

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

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Abstract

Background

Adults living with congenital heart disease (CHD) face ongoing physical, psychological and social challenges that can reduce psychological wellbeing and quality of life. Interoceptive-based interventions (IBIs), which focus on enhancing awareness and regulation of internal bodily signals, have shown potential to improve self-management and emotion regulation across mental and physical health conditions (Heim et al., 2023). However, these approaches have not yet been evaluated in CHD, where access to psychological support remains limited.

Aims

To assess the acceptability and feasibility of an adapted interoceptive-based group intervention for adults with CHD and explore preliminary changes in interoceptive awareness, anxiety, depression and health-related quality of life (HRQoL).

Methods

A randomised controlled feasibility trial will recruit from the Scottish Adult Congenital Cardiac Service (SACCS), allocating participants to intervention or waitlist control groups. The eight-session intervention will be delivered online via Microsoft Teams. Online surveys will be used to collect data at baseline and post-intervention. Exploratory quantitative analyses will examine within- and between- group changes across four outcome measures, alongside acceptability and feasibility data.

Practical Applications

Findings will guide the development of accessible, psychologically informed CHD care, inform the design of larger scale trials and support the integration of IBIs into CHD services.

Introduction

Over 18,000 adults in Scotland live with congenital heart disease (CHD; Scottish Adult Congenital Cardiac Service [SACCS], 2022), a structural heart abnormality present from birth. Advances in cardiac care have increased survival rates into adulthood from less than 20% to over 85% (SACCS, 2022), but many adults continue to experience physical, psychological and social challenges that affect wellbeing and quality of life (Kovacs et al., 2024). Prevalence rates for depression, anxiety, post-traumatic stress disorder (PTSD), autism spectrum disorder and attention-deficit hyperactivity disorder are higher in CHD compared to the general population (Moons et al., 2024). An international study found that around one third of people with CHD experienced elevated levels of anxiety and depression linked to reduced quality of life and perceived health status (Kovacs et al., 2024). As the psychological literature in CHD is still emerging, it remains largely descriptive and offers limited insight into mechanisms that maintain distress.

Health Improvement Scotland (2023) introduced care standards in response to the lack of guidance for local CHD services. As part of this process, the standards acknowledged the unmet psychological needs of people with CHD and need for more integrated mental health support. However, integration of psychological care remains limited and further research on psychological outcomes and appropriate interventions is needed (Kovacs et al., 2022).

Interoception in Mental and Physical Health

Interoception is the process of sensing, interpreting and regulating internal bodily signals arising from within the body (Khalsa et al., 2018). Interoception is important because it signals the body's internal needs (e.g., hunger or thirst), influences emotional experiences, guides behavioural responses and decision-making (often described as 'a gut feeling'), and contributes to the regulation of physical and emotional states (Barret & Simmons, 2015; Dunn et al., 2010).

Impaired interoception has been observed across various mental health conditions, including anxiety, depression and PTSD, as well as physical health conditions such as chronic pain, irritable bowel syndrome and cardiovascular disease (Khalsa et al., 2018; Locatelli et al., 2023).

Interoceptive Interventions

Interoceptive-based interventions (IBIs) have recently gained traction in the field, aiming to improve awareness of bodily states and support individuals to interpret, integrate and regulate internal signals. Some IBIs involve intentional exposure with internal sensations to reduce avoidance and catastrophic interpretations (Boettcher & Barlow, 2019). Other interventions focus on increasing awareness of internal bodily states to improve accuracy or detection of interoceptive signals through practices such as mindfulness (Fischer et al., 2017). Mindfulness-based strategies (e.g., body scan meditation) can also support regulation and reappraisal of bodily sensations through increased noticing and non-judgemental awareness (Bornemann et al., 2014).

The first systematic review of IBIs reported preliminary evidence for improved interoceptive awareness across several mental and physical health conditions (Heim et al., 2023).

Although IBIs have not yet been studied in CHD, emerging evidence suggests that interoceptive processes may play a role in cardiac conditions. For instance, higher awareness of internal bodily states has been associated with more effective symptom management and self-care behaviours in cardiovascular populations (Locatelli et al., 2025). ‘Heart focused’ anxiety involves misinterpreting cardiac sensation as signs of danger (Roseman et al., 2021), and these interpretations can reinforce avoidance of physical activity, as sensations like breathlessness or an elevated heart rate may be perceived as threatening (Willinger et al., 2023). Dizziness or orthostatic intolerance, often associated with arrhythmias, can intensify fear of fainting and restrict mobility (Laranjo et al., 2019). Fatigue, affecting 40 to 60% of patients, is closely linked to interoceptive experiences of energy depletion and autonomic dysfunction (Ternrud et al., 2022). Emotion regulation challenges are often linked to somatic hypervigilance, where an intense focus on internal sensations can disrupt adaptive coping (Lebherz et al., 2022). Taken together, these patterns suggest that interoceptive mechanisms may influence how individuals with cardiac conditions perceive and respond to their bodily sensations.

Developing IBIs for CHD

To our knowledge, no studies to date have evaluated IBIs in adults with CHD. Given the interoceptive difficulties observed in this population, IBIs may offer a theoretically grounded

way to support interpretation and regulation of internal bodily sensations. Heim et al. (2023) noted more broadly that IBIs were shown to be more effective when they targeted both the sensing and appraisal of internal of bodily signals, rather than focusing on bodily awareness alone.

