V5 19/09/19

Participant Information Sheet

1. Research Project Title

Understanding common obstacles and solutions to deliver effective psychological treatment for depression and anxiety

2. Invitation paragraph

You are invited to take part in a research project. Before you decide whether you would like to participate, it is important for you to understand why the research is being done and what your participation will involve. Please take the time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear, or if you would like more information. Take your time to decide whether you wish to take part. Thank you for reading this.

3. What is the study about?

Numerous reviews of controlled trials and practice-based studies have concluded that using outcome feedback (OF) can help to improve psychological treatment outcomes. OF involves the routine monitoring of a patient's symptoms using standardised measures and plotting these onto a graph that displays a trajectory of changes from session-to-session. These graphs help therapists to identify cases that are 'on track' or 'not on track' to a good treatment outcome. 'On track' patients show typical symptoms that are comparable to those observed in similar cases, whereas 'not on track' cases show symptoms that are significantly worse than those of similar cases. The OF method therefore supports therapists to make treatment decisions based on objectively measured, individualised treatment responses, rather than relying on clinical judgment alone.

Although the effectiveness of this OF method is well-established, there is scarce research about its mechanism of action. Previous studies have suggested that the OF method helps therapists to identify and resolve obstacles to improvement in a timely way; however, less is known about the types of obstacles that are identified using OF, or the solutions and strategies that are applied by therapists to improve outcomes.

We therefore aim to investigate the OF process and mechanisms of action. Processes will be captured using qualitative case notesincluding a summary of hypotheses about obstacles to improvement, a plan for trouble-shooting strategies and the implementation and outcomes of that plan. We also aim to explore if certain obstacles and certain solutions are associated with clinical outcomes. We will therefore be gathering quantitative outcome data and qualitative process data.

The time scale for the study will be 9 months: including 6 months for data collection and 3 months for analyses and dissemination. This study is being conducted as a requirement of the doctorate in clinical psychology (DClinPsy) at the University of Sheffield.

4. Why have I been chosen?

You have been chosen because you meet the inclusion criteria for our study. That is, you are a qualified psychotherapist contracted to work within an IAPT service for the expected timescale of the project.

5. Do I have to take part?

No, you do not have to take part. Participation in the study is voluntary and you are not obliged to consent. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You can still withdraw at any time without any negative consequences and you do not have to provide a reason. If you wish to withdraw from the research, please do not hesitate to contact Eleanor Williams (see **16.** for contact details).

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

If you decide to take part, you will be involved in the research for 6 months. You will be invited to attend one 3-hour training session, to learn how to apply OF methods in your clinical practice, and one 90-mintue booster webinar session half-way through the study.

You will then be asked to use OF methods in your usual clinical practice. You will have access to OF monitoring graphs; you will be required to enter scores from the PHQ-9 and GAD-7 into the graph on a sessional basis, in accordance with standard IAPT practice. You will review the graph at the start of each therapy session, to assess if treatment is 'on track' or 'not on track'. In cases that are assessed as 'not on track', you will explore potential obstacles to improvement and consider and implement trouble-shooting strategies. You will also be encouraged to prioritise these discussions in your weekly clinical supervision.

You will be asked to document the above process using an electronic form, which provides a template for you to keep structured case notes. The case notes template will ask you to summarise: your hypotheses about obstacles to improvement, and the actions or strategies taken to address these obstacles. You will be able to type into the boxes on the electronic form and will be able to copy and paste your text to your own routine case notes, to reduce the administrative burden.

You will require verbal consent from patients before completing the electronic form. You will be provided with a script to gain consent and will need to document that the patient has consented on the PCMIS system. The process of gaining patient consent has been designed to be as least burdensome as possible.

You will not require consent from supervisors to participate in this study,since the procedures overlap with routine care (using Outcome Feedback graphs and keeping structured case notes) although you may wish to discuss the study with your supervisor prior to consenting to participate.

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

It is possible that being notified when your cases are at risk of poor outcomes may be anxiety provoking for you and there is the possibility that OF may raise quality of care issues. You will be encouraged to address these issues within your formal and contractual setting of clinical supervision. Responsibility for the quality of care will lay with you and your supervisor through the duration of the study. The research team will not be monitoring the data in 'real time' and it is therefore considered the responsibility of you and your supervisor to address clinical concerns.

8. What are the possible benefits of taking part?

You will gain access to a clinical skills workshop developed by experts in the field of outcome feedback. You may find OF helpful in your practice and you may develop skills in utilising outcome monitoring and strategies to resolve obstacles to improvement in a consistent and timely manner. You will also be contributing to an important gap in the literature which may help to improve the efficacy of psychotherapy in the future.

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

All the information that we collect about you during the course of the research will be kept strictly confidential and will only be accessible to members of the research team. You will not be able to be identified in any reports or publications. If you agree to us sharing the information you provide with other researchers (e.g. by making it available in a data archive) then your personal details will not be included unless you explicitly request this.

10. What is the legal basis for processing my personal data?

According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)). Further information can be found in the University's Privacy Notice https://www.sheffield.ac.uk/govern/data-protection/privacy/general.

11. What will happen to the data collected, and the results of the research project?

Prior to data collection, you will be assigned a unique ID number which you will be asked to enter onto the electronic forms you fill out. Your data will therefore be anonymised. Only the data processors (the lead researcher and two supervisors) will have access to this anonymised data. The results will be analysed by the lead researcher under the supervision of the two supervisors. The results will be written up as a journal article and will be submitted for publication in approximately September 2020. You will not be identified in any publication and you will be informed on how to obtain a copy of the results.

The data you provide will be stored in an anonymised form for 10 years. Identifiable personal data, including the key which links you to the data you provide, will be destroyed once it is clear that this will not affect the research purpose.

Due to the nature of this research, it is very likely that other researchers may find the data collected to be useful in answering future research questions. We will ask for your explicit consent for your data to be shared in this way.

12. Who is organising and funding the research?

This study will be funded by the University of Sheffield.

13. Who is the Data Controller?

The University of Sheffield is the sponsor for this study based in the United Kingdom. We will be using information from you 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. The university of Sheffield will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your 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 about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information by contacting Eleanor Williams (see **16.** contact details).

14. Who has ethically reviewed the project?

This project has been ethically approved via the NHS research ethics committee.

15. What if I wish to complain about the research?

If you wish to raise a complaint about the research, you should contact Eleanor Williams (see **16.** for contact details). If you feel that your complaint has not been handled to your satisfaction, you should contact the Gillian Hardy (see **16.** for contact details), Head of Department, who will escalate the complaint through the appropriate channels. If your complaint relates to how your personal data has been handled, you can find information about how to raise a complaint in the University's Privacy Notice: https://www.sheffield.ac.uk/govern/data-protection/privacy/general.

16. 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	**Supervisor**	**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	

If you wish to participate in this study, please complete the consent form and send it to the research team at the University of Sheffield – either via email (scanned copy of signed consent form) or via post. If you wish to post your consent form, please send it to:

Eleanor Williams
Clinical Psychology Unit
Cathedral Court
The University of Sheffield
1 Vicar Ln
Sheffield
S1 2LT

Thank you for reading this information sheet.