

## Ysgol Seicoleg

Adeilad Stryd y Deon  
Prifysgol Bangor  
Bangor Gwynedd LL57 1UT  
Ffon 01248-382930  
Ffacs 01248-383982  
E-bost [staying-well@bangor.ac.uk](mailto:staying-well@bangor.ac.uk)



## School of Psychology

Dean St Building  
Bangor University  
Bangor Gwynedd LL57 1UT  
Phone 01248-382930  
Fax 01248-383982  
Email [staying-well@bangor.ac.uk](mailto:staying-well@bangor.ac.uk)

## Staying well after depression: a randomised trial

### INFORMATION FOR PARTICIPANTS

#### **Invitation**

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it 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. *Part 1 of this information sheet tells you about the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.* Take time to decide whether or not you wish to take part. Thank you for reading this.

#### **What is the purpose of the study?**

Each year in the United Kingdom a large number of people get depressed. We are very keen to find out more about the reasons for this and how we can prevent it happening again. We are particularly interested in the ability of two treatments to *help people stay well in the future* (by reducing future episodes of depression), when they have been depressed in the past. The treatments, a Cognitive Psycho-Education programme (CPE) and Mindfulness Based Cognitive Therapy (MBCT), are described below. What we learn from this study will be used to improve the care of patients in the future.

#### **Why have I been chosen?**

We are asking people to take part who have been depressed **several times in the past**, but who are now feeling better, in order to compare the ability of different treatments to help people stay well in the future. We are contacting people directly through posters and adverts. We are also asking doctors, psychologists and other people caring for those with depression to mention this study to any patients they think might be interested in finding out more. We hope that about 350-400 people will take part in this study.

#### **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time without giving a reason. Withdrawal will not affect any care you are receiving outside of this research in any way.

#### **The Design of the Study**

We are interested in whether CPE and MBCT can help people stay well and prevent future depression. To see whether the treatments are helpful we need to compare people in the two

treatment groups with a group of people who are not receiving treatment at the moment. We will also compare the two treatment groups to see if one treatment is more effective than the other.

Everyone joining the study will be chosen at random by a computer program to receive either CPE or MBCT, or to wait for treatment. We will use a ratio of 2:2:1: this means that for every five people who enter the study two will join the CPE group, two will join the MBCT group and one will be asked to wait for treatment. All three groups will be followed up in the same way (see below). The *wait for treatment* group will be offered CPE or MBCT at the end of the study (after about 15 months). Everyone in the study will continue to receive other treatments and seek extra help (e.g. from their GPs) in the usual way.

### **What is Cognitive Psycho-Education (CPE)?**

CPE is a new treatment. It is a group-based adaptation of cognitive therapy. Cognitive therapy is a psychological treatment focusing on the negative thinking that is central to depression and despair. Previous research has shown that cognitive therapy reduces the risk of depression recurring. People randomised to CPE will take part in eight weekly classes. These classes will be given by an experienced teacher to small groups of about 12 people. There they will learn ways of handling difficult thoughts and feelings differently. Homework activities and exercises will encourage them to try out new ways of responding to their thoughts and feelings. CPE also includes basic education about depression, with exercises that show the links between thinking and feeling, and that help to establish how best to look after yourself when your moods threaten to overwhelm you. In addition to the 8 weekly classes, you will be invited to two follow-up 'reunion' sessions, 6-8 weeks and approximately 6 months after the end of treatment. These will allow you to refresh the skills you have learnt and reflect on how things have been going since the last class.

### **What is Mindfulness Based Cognitive Therapy (MBCT)?**

MBCT is a new treatment. It combines mindfulness meditation with cognitive therapy techniques. Previous research has shown that MBCT can reduce the risk of recurrence of depression in people who have suffered several episodes of depression in the past. People randomised to MBCT will take part in eight weekly classes given by an experienced teacher to small groups of about 12 people. There they will learn the practice of mindfulness meditation. MBCT includes breathing exercises and homework activities to help you become more aware of the present moment, including getting in touch with moment-to-moment changes in the mind and the body. It also includes basic education about depression, and several exercises from cognitive therapy that show the links between thinking and feeling and how best to look after yourself when your moods threaten to overwhelm you. In addition to the 8 weekly classes, you will be invited to two follow-up 'reunion' sessions, 6-8 weeks and approximately 6 months after the end of treatment. These will allow you to refresh the skills you have learnt and reflect on how things have been going since the last class.