Moore's (2025) IBI for pulmonary hypertension (PH) drew on principles and guidance from Heim's (2023) paper to structure an 8-week group and skills-based programme. The preliminary results of the feasibility study indicated improvements across four domains of interoceptive awareness pre- and post- intervention: *noticing* (awareness of comfortable, uncomfortable and neutral bodily sensations), *emotional awareness* (awareness of connection between body sensations and emotional states), *body listening* (active listening to the body for insight) and *trust* (experiencing one's body as safe and trustworthy). In terms of between group changes, improvements were also reported on two interoceptive domains: *listening* and *self-regulation* (ability to regulate distress by attention to body sensations). While the study was underpowered to draw significant conclusions, the IBI was considered safe, feasible and well accepted by participants.

Building on the structure and components of Moore's (2025) feasibility study, the primary aim of this study is to adapt the IBI developed for PH to meet the specific needs of adults with CHD. A secondary aim is to evaluate the IBI's acceptability and feasibility by answering the following questions:

- What were the overall attrition and retention rates for the intervention?
- What was the completion rate for measures?
- Were there differences in interoception, anxiety, depression and HRQoL scores before and after the intervention, and between the intervention and waitlist groups?
- What are the estimations of effect size (e.g., Cohen's *d*) to use for sample size calculations in future studies on this topic?
- What sample size is required to achieve sufficient statistical power in future studies?

Designs, Methods and Procedure

Design

This randomised controlled feasibility study will use a single recruitment cycle. An online randomisation tool will assign participants to an intervention or waitlist control group. Measures will be completed at baseline and post-intervention, after which the waitlist group will receive the intervention. Researchers and participants will not be blinded.

Participants

Participants will be patients under the care of the Scottish Adult Congenital Cardiac Service (SACCS) at the Golden Jubilee University National Hospital (GJUNH). SACCS currently provides care for approximately 2,400 patients with CHD across Scotland, with most being expected to meet the study's inclusion criteria. The recruitment target of 32 participants (1.3% of this cohort) is therefore feasible.

To be eligible, individuals must be aged 18 or older, fluent in English, able to commit to the full duration of the study (four months) and have access to a device compatible with Microsoft Teams. Exclusion criteria: current suicidal ideation, comorbid alcohol or substance use disorder, diagnosed learning disability, or severe and enduring mental health difficulties (e.g., psychosis). Patients on the surgical or transplant waiting list, or with hearing, visual or cognitive impairments preventing online participation, will not be eligible.

Recruitment

Recruitment will occur through study posters in patient waiting areas (with QR code linking to the information sheet and electronic consent form) and through attendance at SACCS clinics, where a researcher will be able to provide materials, discuss eligibility and support sign-up. Nominated clinicians may also signpost interested patients.

Materials and Measures

The assessment battery was selected to balance breadth and feasibility, with each measure targeting a distinct domain aligned to the study's aims. To minimise participant burden, clear instructions, user-friendly online survey formats and the option to pause responses will be provided.

Demographic Questionnaire

Adapted from Moore (2025), this questionnaire will collect date of birth, gender, ethnicity, highest academic qualification and general practitioner (GP) details. Postcodes will be used to assess deprivation using the Scottish Index of Multiple Deprivation (SIMD). This will explore barriers to engagement and associations with acceptability, feasibility and psychological outcomes.

Feasibility and Acceptability Questionnaire

Adapted from Moore (2025), this will assess accessibility, delivery, group format/content, perceived usefulness of exercises and potential impact on anxiety, depression, HRQoL or interoception, using a five-point Likert scale (from 1= *strongly disagree* to 5 = *strongly agree*). Participants will indicate if they would recommend the intervention and provide qualitative feedback.

Multidimensional Assessment of Interoceptive Awareness – Version 2 (MAIA-2; Mehling et al., 2018)

The MAIA-2 is a 32-item self-report scale measuring eight concepts related to interoception: (1) attention regulation, (2) emotional awareness, (3) noticing, (4) self-regulation, (5) not-worrying, (6) not-distracting, (7) body listening and (8) trusting. Items are answered on a six-point Likert scale ranging from 0 = *Never* to 5 = *Always*. Each subscale is interpreted

independently to reflect different aspects of interoceptive awareness, including in populations with long-term health conditions (Mehling et al., 2018).

Generalised Anxiety Disorder Scale (GAD-7; Spitzer et al., 2006)

The GAD-7 is a 7-item self-report scale assessing the frequency and presence of anxiety symptoms over the past two weeks. Items are rated on a four-point Likert scale, ranging from 0 = *Not at all* to 3 = *Nearly every day*. Total scores range from 0 to 21, with higher scores indicating more severe anxiety symptoms. It is widely validated in primary care and chronic health settings (Löwe et al., 2008).

Patient Health Questionnaire (PHQ; Kroenke et al., 2001)

The PHQ-9 is a 9-item self-report scale assessing the frequency and presence of depressive symptoms over the past two weeks. Items are rated on a four-point Likert scale, ranging from 0 = *Not at all* to 3 = *Nearly every day*. Total scores range from 0 to 27, with higher scores indicating more severe depressive symptoms. It is widely validated in primary care and chronic health settings (Löwe et al., 2004).

Short Form Health Survey (SF-12; Ware & Sherbourne, 1992)

The SF-12 is a 12-item HRQoL self-report scale producing Physical and Mental Component Summary scores from eight domains: (1) physical functioning, (2) physical role limitations, (3) emotional role limitations, (4) bodily pain, (5) general health, (6) vitality, (7) social functioning and (8) mental health. Scores range from 0 to 100; higher total scores indicate better health. The SF-12 has been validated in cardiac populations as an alternative to its longer 36-item version (Müller-Nordhorn et al., 2004).

