**Exploring engagement with between-session work for Low Intensity Cognitive Behavioural Therapy (CBT) delivered in Improving Access to Psychological Therapies (IAPT) services**

**Information Sheet for Patients**

You are being invited to take part in a research study that aims to understand how individuals engage with ‘between-session work’ or ‘homework’ during talking therapy. Between-session work refers to the practice and application of therapeutic skills and techniques outside of treatment sessions. This study is part of a wider PhD project being undertaken by student researcher Mia Bennion.

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. You may wish to read this document in stages or discuss it with others. 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 will be conducted by Mia Bennion, PhD student from the School of Health Sciences at the University of Manchester, supported also by Professor Penny Bee, Professor Karina Lovell and Dr Amy Blakemore (also from the University of Manchester).

* **What is the purpose of the research?**

Many individuals experiencing a common mental health problem (such as depression or anxiety) who seek support from an ‘Improving Access to Psychological Therapies (IAPT)’ service are typically offered a Low Intensity (LI) intervention in the first instance. This is sometimes also referred to as ‘guided self-help’. During LI treatment, patients are encouraged to practice and apply tools and techniques learnt in treatment sessions into their everyday life where difficulties naturally occur. We consider these activities as ‘between-session work’.

Previous research has shown that when patients engage well with between-session work during therapy, symptoms are greater reduced and treatment goals are more likely to be reached. Yet patient engagement between sessions appears to vary and lack of engagement with between-session work is commonly reported.

This study aims to improve engagement with between-session work by better understanding how patients are engaging between sessions. You have been invited to take part in this study because we are interested in understanding your views on between-session work. We would like to know about your attitudes and experience with between-session work, for example, if you like or disliked it, how useful you found it and what factors helped or hindered your ability to engage with between-session work. We are interested in gathering several different perspectives on the topic, both positive and negative.

* **Am I suitable to take part?**

You have been chosen because you are 16 years or over and have recently been referred to/received LI treatment from an IAPT service for a common mental health problem (anxiety, depression).

Individuals who have accessed or have been offered group treatment provided by the IAPT service are unfortunately not eligible to take part (this is due to the possibility that factors affecting between-session engagement in a group treatment may differ to factors affecting engagement with between-session work in individual treatment).

If your first language is not English, we can provide adapted/translated study documents and offer interviews facilitated by an interpreter speaking the language of your choice. Alternatively, you might prefer to participate in the interview with a family member or friend who is able to translate what you say to English.

* **How many patients are we intending to recruit?**

We intend to interview around 25 patients across various IAPT services.

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

At the end of the research, the findings will be published in academic journal papers and will also form part of the student researcher’s thesis. Copies of the published journal paper(s) can be sent to you on request when available (please contact the student researcher for these – contact information at the end of this document). A summary of the findings can also be sent to you. 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 and you will not be able to be identified from this information.

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

The student researcher has been granted an Enhanced DBS certificate via The University of Manchester.

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

To protect your safety, rights, well-being and dignity, this project has been reviewed by the Health Research Authority (HRA) and an NHS Research Ethics Committee (REC); North West - Greater Manchester East Research Ethics Committee 22/NW/0184.

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

This project is funded by the National Institute for Health Research Applied Research Collaboration Greater Manchester (NIHR ARC-GM).

**What would my involvement be?**

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

If you do decide to take part, we would like to invite you to participate in an individual interview conducted over the format of your choice i.e., face-to-face, over the telephone or online via Zoom or Microsoft Teams. Please note, when conducting interviews over Zoom or Microsoft Teams there is no requirement that participants must have their video enabled and can therefore participate in the interview using audio only, if preferred. The interview will last up to 60 minutes, dependent on the time you have available and will be conducted at a time convenient to you. Mia Bennion will conduct all the interviews.

In the interview, the researcher will ask you about your opinions and experiences of engaging with between-session work during a LI treatment delivered in an IAPT service e.g., what do you consider as between-session work? Do you feel between-session work is important? What did you like or dislike about it? What did you find helped or got in the way of you engaging with between-session work? Please note, you do not need to answer any questions that you do not wish to, and you can leave the interview at any time.

If you decide to take part in an interview and require any support, for example having someone with you such as a family member, friend or carer, we are happy for you to invite them to join the interview. If they would like to them to speak to the researcher before the interview, please feel free to pass on the contact details. We are unable to discuss anything related to your care with them but can provide any additional information about the research study.

Prior to the interview, the researcher will ask you some brief questions to determine you are eligible to take part in the study. This should take no longer than 5 minutes. Following this, you will be asked to complete a 5-minute demographic questionnaire, which asks you some demographic information such as age, gender etc. You can return this questionnaire to the researcher electronically or by post, alternatively you can complete it with the researcher at the start of the interview.

