Exploring the Contribution of Psychology in the Self-Management of Pulmonary Hypertension

Derick Moore, M.A. Hons, MSc

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School of Health and Wellbeing

College of Medical, Veterinary and Life Sciences

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Chapter 1

The use and impact of psychoeducation in exercise-based interventions for people with pulmonary hypertension: a systematic review

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Abstract

Objectives

Exercise-based interventions have been successfully used in adjunction to medicines in cardiopulmonary conditions. Psychoeducation is a core component of these interventions. Despite initial reservations, exercise has gained more attention as a possible intervention in pulmonary hypertension (PH). It is unclear to what extent psychoeducation is used as part of these interventions. The aim of this review is to critically appraise literature on the use of psychoeducation in PH exercise-based interventions, including its contents, delivery and outcomes.

Methods

Six electronic databases were systematically searched on 9th September 2024 to identify published studies of any study design where psychoeducation was used within exercise-based interventions for individuals with PH. Eligible studies were quality assessed and due to heterogeneity of study designs and measures, a narrative synthesis was completed.

Results

Twelve articles were eligible, with a total of 476 participants. A variety of psychoeducation was used across studies, with the majority including relaxation and motivational approaches. There was limited information regarding specific contents of psychoeducation and its delivery. All studies showed significant improvements in aspects of physical health. Nine of the 12 studies incorporated a health-related quality of life (HRQoL) measure, with eight finding significant improvements. Two papers included psychological measures, with one finings significant improvements.

Conclusions

Psychoeducation has been included in twelve exercise-based interventions in PH. Details on its contents and delivery are variable and limited. The studies show promising results i.e. improved physical, psychological and HRQoL outcomes. Future studies require clarification on how psychoeducation can be most effectively used as part of exercise-based interventions in PH. This would help inform clinical practice and treatment guidelines.

Introduction

Pulmonary Hypertension (PH) is a rare, progressive and life-limiting condition, affecting 15-50 people per million (NHS England., 2013). It is characterised by increased blood pressure in the pulmonary arteries, which, if left untreated, can cause right heart failure (Ruopp & Cockrill., 2022). PH is most commonly diagnosed between the ages of 50 and 65 years (Orem, 2017), more prevalent in women (female-to-male ratio of around 4:1), with approximately 10% of those 65 or older affected (Hoeper et al., 2016; Mair et al., 2014). There are five primary types of PH, each with different causes and prognoses (Mandras et al., 2020). Individuals typically experience fatigue, shortness of breath, and significantly impaired exercise capacity, which impairs their quality of life (QoL; Rawlings et al., 2022). Physical limitations in PH are also associated with a number of negative psychosocial issues, including anxiety, depression, and social isolation (Ennis et al., 2023; Rawlings et al., 2020).

There is currently no cure for PH and life expectancy varies depending on the type and severity of the condition, on average ranging between two to six years (NHS Digital, 2023). Available treatments can alleviate symptoms and slow disease progression (Radegran et al., 2016), however, individuals often remain symptomatic, despite achieving optimal medical therapy (Ruopp and Cockrill., 2022). Exercise-based interventions have been successfully used in adjunction to pharmaceutical treatments in other cardiopulmonary conditions. For example, Xavier et al. (2021) completed a systematic review of 17 studies with 2332 participants on the impact pulmonary rehabilitation has on individuals with chronic obstructive pulmonary disease, finding improvements in physical ability (reduced levels of dyspnoea and increased walking distances) as well as health-related quality of life (HRQoL). Similar findings have also been indicated in coronary heart disease (Dibbern et al., 2023). Interestingly, it is uncommon for studies, and therefore reviews, to include psychological outcomes within exercise-based interventions for PH, which is surprising given that physical activities have been shown to improve anxiety and depression (Nakazato et al., 2021) and therefore, this is an area that requires further exploration. In PH, exercise-based interventions have traditionally been met with caution due to concerns that exercise may exacerbate symptoms (Mereles et al., 2006). Given the success of these interventions in other cardiopulmonary conditions, exercise has more recently gained attention in PH. Emerging studies have found exercise-based interventions to be safe and associated with significant improvements in exercise capacity,

cardiorespiratory fitness and QoL (Yan et al., 2021 & Zeng et al., 2020). Consequently, clinical guidelines have been revised to include exercise therapy as part of recommended care for PH (Humbert et al., 2022).

Psychoeducation has been a core element of exercise-based interventions in various cardiopulmonary conditions (Popa-Velea & Purcarea., 2014). It has been incorporated as part of these interventions as it has been shown to improve physical and psychological outcomes by challenging illness perceptions, facilitating behavioural change and promoting psychological well-being (Aldcroft, Taylor Blackstock & O'Halloran., 2011; Zoeckler et al., 2014).