Intervention

The intervention will run via Microsoft Teams over eight weekly 90-minute sessions (with one 10-minute break). Participants will receive a resource pack two weeks prior to commencing the intervention.

Adaptation of Moore's (2025) PH intervention will follow the Medical Research Council (MRC) framework for complex interventions (Skivington et al., 2021), incorporating: (1) contextual relevance (tailoring content to CHD using SACCS expertise and literature), (2)

stakeholder input (SACCS clinicians and patients informing resource development), (3) theoretical foundation (structured topic guide and resources informed by existing reviews such as Heim et al., 2023), (4) equity and access (live online delivery with preferred timing options such as evening groups), and (5) adaptability (iterative feedback to refine the intervention). Please refer to Appendix 1 for an overview of possible session content.

Procedure

Following initial contact (email, QR code, or clinic), participants will receive the participant information sheet electronically or in person. All study documents, including consent forms and outcome measures, will be completed and signed electronically via secure online surveys. The lead researcher will provide support at clinics for those needing help accessing documents on their devices. Screening against inclusion and exclusion criteria will be completed at clinic or via a scheduled telephone call. Eligible participants will provide informed consent and complete a demographic questionnaire and baseline measures (MAIA-2, GAD-7, PHQ-9 and SF-12). Participants will be randomised to the intervention or waitlist control group. To promote group cohesion and behavioural change in online settings, groups of 8 to 12 participants will be formed (Borek et al., 2019; Preuhs et al., 2023). The waitlist group will complete repeat measures after eight weeks before commencing the intervention. Sessions will be co-facilitated by the lead researcher and a GJUNH clinical psychologist. Post-intervention, all participants will repeat measures and complete the acceptability and feasibility questionnaire.

Equality, Diversity and Inclusion Considerations

In the absence of an expert-by-experience group, SACCS nurses and patients will inform material development. A plain-language summary of the findings will be shared with participants.

Ethics, Governance and Data Protection

This study will be sponsored by the University of Glasgow. Ethical approval will be sought from the appropriate NHS Research Ethics Committee and GJUNH Head of Research. Participants will provide informed consent and be assigned unique identification codes. Data will be anonymised and analysed in Microsoft Excel and SPSS. Identifiable data will be stored securely on an NHS shared drive, accessible only to the research team and deleted after the study finishes (see Appendix 2).

Analysis Plan

Descriptive statistics will summarise acceptability and feasibility data (percentages), demographics (percentages, means and standard deviations), baseline measures (means and standard deviations), and rates of attrition and completed measures (percentages). Incomplete data from dropouts will be excluded.

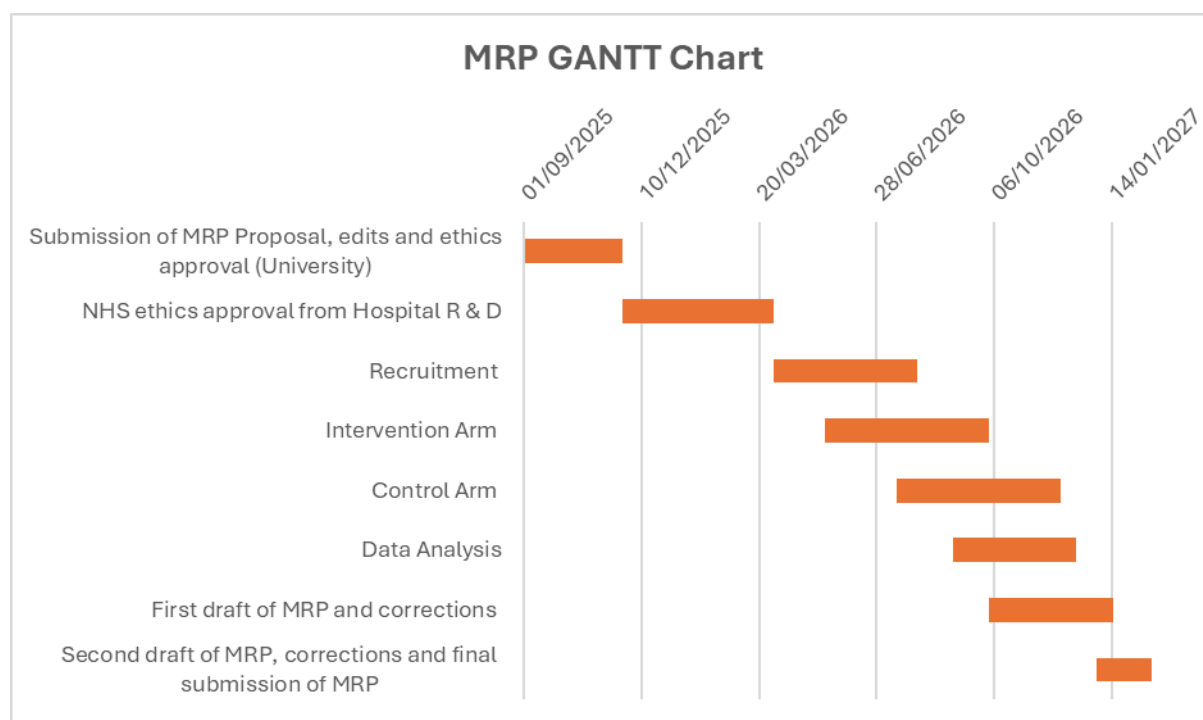
Exploratory analyses of within-group changes in interoception, anxiety, depression and HRQoL pre- and post-intervention will be explored using paired t-tests or Wilcoxon Signed Rank tests, depending on normality of the data distribution. Exploratory between-group differences will be analysed using unpaired t-tests or Mann-Whitney U tests, depending on normality.

