

Participant Information Sheet

Research Project title: Mindfulness based intervention in patients with persistent pain in chest (MIPIC) of non-cardiac cause - a feasibility randomised control study.

Invitation to participate in the above study

We would like to invite you to take part in a research study. Before you decide, it is essential that you understand why the research is being done and what it will involve for you. Please take time to read the following information carefully and discuss it with others if you wish. If anything is not clear or you would like further information, please ask us.

Why have I been invited to take part?

You were referred to our Rapid Access Chest Pain (RACPC) clinic some time ago for chest pain symptoms and assessed for any blockage in the arteries of your heart that may be causing the chest pain. As per our records, you were not found to have any significant blockage or any other problem of your heart that could explain the chest pain. You were referred back to your GP for further investigations if required. You may have been diagnosed to have heart burn, pain in muscles or bones, anxiety, etc., and may have received treatment for these conditions (usual care). However, you may still be having chest pain symptoms although doctors have not found anything wrong with your heart and despite treatment that may have been given by your GP for any other conditions.

What is the purpose of the study?

Many people suffer from chest pain where a physical cause cannot be identified, and no medical treatment is needed. The pain can result in individual suffering, difficulty in performing daily activities and work, and frequent visit to doctors. The purpose of this study is to explore alternative ways to manage chest pain. One of these ways is 'mindfulness', of which you might have heard. Mindfulness is a skill to train the mind to be in the present moment with openness, curiosity, and acceptance. It enhances the awareness of one's external surroundings and inner sensations, allowing the individual to step back, and manage difficult experiences differently, understanding what might be most helpful for well-being.

Mindfulness has been used to reduce longstanding pain from any cause when pain persists despite trying all recommended medical treatment(s). It has also been used for managing stress, pain in fibromyalgia, irritable bowel syndrome, and to prevent recurrent depression. However, there has been no study to evaluate the value of mindfulness in those suffering from chest pain. As a first step, we would like to know whether patients who continue to suffer from chest pain want to participate in a mindfulness programme of 8-weeks and to see if this is a helpful approach for them. We are thus performing a feasibility study to determine some of these unknown factors. For this study, we plan to randomly assign participants to receive either mindfulness with usual care or usual care alone (that you may be receiving through your GP). The process of randomisation is like tossing a coin, and each patient will have a 50-50 chance of being part of the mindfulness programme.

What will the Mindfulness programme involve?

The mindfulness programme to be used for this study is based on well recognised MBCT (Mindfulness Based Cognitive Therapy) course developed by Prof Mark Williams and colleagues in UK and Canada. It will involve attending approximately 23 hours of classes at Harefield Hospital over a duration of 8-weeks. The first and the last class would be of 2.5-hours duration and others from 2nd to the 7th week of 2-hours each week. Also, there will be a 6-hour practice day on the 6th weekend.

The classes are held in groups of up to 15 people and will be delivered by experienced mindfulness teachers. The group sessions are structured and led by the teachers who will explain the focus for each session. The sessions will include the following activities:

1. Meditation practices: These will be guided by the teacher and carried out either in sitting position or lying-down and incorporate sessions on mindful movement and walking.
2. Exercises: These will explore the impact of pain and what might help people to live as well as they can with pain. These exercises focus on current difficulties, helping people to recognize thoughts, emotions, body reactions and behaviors which research shows are an integral part of the experience of pain. You will be invited to reflect on particular difficulties and experiences, and the teacher will provide information about how we understand pain generally.
3. Group discussions: There will be opportunities to share experiences of mindfulness meditation and experiences of living with pain. Discussions will take place both in small groups and as a whole group. The teacher will ask questions to help explore patterns of the mind and body. The discussion will be focused on the experience of your practice and of living with persistent chest pain. There is no requirement or expectation to share anything you do not want to. It can be helpful to hear from others who have similar experiences, but it can

also be emotional to reflect on experiences and difficulties which we might ordinarily try to cope with by avoiding them.

Between the classes, you will be asked to practice at home and do some other tasks (e.g. keep a diary). Home practice is an essential part of the course, and we advise that you allow 45 minutes each day. It can be challenging to find time in our busy lives, but experience has shown that it becomes easier with group support and may even free up more time for other things. There will be time in the course sessions and discussions with the course teachers to help support you with this. However, if you are sure that you cannot make this commitment, it is probably best not to take part in the study.

Do I have to take part?

No. It is entirely up to you. If you choose not to take part, your care that you may be receiving from your GP or hospital will not be affected in any way. If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you do consent to take part, you are free to withdraw at any time without giving a reason. This would not affect the standard of care you receive.

What will taking part in the study involve for me?