Psychoeducation in exercise-based interventions for cardiopulmonary conditions has been defined as "multimodal, educationally based, self-help treatment programs that employ information based material and cognitive-behavioural strategies to promote positive behaviour change" (Aldcroft et al., 2011, p. 274). To reviewer's knowledge, there is no specific definition of psychoeducation used in similar PH research, therefore for the purpose of this review, the Aldcroft's et al.'s (2011) definition will be adopted. A variety of psychoeducation methods have been used as part of exercise-based interventions and rehabilitation programmes for cardiopulmonary conditions with positive results. Aldcroft et al., 2011 systematically reviewed seven articles, including 213 participants to further understand the impact psychoeducation has on behaviour change in Coronary Artery Disease, finding significant improvements in physical activity levels when compared to simply exercise education. Cojocariu et al (2021) shared similar results when reviewing 11 acute coronary syndrome articles, finding improvements not just in behaviour and physical health, but also QoL and psychological variables (including anxiety and depression). Common psychoeducational topics used in exercise-based interventions include self-monitoring, self-management, problem solving, motivation and praise (Aldcroft et al., 2011) as well as cognitive behavioural strategies, motivational interviewing and mindfulness (Cojocariu et al., 2021).

The delivery of exercise-based intervention in cardiopulmonary conditions has been inconsistent with regards to staff roles and qualifications (Crozier et al., 2024). For example, Williams et al. (2023) has recommended that cardiac rehabilitation should be delivered by

nurses, psychologists, occupational therapists and dieticians; each playing a specific role within the intervention. Others, however, have suggested that there is no need for as many professionals to be involved, stating that only one profession is required, and that this can still have positive results (Selzler et al., 2021). It has been suggested that those who deliver psychoeducation receive specialist training and are trained professionals in the associated area they are working in (Palli., 2017). Some studies however, identified potential barriers to staff implementing psychoeducation as part of routine care, including lack of confidence, insufficient time and limited knowledge/training (Wileman et al., 2023). For future service planning and delivery, it would be useful to gain insight into who would be best suited to deliver psychoeducation as part of an exercise-based intervention for PH and identify relevant training needs for staff.

To the researcher's knowledge, this is the first systematic review exploring the use and impact of psychoeducation in exercise-based interventions for PH. It is hoped that this review will inform clinical practice and ultimately treatment guidelines, by providing valuable insights into how psychoeducation might be incorporated as part of these interventions and what elements of it could be important to clinical outcomes.

Review aims:

1. To summarise and critically appraise the use of psychoeducation in exercise-based interventions in PH.
2. To determine who delivers the psychoeducation as part of the exercise-based intervention.
3. To explore the physical, psychological and HRQoL outcomes of these interventions.

Method

This systematic review has been conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA; Page et al., 2021) and the protocol was registered to PROSPERO (ID: CRD42024592045).

Due to the heterogeneity of study designs and measures used, a meta-analysis systematic review was not able to be carried out, and so a narrative synthesis approach has been used to analyse data.

Search Strategy

Using the PEO (Population, Exposure, Outcomes) framework, a systematic search was conducted on 9th September 2024 by the lead researcher. Key words were searched for in titles and abstracts across the following databases: Embase, Medline, Psychinfo, Pubmed, Web of Science and Clinical Trials. The search strategy was developed by performing a scoping search and identifying key terms commonly used in existing literature. Disease terms (concept 1) and intervention terms (concept 2) were linked using *'AND'.* Additional support for this was also sought from a clinical expert in the area and a librarian at the University of Glasgow. Table 1.1 details the search terms used.

Table 1.1: Search Terms

Concept 1	*'AND'*	Concept 2
"PAH OR PH OR pulmonary hypertension OR pulmonary artery hypertension OR pulmonary arterial hypertension"		"Intervention OR exercise* OR rehab* OR education OR therapy OR program* OR psycho* OR behav* OR self-help OR self-help OR conditioning"

Study selection

All peer-reviewed studies investigating exercise-based interventions in adults with PH were eligible for inclusion. No restrictions with regards to study designs or publication date were implemented, due to the expectation that a limited number of studies would be identified. Due to the lack of specific definitions for psychoeducation in exercise-based interventions for PH, Aldcroft et al. (2011) definition as stated previously will be used. This was a worldwide review, with no limitations by region, state or cultural setting, however, only English language studies were included.

Results from the search were exported from data sources and stored using the referencing package 'Zotero'. After duplications were removed, titles and abstracts of all articles identified by the initial search were screened by the lead researcher using the criteria presented in Table 1.2. A Random 10% of these papers were also screened by a second reviewer. Full text reviews were then conducted for the eligible studies and 25% of these were again screened by the second reviewer. Any disagreements were resolved via a discussion between the lead researcher and second reviewer until an agreement was reached.