Guided by Sullivan & Feinn (2012), effect sizes will be estimated using Cohen's *d* (small = 0.3, medium = 0.5 and large = 0.8) and interpreted cautiously due to small samples.

Sample Size

Sample size is based on guidance for pilot and feasibility studies, recruitment practicalities and anticipated attrition. Totton and colleagues (2023) reviewed UK pilot and feasibility trials, noting that while many studies failed to reach 35 participants per arm, most met lower thresholds, such as 12 per arm. Recruiting 32 participants (16 per arm; around 1.3% of the SACCS cohort) is considered achievable within the proposed recruitment timeframe. Accounting for an estimated 31% attrition rate typical of digital interventions in chronic health settings (Melville et al., 2010) will ensure a final sample of 24 participants (12 per arm).

Timetable



Contingency Plan

If recruitment, intervention delivery or other aspects of the study do not proceed as expected, several mitigation strategies will be implemented. To strengthen recruitment, the lead researcher will present the study at team and/or multidisciplinary meetings to increase engagement and buy-in. The lead researcher will have access to an onsite clinic space during recruitment and will be based at GJUNH during the intervention phase to remain responsive to the needs of the study. NHS Golden Jubilee is a research-active department with multiple psychologists embedded within the team, which provides additional capacity for recruitment support and intervention delivery.

Health and Safety

Please refer to Appendix 3 for a detailed health and safety plan. Before commencing the intervention, participants will receive an explanation of the rationale and procedures. During the intervention, participants will be reminded they can take breaks and withdraw from the study at any stage. Remote sessions will be delivered by a minimum of two clinicians to ensure appropriate support is available and maintain study integrity.

Equipment Costs

Please refer to Appendix 4 for a breakdown of project costs. Total estimated costs: £240.73.

Practical Applications and Dissemination

Findings will advance interoception research in CHD, provide effect-size estimates for a larger scale randomised controlled trial and inform the integration of a tailored IBI into CHD care.

All participants, who complete the study, will receive a plain language summary of the findings. The results will be presented to the SACCS team and prepared for academic conferences and submission to peer-reviewed journals, such as the *International Journal of Cardiology* or the *Journal of Health Psychology*.

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Appendix 1: Justification for Intervention Structure and Overview of Possible Session Content

Why online groups?

- As this is a replication study of an online interoceptive-based intervention (IBI) developed for people with pulmonary hypertension (Moore, 2025), retaining online delivery ensures fidelity to the original research design while allowing acceptability and feasibility to be examined in adults with congenital heart disease (CHD).
- Online groups may be a more cost-effective and time-efficient format for both services and participants (Preuhs et al., 2023).
- Research evidence suggests that online psychological interventions can be as effective as face-to-face interventions (Andersson et al., 2019).
- Adults with CHD may face barriers such as work commitments, childcare responsibilities, comorbid health issues, mobility limitations or fatigue. Online delivery can therefore help overcome these challenges and increase accessibility by allowing participation from home. It also helps to broaden geographical reach and supports greater demographic diversity within the group (Preuhs et al., 2023).
- Psychological theory supports the online format:
 - Drawing on Yalom's therapeutic factors, online groups can provide opportunities for universality and vicarious learning, as participants can recognise commonality and learn from their peers in an online setting (Yalom & Leszcz, 2020).
 - Social cognitive theory (Bandura, 1986) highlights the role of observational learning and self-efficacy, which are both processes that can be supported in online groups through peer interactions, modelling and feedback.
 - From an implementation perspective, Normalisation Process Theory (May & Finch, 2009) suggests that online interventions are more likely to be adopted when they are accessible, efficient and perceived as being useful.

How many weeks?

- The current IBI is designed to run for eight weeks (90-minute sessions including one 10-minute break). The decision to retain an eight-week format is based on the original IBI developed for people with pulmonary hypertension (Moore, 2025), which this study is replicating for a CHD population.
- This structure is also supported by findings from a recent systematic review of IBIs (Heim et al., 2023), which reported that group interventions typically ran for 11 sessions across different populations. However, due to practical limitations in terms of time and resources and to ensure feasibility for both participants and facilitators, it was considered appropriate to maintain an eight-week structure.

Group size

- To promote group cohesion and facilitate behavioural change in online interventions, the literature typically recommends group sizes of eight to 12 members (Borek et al., 2019; Preuhs et al., 2023).

Non-attendance

- Full attendance is expected across all sessions.
- If a participant misses a session, the lead researcher will follow up to provide a summary of the missed content to support their continued engagement.
- Participants who miss three sessions will be classified as not having completed the intervention.

Aims and Learning Outcomes

An overview of the potential aims and learning outcomes of the IBI for CHD and possible session content is provided below:

Session 1	Aims	Learning Outcomes
Welcome to the group and overview of interoception	Welcome participants to the group. To establish a safe and secure environment and clear ways of working. Collaboratively set group norms, boundaries and conditions for success. To foster initial engagement and motivations for joining the group. Clarify the distinction between a skills-based group compared to a therapeutic group. Introduce concept of interoception. Introduce and explain a between session task.	Understand the purpose of the group and consider ways of working together safely and respectfully. To reach agreement on how the group context will be used for social support, sharing experiences and useful information. To introduce the rationale for interoception and begin considering its relevance for daily life.

