Research Title: Co-developing Improving Access to Psychological Therapies (IAPT) services to improve long-term benefits for patients with depression and anxiety (CO-IMPROVE)

Interview Study - Professionals

Information about the research

You are being invited to take part in a research project that aims to improve long-term benefits for patients that have received low intensity treatment for depression and/or anxiety in Improving Access to Psychological Therapies (IAPT) services. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve.

Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

ABOUT THE RESEARCH

➢ Who will conduct the research?

The research is led by Dr Cintia Faija and co-led by Professor Penny Bee; both based in the Division of Nursing, Midwifery and Social Work at the University of Manchester. Other members of the team also based in the Division of Nursing, Midwifery and Social Work ate the University of Manchester include, Professor Karina Lovell, Dr Amy Blakemore and Saher.
External members of the Research team include Dr Jaime Delgadillo (University of Sheffield), Professor Dean McMillan (University of York), and Mr Paul Edwards (Patient and Public Involvement representative). We are conducting this research in collaboration with IAPT services located in the North of England.

➢ What is the purpose of the research?

Do you know that:

- **A percentage** of patients successfully completing low intensity interventions for depression and/or anxiety in IAPT services experienced **relapse** within one year following treatment?
- **Many** patients had a **relapse** event during the first 6 months following treatment?

We are conducting this research because we would like to understand **why** patients may relapse and **what** could be done to help patients to maintain treatment gains and prevent deterioration over time following treatment. The findings from this study will inform the next stages of the research project which will involve working together with other patients and professionals to develop resources aimed at preventing relapse.

➢ Am I suitable to take part?

You have been chosen to take part because:

- ✓ You are a psychological wellbeing practitioner, team manager, or service lead working in an IAPT service or in a third-sector service commissioned to deliver IAPT located in the North of England OR

- ✓ An IAPT trainer, a clinical academic, a policy maker, a national lead or a knowledgeable person about IAPT services and/or in this topic

We are looking to speak to participants of different backgrounds (e.g., age, gender, ethnicity, sexuality, educational qualifications, employment status, religion, disabilities). We will be asking you to complete a demographic questionnaire (online via Qualtrics) to identify/select interested people in taking part towards this end.

- **How many professionals are we intending to recruit?**

We intend to recruit between 20-25 professionals. If you have contacted us and recruitment is no longer open, meaning the number of professionals has been reached, we will inform you about this and will retain your contact details with your consent for future research opportunities or for the following stages of this research.

- **Will the outcomes of the research be published?**

At the end of the research, the findings will be made available in reports, academic papers, peer reviewed scientific journals, scientific conferences, and/or online (e.g., social media, research blog). A summary of findings will be sent to you if you provide consent for us to do so. Study sites who were involved in the research will also be provided with a summary of the findings to circulate to their teams. When we write up the results, all personal details will be removed so that no-one will know who you are. We may use direct quotes from your interview, but no real names will be used.

- **Disclosure and Barring Service (DBS) Check**

All researchers involved in this programme have undergone an appropriate level of DBS check as determined by their school and obtained either via The University of Manchester or other external organisations

- **Who has reviewed the research project?**

This study has been reviewed by an independent group of people, called the Research Ethics Committee, to protect your safety, rights, well-being and dignity. The study has been given a favourable opinion by North West - Greater Manchester West Research Ethics Committee (IRAS ID: 323641; REF: 23/NW/0109).

- **Who is funding the research project?**

This study is organised and sponsored by the University of Manchester. The funder is the National Institute for Health Research (NIHR), Research for Patient Benefit (Ref: NIHR 204037)

WHAT WOULD MY INVOLVEMENT BE?

- **What would I be asked to do if I took part?**

We would like to invite you to take part in an interview to know about your views and experiences related to relapse prevention and maintenance of recovery within low intensity treatment interventions delivered in IAPT services. The interview will take place online via the video conferencing software, Zoom or via Microsoft Teams, at a mutually convenient time.

