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Participant Information Sheet

Research Project Title

The Relationship Between Interoception and Psychological Outcomes: A Mind-Body Intervention in Patients with Pulmonary Hypertension

Researchers Involved

Derick Moore (Lead Researcher and Trainee Clinical Psychologist), Dr Lynne Johnston (Research Supervisor and Consultant Clinical Psychologist), Dr Klaudia Suchorab (Field Supervisor and Principal Clinical Psychologist).

My name is Derick Moore. I am doing a research study as part of my training course to become a Clinical Psychologist and you are being invited to take part in this study. Before you decide, it is important for you to understand why the research is being done and what it will involve if you decide to take part. If you decide not to take part, this will not impact the care you receive from the Scottish Pulmonary Vascular Unit (SPVU) in any way. Please take time to read the following information carefully and to decide whether or not you want to take part. You can also talk to others if you wish.

If there is anything unclear or if you would like to know more about the study then please feel free to contact me using the details provided at the bottom of this form.

What is the purpose of the study?

The word 'interoception' relates to how we sense the signals that come from inside our body, such as noticing our heart is beating faster or our breathing becoming quicker. People living with pulmonary hypertension often report having difficulties understanding the changes in their bodily sensations once their symptoms first start. Research suggests that the better we tune into our body's needs, the better we can look after our emotional and physical well-being. For example, with better interoception, we may be less worried about changes in our body or able to balance our activities better by for example, taking time to rest.

We have developed an online group intervention, which we hope will improve people's ability to tune into their bodies and make better sense of their physical sensations. As this is a new intervention, which has not been used by individuals with pulmonary hypertension, we are interested in evaluating how helpful it is.

Why have I been chosen to take part?

You have been invited to take part in the research as you have a diagnosis of pulmonary hypertension and are in the care of the SPVU.

Do I have to take part?

No. It is up to you whether you wish to take part. Your decision will not affect the care you receive within the SPVU. Participation in the study is voluntary and you have the right to withdraw at any time without needing to give a reason.

What will I be asked to do?

If you are interested in taking part in this study, you will complete a brief 'expression of interest' form (via the link or QR code below), which asks your

contact details and your consent for me to contact you for a brief initial telephone call at a time convenient to you.

During the telephone call, I will take you through the study and answer any questions you may have. Consenting to this call does not commit you to taking part in the study. If you would like to participate, I will ask you to complete an online consent form. This will say that you understand what the study involves and agree to take part. After you have consented, a final screening stage will occur to make sure you meet the study's inclusion criteria. I will discuss with you the outcome of screening and whether the study may be beneficial to you. Once you have consented to take part in the study and have met the inclusion criteria, you can decide to withdraw your participation at any point.

As part of the study, you will also be asked to complete a demographic form and four questionnaires about how aware you are of your body sensations and how you respond to them, symptoms of anxiety and low mood as well as your health-related quality of life. These should take no more than 20 minutes to complete. I will also write to your GP to inform them of your interest in the study, and if any risk of harm to yourself is identified through the screening process.

What will the intervention involve?

As part of the study, you will be randomly allocated into either the intervention group, or the waitlists group.

Intervention group

If you are randomly allocated to the intervention group, you will be asked to attend an online group for eight consecutive weeks, lasting 90 minutes per session (including two breaks).

Once the group has finished, you will be asked to complete the same questionnaires again as well as an extra one, asking your thoughts on the intervention.

Waitlist group

If you are randomly allocated to the waitlist group, you will complete the questionnaires at the same time the intervention group does (prior to them starting the treatment). You will then be contacted by me and asked to complete the same questionnaires again after the intervention group has completed the group. You will then be invited to start your intervention. This will include the same content as the first group and will also last for eight consecutive weeks. Once the intervention is complete, you will be asked to complete the questionnaires a final time, including the extra one which asks your thoughts on the intervention.

This study will not impact other areas of your care and you should be able to keep your usual appointments.

The intervention is a virtual group (via Microsoft Teams) running for one session every week for eight weeks. Each session lasts for 90 minutes and includes two breaks. Each group will have between 8-12 participants and we predict that we will run four groups in total. There will be two trained facilitators running each group, myself and a qualified Clinical Psychologist.