Session 2	Aims	Learning Outcomes
Building a deeper awareness of interoception and its relevance for adults living with congenital heart disease (CHD)	To review content from the previous session. To explore participants' interoceptive awareness in relation to their CHD diagnosis. To consider factors that may have influenced change (e.g., their diagnostic journey) To explore how CHD has changed participants' relationships with interoception and their bodies. To set a between session task.	To consolidate learning from the previous session and discuss participants' experiences of the between session task. To develop a shared and empathic understanding of interoceptive experiences before and after CHD diagnosis. To explore the impact of CHD and related lived experiences on participants' relationship with interoception and their bodies.

Session 3	Aims	Learning Outcomes
Understanding how interoception links with emotional experiences	To review content from the previous session. To explore the role of interoception in emotional regulation and well-being. To identify internal and external factors influencing the use of interoception for emotional regulation. To highlight how improved interoceptive awareness can support mood. To set a between session task.	To consolidate learning from the previous session and reflect on practice of the between session task. To enhance understanding of the mind-body connection and its relevance to interoception and CHD. To identify factors that support or hinder the use of interoception in emotional regulation. To build participants' confidence in using interoception for emotional regulation.

Session 4	Aims	Learning Outcomes
Understanding how interoception links with behaviours	To review content from the previous session. To explore how interoception influences decision making and impacts behaviours. To identify internal and external factors that affect participants' ability to use interoception to guide actions. To consider how strengthening interoception may promote positive health behaviours in CHD. To set a between session task.	To consolidate learning from the previous session and reflect on practice of the between session task. To enhance understanding of the role of interoception in behaviour and decision making more generally (e.g. a "gut feeling") and with specific relevance to CHD. To identify factors that support or hinder the use of interoception in guiding behaviours. To increase participants' confidence in using interoception to inform decision-making and health behaviours.

Session 5	Aims	Learning Outcomes
Understanding symptom uncertainty, somatic hypervigilance and cardiac anxiety in CHD through interoception	To review content from the previous session. To explore lived experience of CHD symptoms with a focus on somatic hypervigilance, cardiac anxiety and uncertainty of their condition. To consider the emotional impact of symptom uncertainty (e.g., hypervigilance and fear of bodily sensations) and its influence on behaviour (e.g., safety behaviours and	To consolidate learning from the previous session and reflect on practice of the between session task. To reflect on the impact of uncertainty, somatic hypervigilance and cardiac anxiety in CHD on daily life. To explore emotional and behavioural responses linked to symptom uncertainty, somatic hypervigilance and cardiac anxiety.

	avoidance). To support participants in developing a greater tolerance of uncertainty in relation to CHD symptoms through interoceptive awareness. To set a between session task.	To increase participants' confidence in using interoception to tolerate uncertainty.
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Session 6	Aims	Learning Outcomes
Understanding fatigue in CHD through interoception	To review content from the previous session. To consider the nature of fatigue in CHD. To explore links between fatigue and interoception. To identify internal and external factors influence the use of interoception in managing fatigue. To introduce relevant strategies (e.g., pacing) and discuss their use alongside interoceptive awareness. To set a between session task.	To consolidate learning from the previous session and reflect on practice of the between session task. To understand why fatigue occurs in CHD. To explore the role of interoception in fatigue. To identify factors that support and hinder the use of interoception in managing fatigue. To build confidence in applying strategies (e.g., pacing) to manage fatigue.

Session 7	Aims	Learning Outcomes
Putting skills into practice and building confidence.	To review content from the previous session. To provide extended	To consolidate learning from the previous session and reflect on practice of

	opportunities to practice interoceptive skills and consider their application to daily life. To facilitate reflection experiences and knowledge gained from the intervention. To highlight importance of skill maintenance after the intervention. To start developing individualised plans for ongoing skills practice. To spend more time practicing interoceptive skills and their application in daily life. To begin to reflect on the participants' experience of the group and knowledge gained through the intervention.	the between session task. To share personal and group reflections on which group exercises have been most useful to participants individually and why. To support participants in practicing interoceptive skills during the session to build their confidence practice independently after the group ends. To facilitate peer support in helping participants to construct individualised plans for ongoing skills practice after the group ends.
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Session 8	Aims	Learning Outcomes
Reflection, skill maintenance and group ending	To review content from the previous session. To reflect on group experiences and consolidate learning. To support participants with planning for ongoing skills practice after the intervention. To complete final outcomes	To consolidate learning from the previous session and reflect on practice of the between session task. To reflect on personal learning and relevance of interoception. To support development of a plan for ongoing skills development. To review initial group

	measures. To provide a shared ending and recognise achievements.	expectations and whether these were achieved. To end the group positively and with increased confidence for independent skills use.
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Appendix 2: Data Management Plan (DMP)

Note:

This DMP template is adapted from the guidance provided here:

<https://www.gla.ac.uk/myglasgow/datamanagement/creatingyourdata/dataplanning/>

Trainees should seek advice from their University Supervisor when developing the DMP. Examples of DMPs from different types of projects (including both quantitative and qualitative research) can be viewed here:

<https://www.dcc.ac.uk/resources/data-management-plans/guidance-examples>

The University of Glasgow data repository is Enlighten:

<http://researchdata.gla.ac.uk/>

Title of project

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

What data will be created?