Prior to the interview, you will be asked to complete a questionnaire (online via Qualtrics) which will take approximately 3 minutes to complete and will ask you about your background (e.g., age, gender, ethnicity).

If you are interested in taking part, we will ask you to complete and return the consent-to-contact form provided via email to **Saher Nawaz** using the following email address: saher.nawaz@manchester.ac.uk . Alternatively, you can contact Saher directly using this email address and express your interest in taking part or by telephone using the following number: +441615294302.

- **How long would the interview be and what will I be asked about?**

The interview will last up to 60 minutes, dependent on the time you have available. We will ask you about your thoughts and experiences, including why relapse may happen, what could be done when patients are facing a difficult time after being discharged, what could be done to prevent relapse and support the maintenance of treatment gains following treatment.

You do not need to answer any questions that you do not wish to, and you can leave the interview at any time. The interview will be conducted over the telephone or via video-call (using Zoom or Microsoft Teams) pending on your preference and at a time convenient to you.

- **Will the interview be recorded?**

Yes. We record interviews because it is hard for the researchers to take notes on what people say, listen carefully and think, all at the same time. We do this to help us remember what people said and to make sure that all their comments are available for the research. After the interview, the conversation will be typed up word-by-word by a university approved supplier. Any identifiable information will be removed from the transcripts to protect participant's anonymity. Data will be securely stored in University computers.

Interviews conducted by telephone will be audio recorded with the participant's consent on an encrypted device. Interviews conducted by video-call will be video-recorded with the participant's consent. Please note that the video recording of the interview will be immediately destroyed after the interview and only the audio recording will be kept for transcription. If you decided to have a video-call, you may wish to join the Zoom/Teams interview link and turn off your video if you would prefer not be video-recorded.

- **Will I be compensated for taking part?**

Yes. Participation in the interview is voluntary and if you take part, you will receive a £10 gift voucher as a thank you for your time and participation.

- **What happens if I do not want to take part?**

It is up to you to decide whether or not to take part. If you would like to take part, or if you have any questions about the study, please get in touch via email with one of the researchers (Saher Nawaz or Dr Cintia Faija) using the email address at the end of this information sheet. If you decide to take part you will be given this information sheet to keep and asked to sign a consent form or provide verbal consent prior to the interview. Your participation is voluntary and you are free to withdraw at any time (i.e. before or after the interview) without giving reason and without affecting your medical care in any way. However, it will not be possible remove your data from the project once it has been

anonymised as we will not be able to identify your specific data. This does not affect your data protection rights.

If you decide not to take part, you do not need to do anything further.

If you decide to take part, the audio recording of the interview is essential to the study. Therefore, if you do not want your contribution to be recorded, you should not agree to participate in the study. However, it is important that you are always comfortable with the recording process. If, once your interview has begun, you are not comfortable being recorded, you should let the researcher know, who will stop the recording.

- **What do I need to do if I decide to take part?**

It is up to you to decide if you would like to take part or not.

If you do decide to take part, you should keep this information sheet in a safe place and do one of the following:

If you have any questions and would like to speak to a member of the research team before you consent, you can:

1-Complete the consent-to-contact form and return it by email to **Saher Nawaz** saher.nawaz@manchester.ac.uk
2-Or, if someone from your service has contacted you and you have agreed for them to pass your contact details to the research team, Saher will get in touch with you (following your preferences, email, telephone, post).

If you do not have any questions, you can provide consent to take part in the study without making contact with the research team by completing the online consent form using the link below:

https://www.qualtrics.manchester.ac.uk/jfe/form/SV_5hXl5U6nkmYlWPI

If you do not wish to provide consent online, you can let the researcher know about it via email to saher.nawaz@manchester.ac.uk or by telephone: +441615294302 and she will contact you to audio-record your verbal consent via telephone or Zoom/Teams (pending on your preferences).

- **What if I decided to take part and change my mind later?**

If you decide to take part but you change your mind later, you are still free to withdraw at any time without giving a reason and without affecting your medical care in any way. However, if your interview took place, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. Please note that usually it takes up to two weeks to anonymise your data.