*Please be aware that both treatments involve homework assignments. In particular meditation homework practices in MBCT can take up to an hour per day. It can be difficult to make time for this, so you must think carefully about whether you are able to make this commitment, before agreeing to take part.*

### **What will happen to me if I take part?**

**Initial Assessment:** If you decide to take part in the study we will arrange a **first interview** within the next few days at a time convenient for you. This interview will last about 2.5 hours. We will

ask you a standard set of questions about your mood and any suicidal thoughts you may have experienced (**as this is a common symptom of depression**). We will ask for background information about your past experiences, including traumatic events in the past and during childhood, any drugs or medicines you may be taking at the moment and so on. You will also be asked to complete some standard questionnaires. If after this session you are still interested in the research and the psychologist thinks the treatment is likely to be suitable for you, you will be invited to a second research assessment which will take about 1 hour. This will be arranged at a time convenient for you, and will include more questionnaires and short paper and pencil activities.

***Allocation to CPE, MBCT or to wait for treatment:*** After these two sessions you will be randomly allocated to one of the three groups. If you are in the CPE or MBCT group you will meet the teacher running your class to discuss the classes in more detail. If you are in the *wait for treatment* group you will be invited to talk about the waiting period with a researcher from the team.

***During the initial treatment period:*** Everyone will be asked to complete questionnaires regularly over the eight week period of treatment. CPE and MBCT groups will do this at the treatment classes. The *wait for treatment* group will fill in the same questionnaires at home and post them back to us using a freepost address.

***After the initial treatment period:*** You will be asked to come back for a further research assessment of about two hours. This will be very like the assessments at the beginning of the study. This will tell us whether anything has changed. Changes may be due to CPE or MBCT, or (in the *wait for treatment* group) normal changes over time.

***Follow-up:*** There will be four more follow-up assessments every three months for the next 12 months. Each research assessment will take about 1-2 hours. People allocated to MBCT or CPE will be invited to two follow-up 'reunion' sessions, 6-8 weeks and approximately 6 months after the end of treatment. After the final assessment people in the *wait for treatment* group will be able to choose to take part in a class of CPE or MBCT. These will be exactly the same as the original CPE and MBCT classes.

***Expenses and payments:*** Modest expenses are available. For each research assessment attended £5 will be given plus travel expenses. For the treatment sessions, travel expenses will be paid.

***If I agree to take part, what am I agreeing to do? – A summary***

If you agree to take part in the study you must attend two initial assessments before allocation to CPE, MBCT or the *wait for treatment* group, and a total of five further assessments over the next 15 months. Research assessments will be audio-taped to check they are being carried out consistently and a sample will be checked for accuracy of assessments by an independent psychiatrist. You must also complete a short weekly questionnaire during the initial 8 week study treatment period.

If you are allocated to immediate CPE or MBCT treatment you will be asked to attend an initial meeting with a teacher, followed by eight weekly sessions, each of about two hours, and to complete activities between the classes at home. You will also be asked to attend two reunion sessions, 6-8 weeks and 6 months following the end of the initial treatment period. The class

teacher will be videotaped each week to check that the treatments are being delivered effectively to everyone. If you are in the *wait for treatment* group you will be asked to speak to a researcher about your role in the study. It is important that you think carefully about whether or not you are willing to make the considerable commitment of time needed for both treatment and research assessments.

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

- You can decide to stop any interview at any point.
- 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.
- Audiotapes of research assessments and videotapes of treatment sessions taken during this study will be stored securely (with *no* identifying information to ensure confidentiality). They will be erased at the end of the study.

**A flow-diagram showing the study outline is attached at the back of this information sheet to help make this information clearer.**

## PART 2

This section describes in more detail how the research will be conducted.

