricted to the 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 the NIHR BioResource will be the custodian of all biological samples.

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

There is unlikely to be any benefit to you in terms of your 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 TTRR 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

## **7. What are the possible risks?**

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. There is no risk involved in providing a saliva sample but some people find it unpleasant.

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

## **8. Supporting Information**

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

It will be analysed and then stored in a secure laboratory at NIHR BioResource facilities. 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, analyse and store a sample of your DNA from your donated tissue sample and use advanced laboratory techniques to 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, such as 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 current and future ethically approved research aimed at better understanding the development and treatment of a range of health conditions.

**Will I get information about my genetic results?**

The NIHR BioResource Centre Maudsley does not plan to routinely feedback any genetic results obtained from your sample. The results are general for research purposes only, and thus are not sufficient 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.** If you do not wish for us to contact your GP, you can indicate this on your consent form.

**What will happen to any data produced from the samples I give?**

Anonymous data about you will be made available to researchers who have relevant approvals for their planned research. This could include researchers who are working in the public and charitable sector (Universities, Research Institutes) or in industry, either in the UK or overseas. Researchers will be able to see data/information gathered about you, or obtained from testing your donated samples, but will not know it belongs to you. Access to the data will be managed, which means that the TTRR and/or the NIHR BioResource will have to give permission to others who wish to use the data.

Researchers share the results of their studies by means of reports or publications, which includes placing information/data on the internet, in press articles, in project leaflets and through other media. This will include the sharing of anonymised data obtained by testing your donated samples, e.g. your entire DNA sequence or part of it may be deposited in a database for use by researchers through managed access. Under no circumstances will your personal identifiable information be disclosed in any of these documents.

**What happens if an invention is made using my sample?**

Your donated samples and related information are given as an absolute gift, i.e. without receiving a payment and without conditions. The BioResource is operating on a non-commercial basis, meaning it does not sell your sample to make a profit and will not allow anyone else who is working with the sample to do so either. However, if samples are made available to other research institutions or to commercial companies, a fee may be charged to cover the BioResource operational costs.

In the future, your sample may help researchers in the public and commercial sector to make an invention, for example, develop a new product to diagnose or treat a disease. If an invention results from the research undertaken with your sample, you will not receive any compensation, recognition or payment. BioResource partners in the public sector may work together with commercial companies to develop inventions for the benefit of patient and donor care, and we hope that such products are brought into use to improve healthcare in the future.

**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 any time. You do not need to give a reason.

You can request not to be contacted in the future, and/or to have your electronic data removed and your DNA sample destroyed. In this instance, we would need to retain the consent form you completed so that a record remains of your initial consent and the withdrawal process.

**What if something goes wrong?**

We do not anticipate that anything will go wrong but if you have a concern about any aspect of this project, please call on 0207 848 1640 (or FREEPHONE 0800 019 0718) 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 (020 3228 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. 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, re-contact and how best to approach patients about participation.

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

This project is led by Prof Thalia Eley and Dr Gerome Breen at King's College London and Dr Janet Wingrove, head of Southwark IAPT and is sponsored by King's College London and South London and Maudsley NHS Foundation Trust. This project is funded by the NIHR.

### **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 London – Dulwich Research Ethics Committee (REC Ref: 17/LO/1870).

### **How can I get involved in future studies?**

The TTRR supports many different research studies. We may, on the basis of the data held in the research database, contact you to ask whether you would like to take part. You will be provided with information regarding each of these studies and will be free to decide whether or not to participate. Contact for future studies will only ever be established by staff from the TTRR team or the NIHR BioResource. We will never give your personal contact details to researchers unless you specifically authorise us to do so. You will only be contacted up to 4 times in any one year.