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PATIENT INFORMATION SHEET

Ethics committee reference number: 07-Q1406-41

Study Title: 'Therapeutic mechanisms of mindfulness-based pain management'.

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. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

The long-term aim this research is to understand how patients with chronic pain can best learn to use their own mental resources to cope with pain and become more independent of the need for medical consultations and analgesic drugs. This study in particular aims to investigate a therapeutic 10-week pain self-management programme for patients with chronic pain. Specifically, we wish to find out what mental processes change as a result of the programme, and whether these changes help us to understand how such therapies work. Another aim is to work out how we can best measure these mental processes, so that we can do more detailed clinical investigations in the future.

What will taking part in this study involve?

This study will take place over a 7-8 month period. The primary focus of the study will be your participation in a 9-week long Mindfulness-Based Pain Management Programme. This programme is operated under the name Breathworks, and involves attending weekly classes at the Manchester Buddhist Centre in central Manchester. The programme is aimed at anyone wanting to learn new strategies for managing chronic physical pain and/or ill health. More detailed information about this programme is included as an appendix at the end of this information sheet. There is also a website that includes all this information and more at <http://www.breathworks-mindfulness.co.uk/painmanagementcourses.asp>. It is an essential pre-requisite of your recruitment into this study that you are willing and committed to engage fully with the programme, which will involve practice at home between sessions (30-45 minutes a day).

Please note that after we have received all your details and recruited you into the study, there may be a significant delay of up to a few months before you will be able to participate in the pain self-management programme. This is due to the time it will take to recruit all the other patients needed for the study.

Once you are recruited into the study, we will assign you to one of two groups. Both groups will be asked to attend one of our research laboratories on either two occasions (if you are assigned to Group 1) or three occasions (if you are assigned to Group 2). Our research laboratories are based at Hope Hospital, Salford and also at the University of Manchester campus on Oxford Road, Manchester. On each visit, we will take you through an identical set of experimental tasks (these are detailed below). In total you will need to set aside between 4 and 5 hours on the day that you attend in order to complete these tasks. Group 1 will attend their first experimental session just before starting the pain self-management programme, and their second session just after completing the programme. Group 2 will do the same as Group 1, but will additionally attend an extra experimental session roughly 10-12 weeks *before* the other two sessions. The consequence of this is that patients who are assigned to Group 2 will need to wait longer before starting the pain self-management programme (up to 10 weeks longer).

The experimental tasks that we will ask you to complete each time you visit our laboratory are as follows. It is important that in the preceding few days before visiting our laboratory you are on the same level of medication (for pain symptoms) during each experimental session.

Sustained attention tasks. The purpose of these tasks is to measure your ability to pay attention to sensations under different conditions. These sensations will either be based on vision or touch. The visual version of the task will be displayed on a computer monitor. The touch version of the task involves you feeling mild electrical pulses on your finger. To do this, we will place two electrodes on one finger and apply very brief electrical pulses (less than a second) across the electrodes. This will feel like a brief tapping sensation. For each task, we will ask you to respond to some sensations you see or feel by pressing a button on a response pad, and not to respond to other sensations. Because you will be receiving the sensations very frequently (roughly once every second) you will need to pay careful attention to the task. If/when you make errors on the task, we can use that as a measure of your ability to pay close attention to the task.

For the touch task, sometimes an occasional 'tap' will be a higher intensity sensation that feels painful (this will occur once every 5 seconds on average, for a maximum of 2 minutes at a time). We will ask you to try and ignore these higher intensity pulses, and will measure the extent to which you find them distracting. We will not ask you to put up with an intensity of pain that you cannot easily tolerate, and the intensity of each painful pulse will be tailored to each person to ensure this. In order to find the intensity that will suit you best, we will first spend some time working out the maximum intensity of pain that you're willing to put up with. You are therefore in total control of how much pain you experience, and you can stop participating in the study at any time during this procedure without any consequences and without having to give a reason.

Emotion tasks. We will ask you to complete some basic questionnaires that probe your usual and current emotional state. There will also be a computer task to perform in which you will be responding to words that flash up on a computer monitor; some of these words will have emotional content and we will be recording your responses to them. This will give us a measure of the extent to which you associate certain emotions with yourself.

Brain response tasks. For the following task, we will be recording the electrical activity of your brain by a procedure known as electroencephalography (EEG). It will involve wearing a stretchy elastic cap containing a number of electrodes that make contact with your scalp. This is a totally safe, non-invasive procedure. In order to make good contact with your scalp, each electrode will be filled with a type of gel and we will use a cotton-wool bud to massage the gel onto your scalp. This procedure can sometimes be a bit uncomfortable, and takes around 20 minutes to complete. The gel will be in your hair throughout the task, but we have the facilities for you to wash and dry your hair before you leave. To help obtain good recordings we ask you to have clean hair that day and not to use hair conditioning or styling products such as wax, gel or spray.