The intervention aims to be a safe and supportive space where participants can share their experiences of living with pulmonary hypertension. We will also help you learn how to tune into your body more and better understand your bodily sensations. This may in turn improve your emotional well-being and health-related quality of life. You will be asked to practice various exercises in your day-to-day life and share your experiences with the group.

If you consent to the study, it is expected that you attend all eight sessions. If you miss a session I will contact and update you on the missed session. As this is a brand-new intervention, it is important that researchers have as much data as possible to analyse the feasibility of the project. Missing sessions will impact the results of the study. If you miss three sessions, it is assumed that the intervention cannot be accurately analysed and therefore your results will be removed.

What are the potential disadvantages and risks of taking part?

There are minimal risks involved in this study. Some people may find certain topics upsetting as we will ask you to reflect on your experiences of living with pulmonary hypertension. Sometimes, we might ask you to focus on your physical symptoms to help you connect more to your body, which you might also find difficult.

If you wish to stop, you can do so at any point. If you find any topics or exercises upsetting, you can speak to myself or the other facilitator for additional support. You can also withdraw from the study at any point.

What are the possible advantages and benefits to taking part?

As this is a newly developed intervention, there is no guarantee you will benefit from the treatment. However, similar studies in other areas show that individuals who work on connecting more to their bodies have improved well-being. Better well-being in turn improves people's quality of life.

Your feedback will help us improve the intervention for future users, contributing to the development of psychological therapies for patients with pulmonary hypertension.

Will my participation in this study be kept confidential?

Yes. All information will be kept strictly confidential. You will not be identified in any reports or publications. There are strict laws which safeguard your privacy at every stage of the study. Only researchers involved in this study will have access to your information.

After you have consented to the study, you will be given a 'participant number' and all identifiable information will be removed. This means only the researchers will know who has completed the questionnaires. Your GP will be sent a brief letter informing them that you have expressed your interest in the study, but the letter will not include any details about answers you have provided. If you disclose any information to the researchers that indicate risk of harm to yourself or others, relevant professionals will be informed.

If for any reason you lose your ability to make decisions throughout the duration of the study, we will retain personal data and continue to use this in a confidential manner, with the purpose for which your consent was originally sought.

What will happen to the results of the study?

The results will be written up as part of my coursework and submitted to the University of Glasgow as part of my training in the Doctorate of Clinical Psychology. I will aim to publish the results of this study in an academic journal and present the results to relevant interested groups and conferences to deepen the clinicians' understanding of how the mind and body connection could impact individuals with pulmonary hypertension. These results will be anonymised, meaning that no participants will be named, and all identifiable information will be removed.

You will also be given a written summary of the results of the study if you wish.

Who is organising and funding the study?

This research is funded by the University of Glasgow. The study is sponsored by NHS Golden Jubilee.

Who has reviewed the study?

This study has been approved by the London – Westminster Research Ethics Committee and the University of Glasgow.

The study has also been reviewed by those with personal experience of pulmonary hypertension.

How to contact us

If you have any questions about the study, then please contact the research team using the details below:

Email: gjnh.psychology@gjnh.scot.nhs.uk

Phone: 07970 496554

Address: Psychological Therapies Service, Golden Jubilee National Hospital, Agamemnon Street, Clydebank, G81 4DY

Who can I contact if I have a complaint?

If you have any concerns about this study and/or you would like to make a formal complaint, please use any of the contact details below:

- Dr John Sharp (Consultant Clinical Psychologist), Head of Psychology, Golden Jubilee National Hospital: john.sharp@gjnh.scot.nhs.uk
- Email: feedback@gjnh.scot.nhs.uk
- Call our Clinical Governance Team on: 0141 951 5951
- Write to: Patient Feedback Team, Clinical Governance Freepost, Golden Jubilee National Hospital, Agamemnon Streed, Clydebank, G81 4DY.

Please scan the QR code or follow the link below to complete the short 'expression of interest' form so I can contact you to discuss the study. If you have any difficulties using the QR code or link below, please contact derick.moore2@ggc.scot.nhs.uk

Expression of Interest Form Link

https://forms.office.com/e/LgtDjjQPZM

Thank you for considering taking part in this research project.