If you take part in an interview we would like you to be comfortable with the recording process at all times and you are free to stop recording at any time.

If you change your mind about taking part, you have up to two weeks to withdraw your data. If you withdraw your data, we will destroy the recording and its transcription (typed word-by-word). No one will listen/read to it again after you have changed your mind.

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. To safeguard your rights, we will use the minimum personally-identifiable information possible (e.g. contact details).

You can find out more about how we use your information by contacting the Principal Investigator, Dr Cintia Faija (email: Cintia.faija@manchester.ac.uk).

- **What are the possible advantages of taking part?**

Although we cannot promise the study will help you personally, the information you provide would help us understand what to do differently to help NHS patients in the future to stay well over time and ensure changes made during psychological treatment transition to lifelong skills.

- **What are the possible disadvantages of taking part?**

Occasionally, people can feel upset if they think about something distressing. If this happens, you may like to make use of the support services listed at the end of this information sheet or you may wish to contact the Principal Investigator for this project: Dr Cintia Faija (email: Cintia.faija@manchester.ac.uk).

In the unlikely event that something does go wrong and you are harmed during the research, you may have grounds for a legal action for compensation against the University of Manchester or NHS Trust providing your care but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

DATA PROTECTION AND CONFIDENTIALITY

- **What information will you collect about me?**

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect:

- Your contact details: name, address, phone number and/or email address (pending on your preference mode to be contacted)
- Additional background information about you: age, gender, ethnicity, sexuality, educational qualifications, employment status, religion, disabilities, length of time working in your role and mental health services
- Recording: With your consent, if the interview takes place by telephone we will audio-record (voice only) the interview; if the interview takes place via Zoom/Teams and you turn on your camera you will be video-recorded (voice and face).

- **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law, which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

- **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings. If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research (http://documents.manchester.ac.uk/display.aspx?DocID=37095).

Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team.

- **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

The consent form outlines the different levels of consent you can agree to in relation to the use and storage of your data.

Your personal details will not be used in the reporting of the study.

Only the research team at the University of Manchester with the necessary approvals will have access to your personal information, but they will anonymise it as soon as possible. Your name and any other identifying information will be removed and replaced with a random ID number. Only the research team will have access to the key that links this ID number to your personal information. Your personal details will only be used to contact you about this research project and to provide you with a summary of the research findings when it is complete (if you have indicated that you would like us to do so).

All documents (such as your consent form) will be stored on a password-protected encrypted University server. After the end of the programme, all documents will be sorted in an approved electronic storage facility. Your consent form will be retained for 2 years after the study has finished. After these 2 years, the consent forms will be destroyed.

When you agree to take part in a research study and with your informed consent, the information about you will be shared with researchers running other studies here or at other organisations. The future research will be of a similar nature to this research project and will concern improving mental health services for people experiencing mental health problems. With your consent, your anonymised information will only be used in order to support additional research in accordance with the UK Policy Framework for Health and Social Care Research (https:\\www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research).

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of such research and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.

Interviews conducted by telephone will be recorded using an encrypted recorder device.

Interviews conducted via video-call will be recorded in Zoom/Microsoft Teams and your personal data will be processed by Zoom/Microsoft Teams. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection. The video recording will be immediately destroyed and only the audio will be kept for transcription.

The audio recording of your interview will be transferred to a secure University server. It will be labelled with an assigned ID number known only to the research team. We will retain a transcription key containing these ID numbers which will enable us to identify you if necessary, prior to transcription. The recording will be typed up by a research team member or by an approved university transcription service. Once transcribed we will check your recording and remove any personal or identifiable information such as names or locations. After the recording is checked against the transcription and anonymised, it will be deleted.

In accordance with the University of Manchester's Research Privacy notice and with your consent, we would like to be able to share your anonymised data with other University of Manchester researchers who are doing studies similar to ours.

The research team will transcribe, process, and analyse the recordings in private locations which may include private residences.