For the task, we will deliver painful heat sensations on your arm using a laser stimulator, which delivers very brief (less than a second) pulses of heat to your skin. The intensity of the painful pulses will be tailored to each person, as described above for the electrical pulses. You will be asked to pay attention to the pain experience in two different ways during different tasks. The first way is to try and locate the pain sensation on your arm. We will vary the location of the sensation between the left and right side of your arm at random, without you being able to see which side we've moved it to. We will ask you to indicate whether you thought the pain sensation was on the "left" or "right" side of your arm. The second way is to think about how unpleasant the pain is. This will involve intentionally thinking about the pain in emotional terms. We will ask you to rate how unpleasant the pain was on a 0-10 scale.

During many of these tasks we will be asking you to fill out various questionnaires. These will be measuring your clinical pain, your emotions, the expectations and beliefs you have about the experimental pain, and your ability to pay attention to the tasks.

What compensation will I be given for participating in this study?

We will pay the cost for you to attend the Breathworks programme, unless you have already paid for the programme independently of this research study. We will also reimburse all participants for any travel expenses incurred in getting to and from our research laboratory, but not for travel to the Breathworks sessions.

Are there any reasons why I can't take part in this study?

We are specifically recruiting patients with chronic musculoskeletal pain (e.g. patients with arthritis, fibromyalgia, low back pain, etc.; please contact us if you're unsure of your eligibility). Patients must be right handed, and over the age of 18. You will not be able to take part in the study if you are:

- On certain types of medication that affect mood or brain function
- Affected by the following medical conditions:
 - Neurological illness
 - Psychiatric illness (except for anxiety and depression)
 - Ischaemic heart disease
 - Peripheral vascular disease
 - Reflex sympathetic dystrophy
 - Peptic ulcer disease

- *Uncontrolled* hypertension (if it is controlled by medication that is fine)

With your consent, your GP will be informed of your participation in this research study and may receive a copy of this information sheet. It is also our policy that your GP will be informed if you score very highly on questionnaires assessing your day-to-day levels of anxiety and depression.

What are the possible risks of taking part?

After each experimental session there is a small possibility that you might experience some reddening of the skin on your arm due to the laser stimulator, but this should disappear within a few hours to days. There is a very small risk that you may have some superficial soreness of the skin, in which case advice will be given to you about this before you leave. There is also a very small risk that this area of skin may show a change in pigmentation, which should return to normal within 4-6 weeks. However in the 13 years that our group has been using this technique, one case has been brought to our attention where this pigmentation has persisted beyond 6 weeks.

Do I have to take part?

Your participation in this study is entirely voluntary. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What do I do now?

If you wish to volunteer for the study, please contact **Kath Hartigan** on **0161 206 2605** or at kath.hartigan@srft.nhs.uk. She will firstly assess whether you are suitable for the study and then organise a time for you to visit our research laboratory. If you have any questions about what is involved in the study, please contact **Dr Christopher Brown** on **0161 206 4528** or at christopher.brown@manchester.ac.uk. If you would like to learn more about the activities of the Human Pain Research Group, please visit our website at www.hop.man.ac.uk/painresearch. If you would like to learn more about the activities of the Human Pain Research Group, please visit our website at www.hop.man.ac.uk/painresearch.

Further information: independent advice and complaint procedure

For access to independent advice regarding your participation in this study, you may contact the Patient Advisory Liaison Service (PALS) service at Hope Hospital. If you wish to make a formal complaint about your treatment during the study, please contact **Professor Anthony Jones** on **0161 206 4566**, at anthony.jones@manchester.ac.uk, or at the postal address at the head of this information sheet.

BREATHWORKS – Living Well with Pain and Illness

The Breathworks Living Well with Pain and Illness explores a multi-faceted approach to managing pain, illness and the stress that often arises as a consequence. It provides a tool kit of resources that we can apply in our lives. The programme as a whole is based on the practice of Mindfulness, which we explore progressively over the course – gradually building up a rich awareness of ourselves, as well as our relationships to others, enabling us to lead a more creative life, even when experiencing long-term pain or illness.

Pain and illness are unpleasant sensations that we normally **react** to, causing a host of further problems and physical and emotional stress. We may not be able to do anything about the underlying unpleasant sensation, but we can train ourselves to **lessen and/or overcome this reactive cycle**. This means in time we learn to manage our response to the suffering we experience. The same principles apply to illness, fatigue and stress.