- Note the type and amount of data that will be created, e.g. assessment scores; transcripts; etc
- Explain how you will capture the data, e.g. paper record forms; online survey; spreadsheet
- What file formats will you use and why? e.g. "Microsoft Excel will be used as it is in widespread use" (adapt such statements to suit your project)

- As there are currently no existing interoceptive-based interventions for adults with congenital heart disease, all data will be newly created.
- Data will include four participant outcome measures: MAIA-2, GAD-7, PHQ-9 and SF-12. Data will be collected for intervention and waitlist groups at baseline and again following completion of the intervention. A feasibility and acceptability questionnaire will also be completed after completing the intervention.
- Participant outcomes measures will be administered via a secure online platform (e.g., Microsoft forms or Qualtrics). Survey data will be downloaded and transferred to a Microsoft Excel spreadsheet.
- Microsoft Excel files will be used as it is compatible with most statistical packages. SPSS files (.csv) will be compiled to support data analysis.
- PDF files may also be used to securely store participant consent forms.

How will the data be documented and described?

- What contextual details are needed? e.g. a written description of the data collection and analysis methods; dictionary of variable labels and values (e.g. category labels)
- How will you document this? e.g. in the project write-up; in a 'readme' text file alongside the dataset(s)

- Data will be reported and described within the results section of the final project write-up. This will likely be presented using a range of written descriptions, summary tables and visual graphs.
- The results will be analysed in line with the study's aims and research questions using SPSS. Descriptive statistics will be used to summarise participant characteristics and participant outcome measures. Inferential tests will be used to comment on pre- and post- intervention changes.

How will you manage ethics, governance and intellectual property?

- How will you safeguard the privacy of research participants? e.g. via informed consent (state if consent for future data sharing will be sought)
- What organisational approvals will you obtain?
- If any intellectual property is to be generated in the project, how will this be managed? e.g. if you are developing a novel questionnaire or a software app

- Prior to participation, all participants will provide electronically signed informed consent. The consent form will outline the purpose of the study, procedures, potential risks and benefits, confidentiality and rights to take part voluntarily or withdraw at any stage.
- Participants will be asked to provide consent for their data to be shared with the local team for potential applications to secondary research. This will be optional and not a requirement for participation in the study.
- Participants will be assigned unique identification numbers, and no identifiable information will appear in the study. Any identifiable data will be stored securely on the NHS shared drive, which is only accessible to the lead researcher and research team. While data will be kept for the duration of the study, it will be deleted afterwards unless the participant has consented to future data sharing.
- Approval will first be obtained from the University of Glasgow. Following approval, ethics approval will then be sought from the West of Scotland Research Ethics Service, and then finally being signed off by the Head of Research at the Golden Jubilee University National Hospital to ensure compliance with information governance requirements.
- Intellectual property generated from the study (e.g., treatment manuals) will be owned by NHS Golden Jubilee and Golden Jubilee University National Hospital.

What are the plans for data sharing and access?

- Who is expected to use the completed dataset(s) and for what purpose?
- How will the data be developed with future users in mind? e.g. use of widely used or open source file formats
- How will you make the data available? e.g. deposit in a data repository; forward copies on request; create website
- If there are no plans for data sharing an appropriate justification must be provided

- The research team will use the anonymised dataset for analysis. The lead researcher will record these results within their doctoral thesis, which will be made available via the University of Glasgow.
- The findings will be shared with members of the Scottish Adult Congenital Cardiac Service (SACCS), academic conferences and submitted for publication in a peer-reviewed journal. Plain language summaries will also be provided to participants who completed the study.
- An anonymised version of the dataset will be deposited in the University of Glasgow's Enlighten data repository.

What is the strategy for long-term preservation and sustainability?

- How will you store and back-up the data? e.g. University server with automatic back-up; University OneDrive account
- What are the plans for sustainability? e.g. choose open-source file formats; deposit in data repository
- Which repository/data centre have you identified as a place to deposit your data? e.g. Enlighten; Open Science Framework
- How will you prepare data for preservation and sharing? Indicate the time and resource required for this
- How and when will you transfer ongoing responsibility for preservation/archiving to your University Supervisor?

- All data will be stored on a secure NHS shared drive, which is only accessible to the lead researcher and research team.
- An anonymised version of the dataset will be deposited in the University of Glasgow's Enlighten data repository to ensure long-term preservation and accessibility.
- Once the study is complete and the lead researcher completes their DClinPsy course, responsibilities for data preservation will transfer to the University Supervisor. Prior to this handover, the lead researcher will prepare a final cleaned and anonymised dataset. All remaining data will be clearly organised and identifiable.
- The lead researcher will have retain access to the data for a limited period post-qualification to prepare and submit the research to a peer-reviewed journal.

Version Control v2 – Approved by Jessica Fish (26th September 2022)

Appendix 3: Health and Safety Plan**HEALTH AND SAFETY FOR RESEARCHERS**

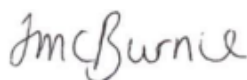
1. Title of project	A Randomised Controlled Feasibility Trial Exploring an Interoceptive-Based Intervention in Patients with Congenital Heart Disease
2. Trainee	Jason McBurnie
3. University Supervisor	Dr Lynne Johnston
4. Other Supervisor(s)	Dr Klaudia Suchorab and Dr Deirdre Holly
5. Local Lead Clinician(s)	Dr Klaudia Suchorab and Dr Deirdre Holly
6. Participants (age, group or sub-group, pre- or post-treatment, etc)	Participants will be current patients of the Scottish Adult Congenital Cardiac Service (SACCS) at the Golden Jubilee University National Hospital (GJUNH) based in Glasgow. Eligible individuals will be aged 18 or over and must provide informed consent to take part in the study. Once consent is obtained, participants will be randomly assigned to either the intervention group or waitlist control group.
7. Procedures to be applied (e.g. questionnaire, interview, etc)	Following recruitment, participants will be randomly assigned to either the intervention group or waitlist control group. All participants will complete baseline measures using an online survey platform prior to beginning the intervention. Participants in the intervention group will engage in sessions remotely and will be asked to complete outcome measures, as well as an acceptability and feasibility questionnaire, during the final session of the intervention. Participants in the waitlist group will be informed that they will be contacted again in eight weeks to complete follow-up measures prior to beginning the intervention. This