Table 1.2: Inclusion and exclusion criteria based on the PEO tool

	Inclusion	Exclusion
Population	Adults (aged 18 years and over) diagnosed with any form of PH.	Children under the age of 18 years. Any individual who does not meet criteria for a diagnosis of PH.
Exposure	The use of an exercise-based intervention to manage the symptoms of PH. Within the text, studies must mention a form of psychoeducation that was incorporated.	If no exercise-based intervention has been implemented. No mention of psychoeducation.
Outcome	Physical outcomes. Psychological outcomes QoL outcomes.	

PH = Pulmonary hypertension, QoL = Quality of life

Data extraction

Data was extracted in a structured way from each eligible study by recording, where available, the following information 1) name of the first author, 2) year of publication, 3) country of origin, 4) type of study design, 5) number of participants, 6) age of participants, 7) gender of participants, 8) type of psychoeducation used, 9) clinician(s) delivering psychoeducation, 10) intervention attrition rate, 11) study outcomes (including physical, psychological and HRQoL if relevant) and 12) group comparator.

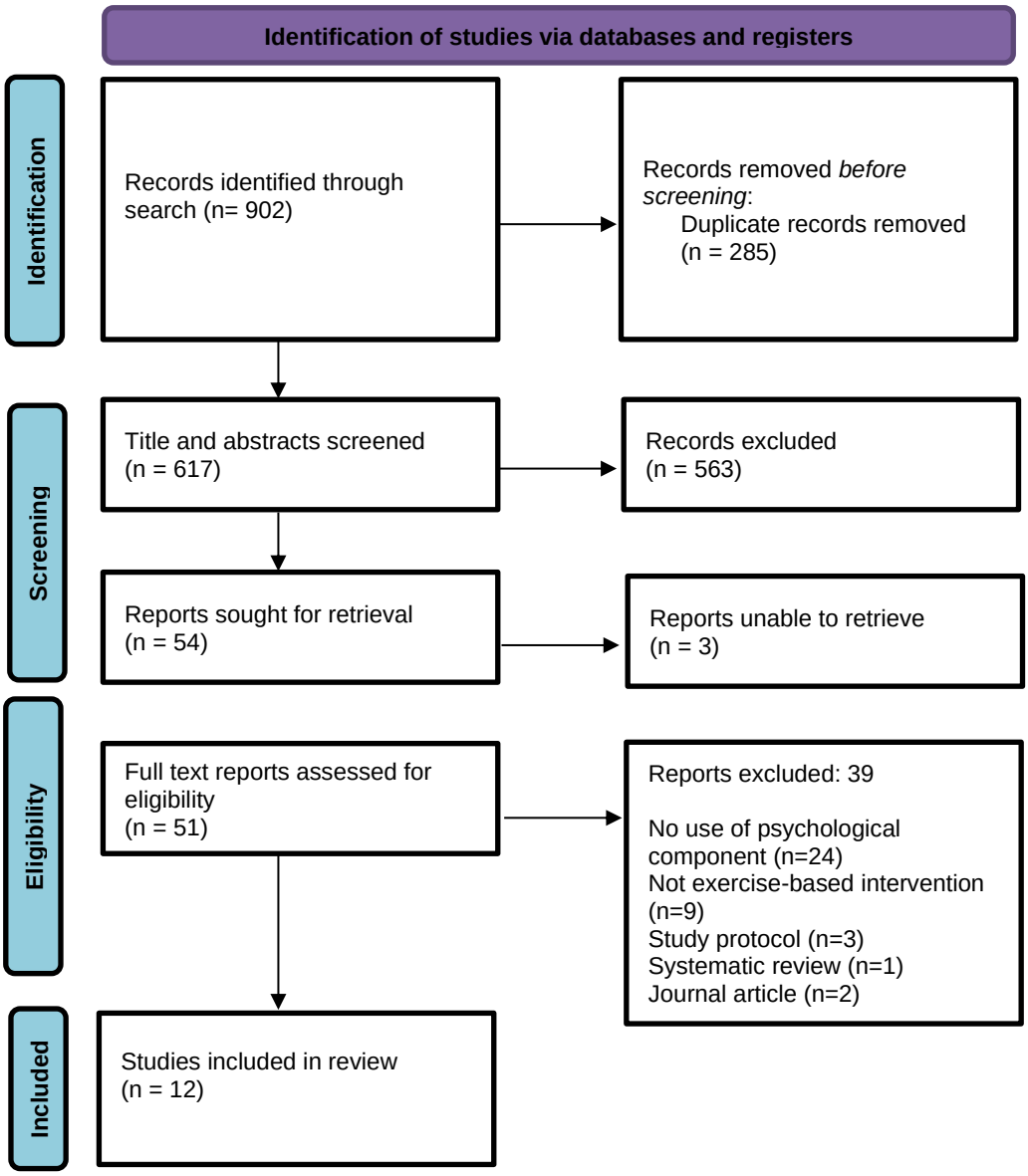
Quality Assessment

The Mixed Methods Appraisal Tool (MMAT; Hong et al., 2018) was used to assess the quality of eligible studies. This tool was chosen as it can synthesise data from differing study designs (e.g. randomised control trials and non-randomised control trials). The MMAT critically appraises papers via a series of five methodological quality criteria, depending on the study design, as well as two screening items. Reviewers respond to each criteria using a 'yes', 'no' or 'can't tell'. Similar to existing reviews (McDonald., 2024), a rating from 0-14 was given to each eligible study, where two points were attributed to a 'yes' response, one to a 'can't tell' response and zero to a 'no' response. Papers were then ranked based on their overall quality rating. Study quality was described as 'poor' for scores 1-7; 'moderate' for scores 8-11, and 'good' for scores 12-14 was moderate and 12-14 was considered to be of good methodological quality (McDonald., 2024). Three (25%) of the eligible studies were also rated with the MMAT by the second reviewer. Any disagreements between the reviewers were discussed until a consensus was reached.

Results

A total of 902 papers were identified. After removing duplicates, 617 titles and abstracts were screened using the eligibility criteria. Fifty-four papers were eligible for full screening. Three papers were subsequently unable to be retrieved and were therefore removed. Of the remaining 51 papers, 12 met the inclusion and exclusion criteria and were included in this review. An illustration of this process can be seen in figure 1.1 below.