The Programme consists of an eight week course, followed by a full day (10.00am – 4.00pm). Since establishing the programme in 2001, with funding from the Millennium Commission, several hundred people have directly benefited from the methods introduced. These include mindfulness, breath awareness, meditation, gentle exercise, pacing, examining our deeper values and learning how to apply mindfulness to all aspects of daily life.

During the course you will also have the opportunity to meet others living with similar experiences of pain and ill health. This has often proved to be both important and beneficial to participants.

The programme is open to all on a self-referral basis. So far we have welcomed people with conditions such as: chronic back pain (the majority), arthritis, fibromyalgia, chronic fatigue, post-operative pain, cancer, nervous disorders, MS, Parkinson's disease, and other non-specific pain. This list is not exhaustive and we welcome your enquiry whatever your condition.

The only pre-requisite for joining the course is a willingness and commitment to engage fully with the programme, which will involve practice at home between sessions (30 – 45 mins a day).

The main components of the programme are:

- 1. Breath Awareness.** We start by investigating our breathing habits, so we can learn to use the natural breath as an aid to managing our pain, illness or stress. We encourage people to develop habits of breathing *into* their

experience, learning how to use the breath to soften resistance to pain or illness and to 'let go' of tension.

- 2. The Body Scan.** This helps us to develop habits of greater ease and awareness of the body. Adopting a comfortable posture (lying down or sitting) we 'scan' through the whole body with our awareness, using the breath to help us 'let go' of areas of pain and/or tension. We give course participants a CD to use at home.
- 3. Mindful Movement.** We discuss the importance of keeping our bodies in as good physical condition as possible, in order to stop a cycle of disuse, loss of function and more pain or fatigue. We include some gentle movements (based on yoga and pilates) in the programme. These have been specially devised for Breathworks by a very experienced yoga teacher and are suitable for all, being easily adapted as necessary so they are appropriate for people suffering from a wide range of physical conditions.
- 4. Mindfulness of daily life (Pacing).** By bringing awareness to the activities of daily life we learn to overcome the very common tendency of overdoing it on good days or collapsing on bad days, with accompanying emotions of unrealistic hope followed by frustration and despair. We do some 'detective work' about our daily activities, using diaries and symptom scoring, to try to become more aware of what activities cause aggravation. We learn how to make choices throughout the day, based on our developing awareness, enabling us to have a more balanced approach to life. We then move on to look at values and goal setting, so we can build on our discoveries.
- 5. Three Minute Breathing Space.** This is a very effective way of coming back to an awareness of yourself in the midst of daily life. We will teach you how to take three minute breaks in the midst of whatever activity you are engaged with, when you can simply rest your awareness quietly with the breath. This can be a remarkably effective way of bringing a sense of calm, peace, and presence into your experience. Then, feeling refreshed and focused, you can go back to what you were doing.
- 6. The Mindfulness of Breathing.** This meditation practice focuses on the breath in more depth than we have done previously. By doing this we learn to be still and to listen to ourselves – we can watch our thoughts, feelings, and sensations come and go, without judging them to be good or bad, without identifying with them or pushing them away, but just letting them be as they are. Changes that we'd like to make sometimes happen when we simply attend to our experience without actively trying to change it. The fact

that we are aware of something can be enough to change it, without us having to 'do' anything. We give you a CD to use at home.

7. The Kindly Awareness. This meditation practice in many respects forms the heart of the Breathworks Programme. We firstly spend time becoming aware of the unpleasant and the pleasant aspects of our own experience in the present moment, without 'tipping' into either pushing away the pain on the one hand or grasping after the pleasure on the other. This gives rise to a sense of gentle stability and strength. We then broaden our field of awareness to include other people and we reflect on all that we share: the simple breath, pleasure, pain and many other basic common human experiences. In this way we come to feel a deep sense of connection with others where our own experience of pain or suffering becomes a moment of empathy, rather than a prison. We give you a CD to use at home.

8. The Human Condition. We also encourage people to use their circumstances as an opportunity to see more deeply into the human condition. All bodies are subject to the sickness and degeneration that comes with age. We need to learn to tread a fine line between doing all that we can to help ourselves on the one hand, whilst accepting the inevitable difficulties of life on the other. By seeing more deeply into humanity it is possible to come to terms with our own difficulties, whilst also developing empathy with others who suffer.

All these methods of mindfulness can be practised on our own at home, enabling us to feel in charge of our own health and pain management. Gradually, over time, progress can be made and confidence improved.

Two Key principles underlie all these aspects of mindfulness and run through the whole course:

- 1. Learning to live in the present moment and breathe *into* our experience.**
- 2. Learning to respond rather than react to our life's circumstances.**