	timing will coincide with the ending of the intervention group. Participants will also be asked to complete outcome measures and the acceptability and feasibility questionnaire during their final session.
8. Setting i) Where will procedures be carried out?	The intervention will be delivered entirely online via Microsoft Teams, with participants joining from home. At least one member of the research team will be based at the GJUNH.
ii) Are home visits involved?	No
9. Potential risk factors identified (see table overleaf) a. Participants b. Procedures c. Settings	A) The participant group is not expected to be associated with dangerous or unpredictable behaviour. To manage any potential distress, two researchers will be present during each session. If needed, one researcher will be available to contact any participant individually via telephone or private communication channels on Microsoft Teams to provide appropriate support. B) As the intervention has not been delivered previously with this population, it is possible that its content may cause some level of frustration or emotional discomfort for participants. To mitigate this, a clear rationale and explanation of procedures will be provided during the consent process and before commencing the intervention. During sessions, researchers will monitor participants for signs of distress and be available for individual support via telephone or private communication channels on Microsoft Teams. In cases of ongoing distress, participants will also be signposted to appropriate support services. C) As sessions will be delivered remotely, participants will likely be engaging with the intervention from their home. Some home environments may have a lack of privacy or

	potential for external distractions. To help manage this, researchers will encourage participants to join from a private and quiet area of their home where they are less likely to be disturbed.
10. Plan for mitigating risk (for researcher and participant safety) a. Participants b. Procedures c. Settings	A) Participants will be taking part in an online group setting with other participants and the researchers. If technical issues arise, participants will be offered basic guidance on how to navigate Microsoft Teams. Should any participant become disconnected, researchers will assist with helping the participant rejoin the session. To promote a safe and respectful environment, clear expectations around confidentiality and ground rules for participating will be agreed in the first session and upheld across the entire intervention. The researchers will monitor group dynamics and intervene if any interpersonal difficulties arise within the group. During sessions, participants will be encouraged to engage during group discussions, however they will not be pressured to contribute or share personal experiences. Participants will also be reminded to join sessions from a private area of their home, as sensitive discussions may take place. If participants experience distress during a session, they will be offered individual support with one of the researchers and signposted to appropriate services. B) Participants will complete measures individually at various points during the intervention using a secure online platform. Data will be stored in a secure NHS share drive folder, which will have access restricted to members of the research team to ensure confidentiality. All responses will be anonymised, and any identifiable data will be stored separately from response data. Participants will be reminded that they have the right to withdraw from the study at any

	time without giving a reason. To promote safety and comfort, participants will be encouraged to consider the most suitable time and environment to practice intervention activities between sessions. C) Participants will be asked to join from a quiet location (ideally their home or another suitable and private space). It is recognised that some participants may not have access to complete privacy within shared living environments. To protect confidentiality, participants will be advised to use headphones where possible to reduce the risk of sensitive discussions being overheard by others.
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Trainee signature:



Date: 17.11.25

University Supervisor signature:



Date: 18.11.25

Appendix 4: Equipment Cost Form

RESEARCH EQUIPMENT, CONSUMABLES AND EXPENSES

Trainee Jason McBurnie.....

Year of Programme 2..... **Intake Year**.....2024.....

Please refer to latest **stationery costs** list and **departmental test** list (available on Moodle)

Item	Details and amount required	Cost (or state if to request to borrow from department)
Stationery	1x ream (500 sheets) white paper: £3.97 1x box of envelopes (A4): £21.41 1x box of labels: £20.39	Subtotal: £45.77
Postage	32x freepost per letter: £0.93 each	Subtotal: 29.76
Photocopying and printing	104x B&W photocopy/printing (5p each)	Subtotal: £5.20
Equipment and software		Subtotal:
Measures		Subtotal:
Travel		Subtotal:
Miscellaneous	32 x participant intervention booklet: £5 each including postage.	Subtotal: £160

Total		£240.73
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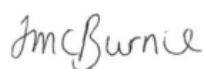
For any total request over £200 please provide further justification for all items that contribute to a high total cost estimate. Please also provide justification if costing for an honorarium for participants:

While only 32 envelopes and labels are required for the study, these items do not appear to be available in smaller quantity options, which partially contributes to the higher total cost.

Additionally, each participant will require a printed copy of the intervention booklet, and this will need to be posted to them. Predicted costs for printing and postage of intervention materials are based on estimates from a previous MRP project involving similar procedures (Moore, 2025)

MRP Project: Moore, D. (2025). *Exploring the contribution of psychology in the self-management of pulmonary hypertension* (Doctoral dissertation, University of Glasgow).

It is hoped the intervention material will be available electronically as a PDF, however a physical copy may still be necessary to ensure accessibility.



Trainee signature:

Date: 17.11.25

University Supervisor signature:



Date: 18.11.25

Appendix 5: Plain Language Summary

Title

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

Background

People born with heart problems often face physical, emotional and social challenges that can affect their mental wellbeing and quality of life.

Interoception means noticing and understanding signals from inside your body, like your heartbeat or breathing. Research shows that better body-awareness may help people with long-term health conditions feel better emotionally and handle everyday life.

