The University Of Sheffield.

V5 - 16/09/19

Patient Information Sheet

Your IAPT Psychological Service is taking part in a study called 'Personalised Mental Health'. Thank you for considering taking part. The information provided below will give you more details about this study, your involvement, and how IAPT patients' anonymised information will be used.

Introduction

IAPT Psychological therapy services use only therapeutic methods which have been proven successful for many people. These methods are referred to as 'evidence based approaches', and are based on valuable information and results gathered from people in previous research trials. As IAPT continually strives to improve these methods, it's important to conduct more research to further improve the effectiveness of therapy.

This 'Personalised Mental Health' study will help us to explore some of the specific problems people face, and will enable us to identify the best approach for overcoming these problems.

All information collected for this study will be saved anonymously, so it will be impossible to personally identify anyone who takes part (with the exception of your therapist).

1. What is this study about?

Before each treatment session, patients routinely complete one or more questionnaires. The results of these questionnaires enable therapists to monitor their patients' progress and detect if there are any problems or obstacles which may prevent their patients from improving. Detecting issues as they arise in the treatment programme can help therapists to better advise their patients and improve their chances of a good recovery. This process is called 'Outcome Feedback', and there is strong evidence to suggest that Outcome Feedback helps to improve treatment outcomes. Less is known however, about the types of obstacles patients encounter, or the solutions that are applied by their therapists. In this Personalised Mental Health study, we aim to observe and capture this information. Identifying common obstacles and their solutions will help us to improve personalised treatments plans which target the specific needs of each patient.

We will learn more about:

- the types of barriers patients encounter which slow down their improvement
- the therapists plan to help their patients overcome these barriers
- and the effect of the plan on their patient's recovery.

Taking part in this study will not alter the treatment you receive, as your therapist will continue to use the same best therapy methods that s/he has been using. However the additional benefit of this process will contribute to improving the effectiveness of the therapeutic process.

2. Why have I been chosen?

The IAPT therapist that assessed you is participating in the Personalised Mental Health study.

3. Do I have to take part?

No, you do not have to take part. Your therapist will ask for your consent to participate when you first contact the IAPT service. You can refuse to consent without any consequences to your treatment in the service. You can withdraw from the study at any time without any negative consequences, and you do not have to give a reason. If you wish to withdraw from the research, please use the contact details at the end of this form.

4. What will happen to me if I take part? What do I have to do?

After you provide consent, there is nothing else that you need to do. The research team will collect only anonymous information about your treatment from an NHS database to see how your therapist used Outcome Feedback to inform your treatment.

5. What are the possible disadvantages and risks of taking part?

We do not expect that taking part in the study will lead to any disadvantages or risks to any patients.

6. What are the possible benefits of taking part?

You will be contributing to important research which may help to improve the effectiveness of psychotherapy.

7. Will my taking part in this project be kept confidential?

Yes. All the information that we collect about IAPT patients will be entirely anonymised, making it impossible to personally identify anyone. Information gathered will be kept strictly confidential and only unidentifiable information will be accessible to members of the research team.

8. What will happen to the data and the results of the research project?

The researchers will analyse the information to look for common obstacles which may prevent recovery, and common solutions applied to overcome them. Our results will be communicated to the IAPT Service in a summary newsletter. We will also communicate our results through publications in scientific journals and presentations at conferences.

9. Who is organising and funding the research?

The study is led by the University of Sheffield and partly funded by a technology company called MindLife UK. The University of Sheffield is responsible for collecting all study data and for ensuring that it is used properly.

10. Does the study have ethical approval?

This study was independently reviewed and approved by an NHS Research Ethics Committee (Ref:19.YH.0178).

11. What if something goes wrong and I wish to complain about the research?

If you wish to discuss the study or make a complaint you can contact the lead researcher.

12. Legal statement under the General Data Protection Regulation (GDPR)

The University of Sheffield is the sponsor for this study based in England. We will be using anonymised information from you and from your service's clinical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. We will not keep identifiable information; but anonymised information from your sessions will be kept for 10 years after the study has finished until 2028. Your rights to access, change or move your sessions' information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information that we have already obtained. To safeguard your rights, we will not gather or keep any identifiable information.

Information obtained from you or obtained from clinical records will not identify any individuals and will not be combined with other information in a way that could identify individuals. The information will only be used for the purpose of health and care research, and cannot be used to contact or to affect the care of any individuals. It will not be used to make decisions about future services available to you, such as insurance.

If you want to find out more about how we use your information, or if you wish to withdraw your information from the Personalised Mental Health study, please contact the Chief Investigator.

13. Contact details

Please see below for contact details. Please contact Eleanor Williams (lead researcher) if you wish to obtain further information about the project. If you do not hear back from the lead researcher after one week, please email Jaime Delgadillo (supervisor). Please only email the head of department if you are escalating a complaint.

Lead Researcher	**Chief Investigator**	**Supervisor**	**Head of Department**
Eleanor Williams	Jaime Delgadillo	Heidi Christensen	Gillian Hardy
Ewilliams9@sheffield.ac.uk	j.delgadillo@sheffield.ac.uk	heidi.christensen@sheffield.ac.uk	g.hardy@sheffield.ac.uk
	0114 222 6614	0114 222 1950	

Thank you for taking time to consider participating in this study