

Psychological Therapies Service

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CONSENT FORM

Participant Number:

Title of Study: A Randomised Controlled Feasibility Trial Exploring an Interoceptive-Based Intervention in Patients with Congenital Heart Disease

Name of Researcher: Jason McBurnie

Please initial box

1. I confirm that I have read the information sheet dated..... (version.....) for the above study, including information about the screening process and eligibility criteria. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

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2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

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3. I understand that the project is a randomised controlled trial. This means that I may be allocated to either an immediate intervention or a delayed intervention (waitlist) group and may not receive the intervention immediately. I understand that participants in the delayed intervention group will continue to receive usual care during this period, be asked to complete questionnaires and offered the intervention after the first group has completed treatment.

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4. I agree to provide my contact details for the purposes of the study and for Jason McBurnie (Lead Researcher) to contact me to complete questionnaires related to the study.

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5. I understand that relevant sections of my medical notes and data collected during the study may be looked at by researchers, regulatory authorities, or representatives of the NHS board, where it is relevant to my participation in this research. I give permission for these individuals

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to have access to my records.

6. I understand that if, for any reason, I lose the capacity to make decisions during the study, the researchers will retain my personal data and continue to use it confidentially for the purposes for which I originally provided consent. ☐
7. I understand that any identifiable information collected about me will be deleted within six months of the study's completion. ☐
8. I understand that my General Practitioner (GP) will be informed that I am taking part in this study. ☐
9. I understand that if I disclose information that indicates a risk to myself or others, the researchers will be required to share information with appropriate staff. ☐
10. I understand that the study involves group sessions and that participants will be encouraged to respect the privacy and confidentiality of others by not sharing personal information outside sessions. ☐
11. I understand that by providing consent I am agreeing to take part in the screening process for this study to determine whether I meet the study's inclusion and exclusion criteria. I understand that I may not be eligible to continue in the study and that, if this is the case, I will be informed sensitively by a member of the research team. ☐
12. I understand that anonymised data from this study may be used in future ethically approved research studies by the research team, and that no information that could identify me will be shared. ☐
13. I understand that the comments I provide in feedback questionnaires may be used anonymously as quotes in research projects, presentations or publications about the study. ☐
14. I understand that all research data will be stored for at least 10 years after completion of the study in an appropriate data repository, in compliance with the University of Glasgow's research data management regulations. ☐
15. I agree to take part in the above study. ☐
16. I would like to receive a summary of the research findings by email (optional): YES ☐ NO ☐

Name of Participant

Date

Signature

Jason McBurnie

Name of Researcher

Date

Signature