Before we ask you to take part in the study, we will tell you about the mindfulness programme in full and you will have the chance to talk through any questions or concerns you might have. You will be required to come to the hospital for this purpose but if for any reason you are not able to attend the hospital, we can offer most of the initial assessment using an online video service over the internet. If you agree to take part, you will be required to go through the following process:

1. **Initial assessments** including measurement of your blood pressure, heart rate, height, and weight (for those who choose to do the assessment online, we will ask for the height and weight, while take the blood pressure and heart rate when you come for the first mindfulness class). We will collect information regarding your medical history and current medication, and ask you to complete some questionnaires to assess:
 - a. Your chest pain, how severe it is and how frequently it occurs.
 - b. Your general health and if the pain affects your daily activities.
 - c. Your mood
 - d. The degree of awareness of the present moment (mindfulness)
 - e. The number of times you visit your GP or A&E with chest pain.

2. A computer programme will randomly assign you to either receive:

Usual Care

This is simply the treatment that you are currently receiving as recommended by your GP or hospital doctor

OR

Mindfulness programme with Usual Care

You will continue with any treatment as prescribed by your GP or hospital doctor, as usual. In addition, you will be invited to attend Mindfulness classes at Harefield Hospital as follows:

Week 1:	2.5-hour duration
Week 2 to 8:	2-hour duration
Weekend 6:	6-hour retreat

We will video record the sessions. The camera will be focused on the teachers and for group participants, only the audio will be recorded. Recording the sessions allows the researchers to refine the content of the therapy for patients with chest pain. We will need your permission to do so. The recording will be stored securely and will only be kept as long as needed.

3. Follow-Up Assessments

All patients involved in the study (mindfulness group as well as just usual care group) will be asked to return to Harefield Hospital to complete the questionnaires and other measures which were completed at the initial assessment. This will be after one to four weeks after the 8-weeks MBCT course or usual treatment.

Expenses and payments

You will not be paid for participating in the study. However, additional travel expenses will be repaid to you.

What are the possible disadvantages and risks of taking part?

The Mindfulness programme will be delivered by experienced teachers and there are no serious risks in taking part. Some sessions involve some gentle movement, but you will always be guided to make personal adaptations and do what is right for

your body. If, for any reason, you need additional or urgent help during the course sessions we will support you to access this.

What are the possible benefits of taking part?

We cannot promise that you will benefit from taking part in the study, but the information we receive will help us to understand if mindfulness is of benefit to patients who have persistent chest pain.

What happens when the research study stops?

At the end of the research study, your care will continue as usual. Although you will not be offered any further Mindfulness classes by the hospital, you may wish to continue your practice on your own.

If I am chosen in the Usual care group will I still be able to access mindfulness programme at some point?

The participants allocated to the 'usual care' group will be offered the opportunity to participate in the mindfulness group programme once the study is complete (after the follow-up) at no additional cost. However, the participants will have to cover their own travel expenses.

What if there is a problem?

If at any point you have a concern about any aspect of this study, please ask to speak to the researchers who will do their best to answer your questions. Paula Rogers, Research Nurse Manager, can be contacted on 01895 823 737, ask for extension 83575 or Bleep 6085 or Claire Prendergast, Research Nurse 01895 823 737, Bleep 6429.

In the event that something goes wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for legal action

for compensation against the study sponsor, The Royal Brompton and Harefield NHS Foundation Trust, but you may have to pay your legal costs. The standard NHS complaints system will still be available to you.

General Data Protection Regulation (GDPR)

The Royal Brompton and Harefield NHS Foundation Trust (RBHFT) is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Royal Brompton hospital will keep identifiable information about you for 3 years after the study has finished.

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. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at the following website:
<https://www.hra.nhs.uk/information-about-patients>

The RBHFT will collect information from you and/or your medical records for this research study in accordance with our instructions. The hospital will keep your name, NHS number, contact details and any other identifiable data confidential and will use this information 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. Individuals from RBHFT and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in RBHFT who will have access to information that identifies you will be people involved in your clinical care and facilitating this study or who need to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Will my taking part in the study be kept confidential?

Yes, we will follow the ethical and legal practice, and all information about you will be handled in confidence. We will use the computer to store the study information. All data will be password protected and only study team members will be able to access the information. Once we have analysed the data, it will be stored for up to three years. We will ask for your consent before informing your GP about your participation in the study.

What will happen if I don't want to carry on with this study?

If you do not want to carry on with the study, you will receive the usual care as determined by your GP. Your participation is voluntary, and you may withdraw at any time without prejudice to your future medical care. Should you decide to withdraw for any reason, please contact a member of the research team to let them know.

What will happen to the results of the research study?

At the end of the project, the research results will be analysed. We have a professional responsibility to publish our research findings. However, your identity will not be revealed. The results will be presented and may lead to additional research. We are happy to share the results of the study with you if you would like to receive more information.

Who is organising and funding the research?

This research is organised and funded by The Royal Brompton and Harefield NHS Foundation Trust.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and approved by the London - Riverside Research Ethics Committee Research Ethics Committee (REC).

Further Information and Contact Details:

If you would like any additional information about the study, either now or at any time during the course of the study, please contact a member of the Research Team at Harefield Hospital:

Research Nurse Manager: Paula Rogers, Telephone 01895 823737, Bleep 6085

Research Nurse: Claire Prendergast, Telephone 01895 823737, Bleep 6429.

Chief Investigator: Dr. Tarun K Mittal, 01895 540312 / 07497 139873