### Contacting your GP

If you are interested in taking part in this research and the initial interview with the research psychologist indicates that the treatment is likely to be suitable for you we will need to tell your GP that you are taking part. This means that your GP will know you are involved in this project and can help you to take it into account when planning other treatments. We may ask your GP for some information from your medical notes at the beginning and end of the study, and to keep us updated about your progress over the duration of the trial. This information will be used to reduce the number of questions we have to ask you, and to monitor the safety and wellbeing of the people involved in the study.

### What are the possible risks and benefits of taking part?

*Possible Risks:* You will be asked some quite detailed questions about your mood and your past experiences. Occasionally these questions can be a bit upsetting so it is important to remember that you will not have to answer any questions you do not want to. As well as this, part of the process of CPE and MBCT involves facing past difficulties which can sometimes bring up negative feelings. These difficulties are often part of the therapeutic process and the trained therapists will be available to offer advice on overcoming these difficulties during the treatment period.

*Possible Benefits:* Everyone taking part in the research will at some point have the opportunity to receive a new treatment designed to reduce symptoms of depression, and reduce the risk of depression coming back. We hope that, by carrying out this research, we can get a better understanding of how to prevent recurrence of depression.

### What will happen if I withdraw from the study?

You are free to withdraw from the study at any time, simply by telling a researcher your wishes. You do not have to give a reason. If you withdraw completely from the study, we still need to use

the data collected before your withdrawal. If you withdraw from the research assessments before treatment begins, we cannot offer you treatment, as your place will have to be made available for another person who can complete the research assessments. However, if you begin treatment but then decide that the treatment is not right for you and stop attending classes we would still like you to complete the remaining research assessments. This is important so that we can get a balanced comparison of the treatments, and find out which groups of people they help. Even if you feel unable to do further assessments, we would be very pleased to keep in contact with you anyway to let us know your progress. However you do not have to do so if you do not want to.

### **What if something goes wrong?**

The University of Oxford is acting as the sponsor of this trial. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you can either contact the Trial Team Leader directly (Rebecca Crane, Bangor University, School of Psychology. Email [r.crane@bangor.ac.uk](mailto:r.crane@bangor.ac.uk)), or contact the University of Oxford Clinical Trials and Research Governance office on 01865 743005. As well as this the normal NHS complaints mechanism is available and the University procedure for reporting misconduct will also be open to you. Allegations of misconduct can be reported to: Professor Oliver Turnbull, Head of School, Psychology, Bangor University Bangor, Gwynedd, LL57 2DG.

If you are harmed due to someone's negligence then you may have grounds for legal action for compensation against University of Oxford (in respect of any harm arising out of the participation in the clinical trial) or the NHS (in respect of any harm which has resulted from the clinical procedure being undertaken).

### **Will my taking part in this study be kept confidential?**

All information collected about you during the course of the research will be kept strictly confidential within the limits of the law. If you join the study, some parts of your medical records and the data collected for the study may be looked at by authorised persons from the University of Oxford and NHS Trust to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site. Any information about you will be assigned a number, and will not have your name on it, so you could not be recognised from it. Data will be stored for 10 years and will be destroyed after this time.

Confidentiality would be only be breached if it was judged that someone was at immediate risk of serious harm (for example if someone was seriously planning to end their life). In these rare circumstances we would disclose to a third party (normally the participant's GP) only information essential to ensure the safety of the person at risk and would always discuss all alternative options with the person in question first.

### **What will happen to the results of the research?**

Any research publications will not identify you individually. If you would like a copy of the published results, let one of the researchers know, and we will be delighted to send them to you when they became available.

