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INFORMATION SHEET FOR PARTICIPANTS

Title of Project: **A Research Study Comparing the Effects of Mindfulness-Based Cognitive Therapy and Treatment as Usual in Patients who are Continuing to Suffer from Depression after IAPT High-Intensity Therapy**

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

We would like to invite you to participate in this research. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Before you give your consent to take part (if you decide to do so), one of our team will go through this information sheet with you and answer any questions you might have.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen if you take part.

Then we give you more detailed information about the conduct of the study.

Please do ask if anything is unclear.

What is the purpose of the study?
Since their introduction in 2009, Increasing Access to Psychological Therapies (IAPT) services have been providing psychological therapies to people who suffer from emotional disorders in the UK. These services now reach a large number of patients, who previously would not have had access to psychological therapies. However, it has become obvious that there is still a considerable number of patients who continue to suffer from symptoms after they have finished intensive therapies in IAPT services. The current research will test whether there are benefits to offering a further psychological treatment to those who have come to the end of their IAPT therapies and still suffer from significant symptoms of depression.

The purpose of this study is to compare a treatment referred to as Mindfulness-Based Cognitive Therapy (MBCT) to what patients receive as their usual care if they still suffer from symptoms of depression after they have finished their IAPT therapies. Mindfulness-Based Cognitive Therapy is a psychological treatment that combines intensive training in mindfulness meditation and elements from cognitive behavioural therapy, a form of therapy that is aimed at helping people change negative thinking patterns. We are interested in finding out how the effects of this treatment compare to the effects of the treatment that patients at this stage would usually receive, both in the short term (over a period of two months) and in the longer term (over a period of eight months).

Why have I been invited?
You have been invited to take part in this study because you are someone who has recently received psychological treatment of high intensity for depression within an IAPT service, but are still suffering from symptoms of depression. We hope that 234 people will eventually take part in this study.

Do I have to take part?
No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect whether you receive other forms of treatment within the NHS, and the standard of care you receive.

Will I be suitable for the study?
If you are interested in taking part in this research, we will contact you for a brief conversation via videoconference or telephone in which we will ask some questions to determine whether you might qualify for this research. If it seems that you might be eligible, we will invite you to take part in an initial assessment session that will be conducted via videoconferencing or telephone. Before the start of the assessment, you will be given the opportunity to ask any questions you might have about the study. Once all questions have been answered satisfactorily, we will ask you to give your informed consent to take part in the study by electronically signing and returning a consent form. A copy of the form, signed by the researcher, will be send back to you for your records. Once you have given your written consent, the researcher will carry out an assessment asking questions about current and past symptoms of depression and other disorders and the treatments you have received in the past. After this, the researcher will send you a link to a secure webpage and ask you to follow this link to complete a questionnaire about current symptoms of depression online. All of these assessments serve to determine whether you qualify for the study.

What will happen to me if I take part? What will I have to do?
If the study is appropriate for you, the researcher will then describe in more detail what would happen, if you were randomly allocated to receive MBCT or if you were randomly allocated to continue with your treatment as usual. You will be given the opportunity to ask any further questions you might have about the two arms of the study. If you wish to go ahead with participating in the study, the researcher will send you another link to a number of further questionnaires, which you would also be asked to complete. These questionnaires will ask about a broader range of current symptoms and will also include questions about your current psychological functioning and wellbeing. Following this, you will be provided with practical information about the next steps of the study. The initial assessment session will last about 1 ½ hours in total.

Two weeks before the start of the treatment period, you will receive notification via email whether you have been randomly allocated to participate in MBCT or continue with treatment as usual. This email will include an invitation for an information interview that will also be conducted via videoconference or telephone. For participants who have been randomly allocated to MBCT, this information interview will serve to prepare them for participation in the MBCT course. For participants who have been randomly allocated to continue with treatment as usual, this interview will serve to prepare them for their continuing role in the research.