Aims and Questions

The study aims to create a new kind of body-awareness activity and see if it is suitable and acceptable for people to take part in. It also looks at how many people stayed in the study and finished questionnaires. Researchers want to see if it could help with anxiety, depression, quality of life and body-awareness.

Methods

Participants

Adults receiving care from the Scottish Adult Congenital Cardiac Service (SACCS) will be invited to take part.

Recruitment

Study posters with the lead researcher's contact details and a QR code will be in SACCS waiting areas. Patients can email or scan the QR code to receive an information sheet and link to the online consent form. The lead researcher will also attend weekly clinics to support access to study materials and talk with patients. SACCS staff may inform patients and direct them to the poster or materials.

Consent

Participants can follow the emailed link or scan the QR code to sign an online consent form.

Participants can withdraw from the study at any time, and this will not affect the care they receive from SACCS.

Design of study

This will be a randomised controlled feasibility study. Participants will be placed randomly into one of two groups. One group will start the intervention early; the other (waitlist) group will receive it later.

Data collection

Participants will complete a questionnaire about their experiences of the group. They'll also fill out short surveys on anxiety, depression, health-related quality of life and body-awareness.

Ethical Issues

A research plan will be reviewed by the University of Glasgow. Approval will then be sought from the West of Scotland Research Ethics Service. A confirmation letter will be shared with the Head of Research at the Golden Jubilee University National Hospital to ensure data protection.

Each participant will get a special code instead of using their name. Personal information will be stored on a secure NHS drive, accessible only to the research team. All identifiable data will be deleted after the study is completed and published.

Practical Applications and Dissemination

The results will help researchers understand if body-awareness activities can benefit people with heart problems. It will guide how many people might be needed for a larger future study.

A plain language summary of the results will be emailed to everyone who completed the study. Results will be shared with the SACCS team, submitted to scientific journals and presented at academic conferences.

Word count: 477

Appendix 6: Reflexivity Form

‘Reflexivity is the process of engaging in self-reflection about who we are as researchers, how our subjectivities and biases guide and inform the research process, and how our worldview is shaped by the research we do and vice versa’ (Wilkinson, 1988).

Jamieson and colleagues (2023) created a list of prompts to support researchers to incorporate reflexivity into their research process. Some of the questions below have relatively clear-cut answers, whereas others will be more complex and nuanced.

Reflexivity Prompts (adapted from Jamieson et al., 2023)

Stage of research	Broader reflexivity prompts
Research question and design	• Why do I want to research this group? • To what extent am I “within” the participant group that I am researching? Am I an “insider” or “outsider” researcher (or do I occupy both positions?) • What can I give to this group? Who is represented within the research team?
Data collection	• Am I intruding on this group? How can I make this as non-coercive as possible? • How can I make this research accessible to the population? • Do participants understand what their data will be used for? • Have I thought beyond traditional ethics? Am I acting ethically? • Could my collection methods be problematic?
Data analysis and interpretation	• Am I aware that people have given me this data and that they may not know me (e.g., survey, health, admin data)? • Who are these people behind the data? • If I am using existing datasets, are there any silent assumptions in this dataset? • Could my analysis of the dataset reproduce existing inequalities?
Conclusions and framing	• How does my use of evidence reflect my biases (or the biases of the research team) as researchers and as individuals with their own life, wants, emotions, needs? • What do I gain from this research? What does the population I have studied gain? • Is there a disconnect between the two questions above? If so, consider the first few questions in this table again.

Please provide a short statement describing how you will consider the above reflexivity prompts as the project progresses (e.g. plans for discussing with supervisors, recording in research log, considering relevance to systematic review plans too, etc). Some of the prompts may be of more relevance to you and your project than others. You do not need to address every prompt listed above.

This statement will not contribute to your grade but is designed to be a starting point for self-reflection and dialogue with your supervisor around these issues. **Please remember that this will form part of your portfolio to be uploaded to a public website as part of the open science requirement on the programme.** There is no fixed word limit for this section, but it is suggested that you write around 200-300 words.

At the outset, I acknowledge I am an outside researcher with respect to the congenital heart disease (CHD) population, as I do not share the lived experience of participants. However, through undertaking a specialist placement and direct involvement in delivering the proposed intervention, I anticipate that I will develop a deeper understanding of the group's experiences and unique context. It will therefore be important to maintain awareness of my position throughout the duration of the study. Reflections on how my assumptions, experiences and professional background influence the research process will be documented within a research log to ensure transparency and reflexive practice.

I am aware that participation requires considerable effort and a degree of openness from participants and aspects of data collection may feel personal. To ensure autonomy, participants will be reminded throughout the intervention that their participation will be voluntary, and they can choose to withdraw at any time. Participants will be fully informed on how their data will be stored, analysed and used. To enhance accessibility, the intervention will include plain language materials, be delivered online and scheduled flexibly (e.g., daytime or evening group sessions) to align with participants' availability and commitments. As some tasks or discussions may be emotionally challenging, feedback will be sought from clinicians and patients within the service to ensure clinical appropriateness of the resources.

Quantitative analysis will be conducted in line with an agreed data analysis plan. A research log will be maintained to document decision-making processes and any reflections on potential biases within the data. This will also be discussed further with supervisors to provide appropriate clinical oversight. The findings will be reported accurately and framed to acknowledge the limitations of the data and approach.

References

- Jamieson, M. K., Govaart, G. H., & Pownall, M. (2023). Reflexivity in quantitative research: A rationale and beginner's guide. *Social and Personality Psychology Compass*, 17(4), e12735. <https://doi.org/10.1111/spc3.12735>
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