### **Who is organising and funding the research?**

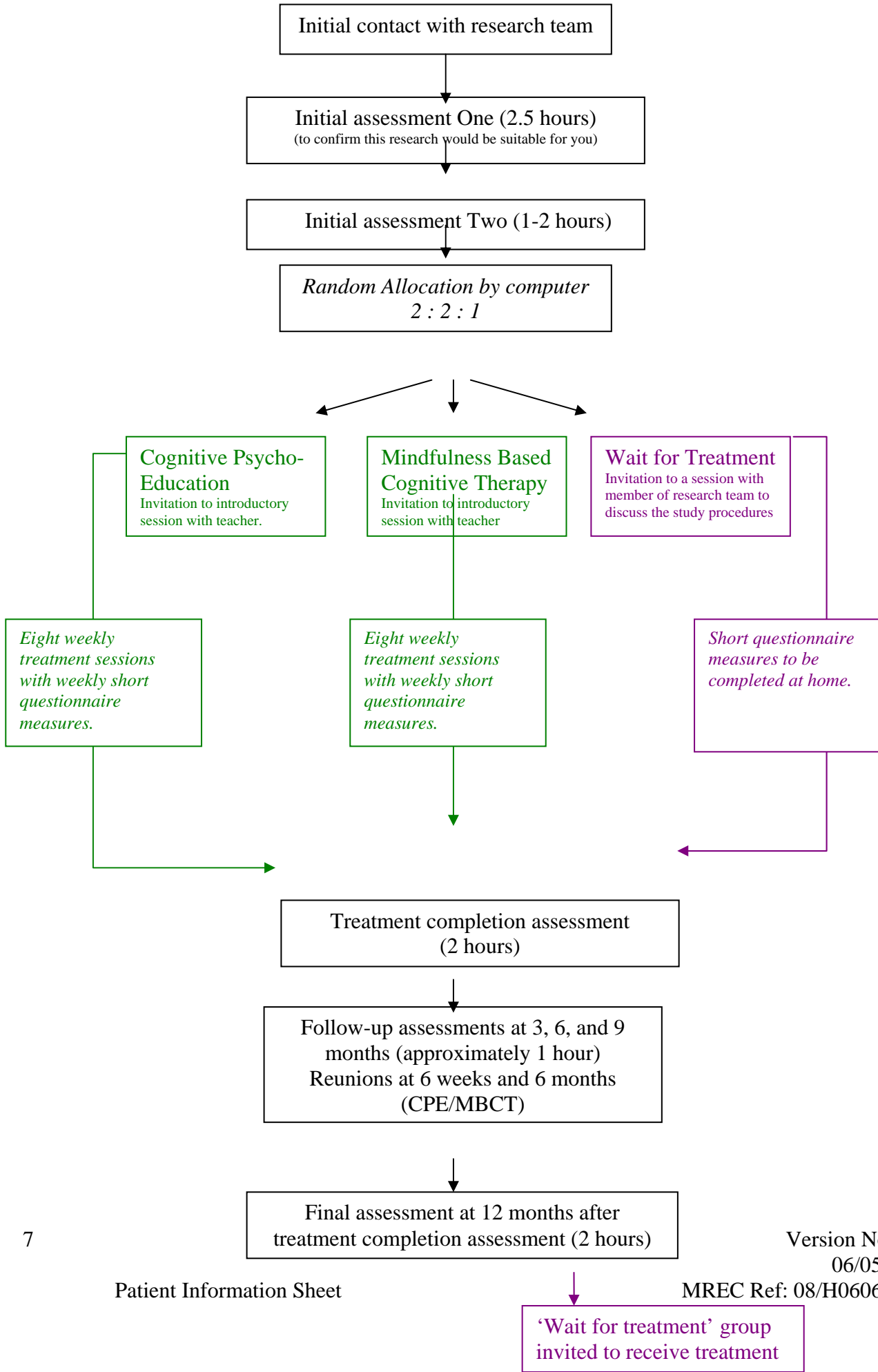
This is one of a series of studies that has been funded by The Wellcome Trust (a medical charity).

**Who has reviewed the study?**

This study has received ethical approval from the National Research Ethics Service, Oxfordshire REC C Ref: 08/H0606/56 and site specific ethical approval from North West Wales NHS Trust R&D department.

**Contact for Further Information**

If you have any further questions about this research, please feel free to speak to one of our team on 01248 382930, or e-mail [staying-well@bangor.ac.uk](mailto:staying-well@bangor.ac.uk)



'Wait for treatment' group invited to receive treatment

**THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION SHEET AND  
CONSIDERING WHETHER TO TAKE PART IN THIS RESEARCH.**

*YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET AND A SIGNED CONSENT FORM TO KEEP IF YOU DO TAKE PART.  
FEEL FREE TO SHOW IT TO ANY DOCTOR INVOLVED IN YOUR CARE.*