Treatment period
For those in the mindfulness group, the course would start about a week after the information interview. In the MBCT course, participants will learn the practice of mindfulness meditation in eight weekly classes and by practicing with audio recordings at home during the week. Mindfulness meditation aims to train awareness of present experience in order for participants to be better in touch with moment-to-moment changes in the mind and body. The treatment also includes interventions that are aimed at increasing positive activities, basic education about depression and the mechanisms that maintain depression, several exercises from cognitive therapy that show the links between thinking and feeling, and exercises that help to find ways to best look after yourself when your moods threaten to overwhelm you. The classes will be given in a group of about 13 people, by an experienced mental health practitioner, and will be offered via videoconferencing. Because the MBCT course is offered via videoconferencing, it may include participants from the different regions in which the trial is

conducted and the therapist may be based at a site different from local site, which conducts all the study assessments with a given participant. Participants will be asked to fill in brief questionnaires to report current symptoms each week during the treatment.

Follow-up assessments
After the end of the treatment period, you will receive an email inviting you to take part in the first of two follow-up assessments. At these assessments, we will ask you to fill in the same questionnaires that you completed before the beginning of the treatment period. This will enable us to see whether anything has changed as a result of the treatment you have received and is vital for the research. We will conduct the assessments online so that you will not have to travel. The email will include a link to a secure webpage that will guide you through the questionnaires. The whole sessions will last about 45 minutes in total. The research team will be available via email, videoconferencing or telephone should you have any questions while you are completing the questionnaires or at any time before or afterwards.

The second follow-up assessment will be conducted about 6 months after the first follow-up assessment. It will follow the same procedure as the first follow-up assessment. The whole session will last about 60 minutes. Just as during the first follow-up assessment, the research team will be available via email, videoconferencing or telephone should you have any questions while you are completing the questionnaires or at any time before or afterwards.

Interviews to ask about the experience of being part of the research
After the second follow-up assessment, we will contact a small number of participants in the mindfulness group (MBCT) via email and ask them whether they would be willing to share their experience of having taken part in the treatment in a brief telephone interview. For all other participants, the participation in the research study would end after the second follow-up assessment. If you are asked, and are willing, to participate in the additional interview, a research assistant would call via telephone at a time that is convenient for you and conduct the interview with you, which will last for about 30 minutes. The interview will be audio recorded and what has been said during the interview will be transferred into a written transcript by an academic transcription service. The recordings will be treated as confidential throughout this process. Both the recording and the written transcript will be stored on a secure server and access will be restricted to the research team. We will use the information from the interview to get a better sense of what people found helpful and what could be improved in the provision of the treatment.

If I agree to take part, what am I agreeing to do? – A summary
If you agree to take part in the study, you would be required to attend an assessment session before the treatment period and fill in questionnaires online at two occasions, directly after the treatment period and 6 months after that. You would be randomly allocated to either take part in MBCT or continue with your treatment as usual. In either condition you would have an initial interview and would then be asked to fill in brief weekly questionnaires about symptoms over eight weeks. If you are randomly allocated to MBCT, you would attend eight weekly classes, and would be asked to complete activities at home between the classes (e.g. meditation exercises) for about an hour per day. All of the sessions will be held via videoconference so that you would not have to travel. The treatment itself and the research assessments involve a considerable commitment, so it is important that you think carefully about whether or not you are willing to make this commitment.

It is also important to remember that although you are agreeing to take part in the study –

- You can decide to stop at any point and withdraw your participation
- In addition to withdrawing yourself from the study, you may also withdraw any data/information you have already provided up until it is transcribed for use in the final report.
- A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.
- You need not answer questions that you do not wish to.
- Anything you tell us will be absolutely confidential. Your name will be removed from the information and it will not be possible to identify anyone from our reports on the study.

What are the possible disadvantages and risks of taking part?
MBCT has been proven to be effective and safe for relapse prevention, however to date there is only preliminary evidence for its effectiveness in people who are currently suffering from symptoms and have not recovered fully with previous psychological treatments. We do not anticipate that this research study will place you at any more risk than you would face if you attended other treatment programmes. Naturally some of the material that is discussed during therapy sessions will be emotional in content and you may experience a range of feelings as you go through the therapy programme. However, this reflects the experience of most psychological therapy programmes in the health service.