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

As a thank you for taking part in the study, you will receive a £20 gift voucher (Love 2 Shop voucher).

If you are happy to receive this as an electronic voucher, your email address will be shared with the University of Manchester’s Finance department who will send the voucher to you. Your email address will be securely retained by the Finance department for a period of up to 7 years for audit purposes only and then destroyed. It will not be used by them for any other purpose.

* **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. If you decide not to take part you do not need to do anything further and this would not affect the care you are currently receiving.

If you do decide to take part you will be given this information sheet to keep and can either complete and return the consent-to-contact form provided alongside this information sheet (you can do this via email or post) or get in touch with the researcher directly, contacts details at the end of this document (the researcher can be contacted by email or telephone). Please also keep this information sheet available.

If you decide to take part, you will be asked to provide consent. You can provide consent by completing a consent form given to you by the researcher (this can be returned via email or post), or you can provide verbal consent which will be audio-recorded before the start of your interview. Please note that consent forms returned via email require either an electronic signature or a scanned copy of your consent form where you’ve provided a ‘wet signature’. We aren’t able to accept a signature in which you have typed your name only.

Interviews will be audio-recorded. Interviews are recorded as it is hard for the researchers to take notes on what people say, listen carefully and think, all at the same time. After the interview, the conversation will be typed up word-by-word by a University approved supplier. This is done to help us remember what people said and to make sure that all their comments are available for the study. If you take part in an interview, we would like you to be comfortable with the recording process throughout and you are free to stop recording at any time.

If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the study once has been anonymised (once data analysis begins) as we will not be able to identify your specific data. If you change your mind about taking part, you have up to one week following your interview to withdraw your data. After this time data analysis will have commenced. If you withdraw your data, we will destroy the recording and its transcription (typed word-by-word). This does not affect your data protection rights.

* **What are the possible advantages and disadvantages of taking part?**

Although we cannot promise the study will help you personally, the information you provide might help to improve how future patients engage with between-session work and may work to enhance future treatment outcomes.

If you decide to take part, we hope that you find participating in the interview interesting. However, occasionally people can feel upset if they think about something distressing that has happened to them. If you find any part of this experience distressing you may wish to discuss this with the researcher. There are also a number of organisations listed at the end of this document that you can contact too.

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, phone number and/or email address (pending on your preference mode to be contacted)
* Additional background information about you: gender, date of birth, ethnicity, details of your GP, name of the IAPT service you received/are receiving treatment from, type of Low Intensity treatment offered/received i.e., telephone or face-to-face treatment etc., main mental health difficultly which you sought support for and number of treatment sessions attended.

One of the reasons we collect this additional information is to help us understand the diversity of the study sample. We collect details of your GP only so that we are able to contact them if we become concerned about your safety or the safety of another individual known to you. We will not contact your GP for any other reason, for example to let them know you are taking part in the research.

With your consent, we will also audio record the interview using an encrypted audio recorder. This will involve the recording of your voice only. Interviews conducted using Microsoft Teams or Zoom will be recorded using the platform software. The file will be downloaded immediately and saved on the University secure server, only the audio part of the recording will be retained. The recording will then be deleted from the platform.

* **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.

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. 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) (<https://documents.manchester.ac.uk/display.aspx?DocID=37095>).

* **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. The research team are trained with this in mind, and your data will be looked after in the following way:

All the data you provide us with will be stored on a password-protected University server which only the research team have access to. The research team will store your identifying information (name and contact details etc.) securely and separately from your study data (still on a password-protected University server but in a different share/folder). Your data will be marked with an ID number and not your name. The key for linking your ID number to your identity will be accessible only to the student researcher and one other member of the research team. Once all the data has been analysed, we will destroy the key, anonymising your data.

For audit purposes, your consent form (including your name and signature) will be retained separately for 5 years after the end of the study in a locked filing cabinet on University premises (if a paper copy) or in a secure server/data management service, offered by the University of Manchester (if a digital copy). Other than your consent form, no other personal identifiable information will be kept following the end of the study and this information will be securely destroyed in accordance with the University’s guidance on the disposal of confidential material. The anonymised study data (i.e., interview transcripts) will be retained for 5 years again on a secure server/data management service, offered by the University of Manchester.

If you chose to conduct the interview over Microsoft Teams or Zoom, we will need to record it using the platform software meaning your personal data will be processed by Microsoft Teams/Zoom. 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. Only the audio part of the recording will be retained.