Personal data may be stored in hard copy format or electronically. Hard-copy material will be kept in locked filing cabinets within locked University offices. All electronic data, including the original recordings, will be stored on University of Manchester secure servers and devices, including encrypted external hard drives or pen drives, and will only be used in the ways outlined above and that you consent to explicitly in the consent form.

In line with the University of Manchester Information Governance Office Records Retention Schedule Research Data Management Policy, the minimum default period for research data is 5 years after publication.

Clauses 11 -13 of the consent form are optional and if you do not agree to them, this will not affect your eligibility to take part in the current study.

So that we can provide the gift voucher as a thank you for your time, your full name and email address will be shared with our Finance department who will send the voucher to you. Your full name and email address will be securely retained by Finance for a period of up to 7 years for audit purposes only and then destroyed. It will not be used for them for any other purpose.

- **What are the circumstances where confidentiality would be broken?**

Everything you tell us during the interview is completely confidential. The only exception to this would be if during the interview you disclose information about any of the following:

Disclosure of dangerous professional practice: Members of the research team include clinical professionals who have a professional duty to disclose information relating to dangerous practice. If, during the interview, you disclose information about misconduct/poor practice or the researcher feels risks the safety of patients, this information will be disclosed through appropriate line

management channels in keeping with professional guidance (e.g. IAPT/NHs Trust, professional body). We anticipate this is highly unlikely.

Disclosure of illegal activities: If you disclose information about any current or future illegal activities, we have a legal obligation to report this and will therefore need to inform the relevant authorities. We anticipate this is highly unlikely.

Disclosure of risk: If you disclose any information which means you may be at risk of harming yourself or others, we will be required to break confidentiality to provide the correct support. This may involve signposting you to relevant support services, calling a family member or friend, or calling emergency services. We anticipate this is highly unlikely.

Participant distress: It is possible that discussion in the context of this research study could be distressing to you. Researchers will monitor for signs of emotional distress and will respond appropriately. This ranges from offering simple emotional support to recommending that the participant seek appropriate support through their professional networks. We anticipate this is highly unlikely.

Individuals from the University of Manchester, NHS Trust or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data but all individuals involved in auditing and monitoring the study, will have a strict duty of confidentiality to you as a research participant.

If you would like more general information on how researchers use data about patients, please visit: www.hra.nhs.uk/information-about-patients/

- **What if I have a complaint?**

Contact details for complaints
If you have a complaint that you wish to direct to members of the research team, please contact Dr Cintia Faija (email: cintia.faija@manchester.ac.uk) or Professor Penny Bee (email: penny.bee@manchester.ac.uk)

Formal complaints

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact:

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information (https:\\ico.org.uk/make-a-complaint/). Tel 0303 123 1113

ADDITIONAL INFORMATION:

COVID-19

➢ **Is it safe to take part in this research project considering the COVID-19 pandemic?**

Due to the current COVID-19 pandemic, we have made some adjustments to the way in which this research project will be conducted, ensuring we are adhering to the latest government advice as well as taking all reasonable precautions in terms of limiting the spread of the virus. You should carefully consider all of the information provided below before deciding if you still want to take part in this research study. Therefore, as mentioned above, if you decide to take part, we will be interviewing you via telephone, what will ensure to keep everyone safe. If you choose not to take part, you need to inform research team. If you have any additional queries about any of the information provided, please speak with a member of the research team.

If you would like to know about the latest government advice on COVID-19, you can visit the following websites:

Information about coronavirus: https://www.gov.uk/coronavirus

Daily update for data and insights on coronavirus: https://coronavirus.data.gov.uk

LIST OF SUPPORT SERVICES

If you require further support, we recommend that you contact/attend one of the following:

- Your GP
- The Samaritans 116 123 (available 24/7)
- NHS 111 (available 24/7)
- Your local A&E department

CONTACT DETAILS

If you have any queries about the study or if you are interested in taking part, then please contact the researcher:

SAHER NAWAZ
Research Assistant
The University of Manchester
Email: saher.nawaz@manchester.ac.uk
Telephone: +441615294302

THANK YOU FOR TAKING TIME TO READ THIS INFORMATION SHEET