We would ask all participants not to engage in individual psychotherapy or counselling from other sources than the NHS at a frequency of more than once a month during their time in the study. This is to make sure that the study provides an accurate reflection of the care that is available within the NHS.

Some of the questionnaires you will complete as part of the research study ask about personal and sensitive areas (such as your current and past mood, and your typical patterns of thinking and acting). In our experience people have different experiences of completing these sorts of questionnaires, including finding them distressing, interesting, frustrating or helpful. You are free to decide not to answer any question at any time, and you may also contact the researchers if there are parts of the questionnaires, or your reaction to them, that you would like to discuss.

Before participating in this research, you should consider whether it affects any insurance that you have and take advice if necessary.

What are the possible benefits of taking part?
Those who are randomly allocated to MBCT will have the opportunity to receive this treatment. MBCT has previously been shown to be helpful for the prevention of relapse in patients who suffer from recurrent depression. However, previous studies have not delivered the treatment via videoconferencing and it is unclear whether this form of delivery will produce similar effects. We hope that, by carrying out this research, we can get a better understanding of how to help patients who are still suffering from symptoms after having received psychological therapy within IAPT and potentially help to improve care. Your participation in the research would greatly contribute to this endeavour. All participants will be sent a copy of the final report.

Expenses and Payments
You will receive £20 for the participation in the initial assessment session and £10 for the participation in each of the two follow-up assessments to compensate for your time and effort.

What are the alternatives for treatment?
If you do not take part in this study, we would advise you to talk to your GP about options for receiving psychological therapy through the health service locally.

What happens when the research study stops?
When you finish the last assessment, one of the researchers will talk with you about future options for support, via videoconferencing or telephone, and we will let your family doctor/general practitioner (GP) know that the study has finished. We would advise that you talk with your family doctor/general practitioner (GP), if at this point you would like to pursue further psychological therapy.

What if relevant new information becomes available?
Sometimes we get new information about the treatment being studied. If this happens, one of the therapists will tell you and discuss whether you should continue in the study. If you decide not to carry on, we will discuss alternative options with yourself and your family doctor/general practitioner (GP). If the study is stopped for any other reason, we will tell you and help arrange your continuing care.

What will happen if I don't want to carry on with the study?
You are free to leave the study at any point without it affecting the general standard of care you receive in the health service, or your access to other treatments. If you do decide that you no longer wish to take part, we will use the information you have provided up until that point in evaluating the study, unless you tell us otherwise. You may opt to decline the research assessments, but remain in the MBCT treatment, however some of the assessments (the weekly questionnaires) are an important part of the treatment and we would encourage you to continue to complete these. If you remain in the MBCT treatment we will continue to use the information you provide in these measures in our research evaluation of the therapy, unless you tell us otherwise.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. You can reach the Chief Investigator, Thorsten Barnhofer, via email, t.barnhofer@surrey.ac.uk, or telephone, 01483 686485. If you remain unhappy and wish to complain formally, you can contact the Patient Advice and Liaison Service at Sussex Partnership NHS Foundation Trust, Swandean, Arundel Road,Worthing, West Sussex BN13 3EP, via email pals@sussexpartnership.nhs.uk, or telephone, 0300 3042198.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the Sussex Partnership NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

If you are feeling distressed and need immediate support, telephone helplines by mental health charities such as Mind (0300 1233393) and Samaritans (116 123) can offer help.

Will my taking part in this study be kept confidential?
Any information that is collected about you during your time in the study will be kept strictly confidential within the research team and the services involved. Both within the research team and the services confidentiality will be broken only in exceptional circumstances, for example if it is felt by the researcher or therapist that you or someone else may be at immediate risk. In such circumstances it may be necessary for us to inform another person or several other persons, for example your GP, but as far as possible we will do this in discussion with you.

How will we use information about you?