The recording of our conversation will be used to make a transcript. Audio recordings will be securely transferred to an approved University transcription service for transcription who have signed an agreement with the University which includes a confidentiality agreement. Once transcribed we will check your recording and remove any personal or identifiable information such as names or locations. Once we have checked that the transcript is correct, the audio recording will be deleted. Other than the University approved transcription service, study data will not be shared with any others outside of the research team.

During the interview, the researcher will be using a standard personal safety device. The device is activated if the researcher feels they are in an unsafe situation, at which point an Incident Management Centre will be connected to the device and two-way audio will be enabled. If you have any concerns about the use of these devices please speak to the student researcher, Mia Bennion. For further information regarding this please contact Susan Crofts (susan.l.crofts@manchester.ac.uk).

Everything you tell us during the interview is completely confidential. The only exception to this would be if you share something with us which reveals that your safety or the safety of others is at risk of harm. In this case, we may be required to act on this information but we would not do this without involving you in the process. If, during the interview, we have any of these concerns, we may need to report this to an appropriate level, such as your GP. If, during the study, you disclose information about misconduct/poor practice, we have a professional obligation to report this and will therefore need to inform your IAPT Service if deemed necessary. If, during the study, 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.

Please also note that individuals from The University of Manchester 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. 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: <https://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 **Penny Bee** who will do their best to answer your questions (**email:** **penny.bee@manchester.ac.uk****, telephone: 0161 306 7811** – when calling this number please outline you are wishing to speak to Penny Bee and request to be contacted).

**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 -**

TheResearch 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](https://ico.org.uk/concerns) about complaints relating to your personal identifiable information (<https://ico.org.uk/make-a-complaint/>) or Tel 0303 123 1113.

**Additional information in relation to COVID-19**

The Government have announced that as of 24th February 2022 all restrictions imposed in relation to COVID-19 in England will be removed and that it is the responsibility of all individuals to take appropriate precautions and preventative measures to reduce the spread of the virus in the community.

* **What additional steps will you take to keep me safe while I take part?**

The research team will continue to be proactive about protecting any potential research participants as well as themselves. With this in mind we have made some adjustments to the way in which this research study will be conducted and as mentioned earlier, are offering the choice of a remote interview, conducted over telephone or online using Microsoft Teams/Zoom. Please chose the interview format that you are most comfortable with. In the first instance, we are also using electronic means to provide you with your gift voucher as a thank you for taking part.

If you would like to know about the latest government advice on COVID-19, you can visit the following website[: Information about coronavirus](https://www.gov.uk/coronavirus) (https://www.gov.uk/coronavirus).

You should carefully consider all of the information provided below before deciding if you still want to take part in this research study. If you have any additional queries about any of the information provided, please speak with the student researcher.

* **Are there any additional considerations that I need to know about before deciding whether I should take part?**

Additional risks to consider if you decide to conduct a face-to-face interview may include possible infection through travelling to and from the venue and coming into contact with the researcher. You may wish to consider limiting the amount of travel involved if possible (including public transport).

You should not take part if in a vulnerable group or if you have symptoms. The main symptoms of coronavirus (COVID-19) are:

* a high temperature – this means you feel hot to touch on your chest or back (you do not need to measure your temperature)
* a new, continuous cough – this means coughing a lot for more than an hour, or 3 or more coughing episodes in 24 hours (if you usually have a cough, it may be worse than usual)
* a loss or change to your sense of smell or taste – this means you've noticed you cannot smell or taste anything, or things smell or taste different to normal
* **What if the Government Guidance changes?**

We will adhere to any changes in Government guidance, this may include making adaptions to the study or postponing contact.

* **What if I have additional queries?**

Please do not hesitate to contact the student researcher to further discuss any of these points:

**Mia Bennion**

**Email: mia.bennion@postgrad.manchester.ac.uk**

**Phone: XXXX**

**Mia Bennion**

**The University of Manchester**

**Division of Nursing, Midwifery and Social Work**

**Jean McFarlane Building (6th Floor)**

**Oxford Road**

**Manchester M13 9PL**

(If you would like to send something to the research team via post, please contact the student researcher and she can discuss with you how this can be done free of charge).

**Support service contact details**

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 student researcher**:**

**Mia Bennion**

**Email: mia.bennion@postgrad.manchester.ac.uk**

**Phone: 07933 611 477**

**Post: Mia Bennion**

**The University of Manchester**

**Division of Nursing, Midwifery and Social Work**

**Jean McFarlane Building (6th Floor)**

**Oxford Road**

**Manchester M13 9PL**

(If you would like to send something to the research team via post, please contact the student researcher to discuss how this can be done free of charge).

**THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION SHEET**