We will need to use information from you for this research. This information will include your NHS number, name and contact details as well as the information you provide in interviews or by filing in questionnaires for this research. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. We will remove all personal information that could directly identify you from the data file and your data will have a code number instead. Data that will not have personal information included will be shared between the research institutions involved in this research including the University of Exeter, King's College London, the University of Surrey and Sussex Partnership Foundation Trust. Transcripts of recordings will be anonymized by removing all information that could make you identifiable. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results.

If you are randomly allocated to take part in MBCT, all clinical information you provide whilst you attend the service providing MBCT, including recordings of sessions, will be stored securely by the service according to their standard procedures. Information held on computer will be stored on the secure network hosted by the University of Exeter, Clinical Trials Unit. With the exception of consent forms and video recordings, personal information that could identify you will be destroyed as soon as the study is closed, unless you give permission to be contacted for other ethically approved research, in which case we will keep your contact information for 5 years on a secure server. Agreeing to be contacted does not mean that you are obliged to take part in any further research. All original copies of research information will be retained for 10 years and then destroyed securely. An anonymised database of information collected in the research may be accessed by other researchers. Access to this database will be controlled by the Chief Investigator and it will not be possible to identify you from the data it contains.

We will write our reports in a way that no-one can work out that you took part in the study. Our reports may include quotations from interviews (such as comments about the experience of being in the treatment), but these will not identify individuals. The report of the research will be available to members of the public including the other participants in the study (to whom we will also send a summary of the research findings if requested).

What are your choices about how your information is used?
We will be using information from you in order to undertake this study. Research is a task that we perform in the public interest. Sussex Partnership NHS Foundation Trust, as sponsor, is the data controller. The research team is responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. We will store the anonymised research data and any research documents with personal information, such as consent forms and video recordings, securely at the Sussex Partnership NHS Foundation Trust for 10 years after the end of the study. All personal identifiable data other than the consent forms and video recordings will be destroyed as soon as the study has closed, unless you have consented to be contacted for future research, in which case we will keep your contact details for 5 years.

The local study team will use your name, NHS number, home address and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. They will keep identifiable information about you from this study for 10 years after the study has been finished. You can find out more about how we use your information by contacting the research team [study team email].

Your rights to access, change or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. However, you will be able to opt out of the use of your confidential information for research and

remove your data from the study at any time. We may share anonymised data for future research, here or abroad, which has ethical approval.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available at www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to [trialmanager@exeter.ac.uk]
- by ringing us on [phone number of the trial manager]

Will my family doctor/general practitioner (GP) be informed?
If you take part in this study, we would inform your family doctor/general practitioner (GP)you're your IAPT service that you are taking part in the study and which treatment condition you are in. It is standard practice to involve GPs and referring clinicians in this way, so that they are aware of what care you are receiving and can take this into account in their work with you. We would liaise with your GP and the IAPT service in the same way that services usually do whilst you receive treatment with them (for example, informing them that you had finished treatment). However, information that you share with us as part of the research assessments will be shared with them only in exceptional circumstances, such as a report that you or somebody else is at significant risk.

What will happen to the results of the study?
The researchers will publish the results of the work in academic journals and will also report the findings at academic conferences. We will give all participants who request one a summary of the results of the research and will give this summary to the organisations who assisted with advertising our study. Your identity will not be revealed in any report or publication.

Who is organising and funding the research?
The research sponsor is the Sussex Partnership NHS Foundation Trust. The research is funded by the National Institute for Health Research (NIHR) through the Research for Patient Benefit Programme (NIHR200750). The researchers will not obtain any payment for conducting this research above their usual salaries.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Research Ethics Committee 4, West of Scotland.

What do I do now?
We will discuss the project with you to make sure you understand the aims of the project and what is involved. If you wish to take part, you will be given an electronic version of this information sheet to keep and we will ask you to sign a consent form with your electronic signature. It is up to you to decide whether to take part or not. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

Contact for further information
If you would like any independent advice about participating in research you can contact PALS (the local Patient Advice and Liaison Service), or INVOLVE at www.invo.org.uk .

If you have any further questions please feel free to talk to Thorsten Barnhofer, the study's Chief Investigator.

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