Figure 1.1: PRISMA Flow Diagram



Study Characteristics

Table 1.3 provides information on general characteristics and demographics of each included study, which were published between 2006 and 2022. Five were located in Germany (Becker-Grunig et al., 2013; Ehlken et al., 2016; Kabitz et al., 2014; Mereles et al., 2006; Nagal et al., 2012), two in the USA (Chan et al., 2013; Hemnes et al., 2021) and one in each of the following countries: Japan (Fukui et al., 2016), Israel (Fox et al., 2011), Australia (Chia et al., 2011), Latvia (Butane, Spilva-Ekerte, Skride & Smite, 2022). One study had multiple sites across Europe (Grunig et al., 2020). Seven of the papers were randomised control trials (RCT; Ehlkin et al., 2016; Butane et al., 2022; Chan et al., 2013; Chia et al., 2022; Grunig et al., 2020; Hemnes et al., 2021; Mereles et al., 2006; Nagel et al., 2012), two were non-randomised control trials (Fox et al., 2011; Fukui et al., 2016) and three were prospective in design (Becker-Grunig et al., 2013; Kabitz et al., 2013). Of the nine papers including comparison groups, seven were control, treatment as usual groups (Mereles et al., 2006; Fox et al., 2011; Ehlken et al., 2016; Fukui et al., 2016; Grunig et al., 2020; Hemnes et al., 2021; Butane et al., 2022), one was a home walking group (Chan et al., 2013) and one was an education group (without exercise; Chia et al., 2022)

The total number of participants across all twelve studies was 476, with the largest study including 129 participants (Grunig et al., 2020) and the smallest including seven participants (Kabitz er al., 2013). The mean age across studies was 56 years, with the youngest average being 47 years (Hemnes et al., 2021) and the oldest being 68 years (Fukui et al., 2016). Females accounted for 73% of all participants, with only Nagel et al.'s (2012) study including less females than males (46% female).

Six of the studies included participants diagnosed with Pulmonary Arterial Hypertension (PAH; Fox et al., 2011; Becker-Grunig et al., 2013; ; Kabitz et al., 2014; Hemnes et al., 2021; Butane et al., 2022; Chia et al., 2022), two included those diagnosed with Chronic thromboembolic pulmonary hypertension (CTEPH; Nagal et al., 2012; Fukui et al., 2016), two include any form of PH (Mereles et al., 2006; Chan et al., 2013) and two included both PAH and CTEPH (Grunig et al., 2020; Ehlken et al., 2016). Participants in seven of the studies were community dwelling (Fox et al., 2011; Becker-Grunig et al., 2013; Chan et al., 2013; Grunig et al., 2020; Hemnes et al., 2021; Butane et al., 2022; Chia et al., 2022) and five were initially inpatients, before

completing the intervention at home (Mereles et al., 2006; Nagal et al., 2012; Kabitz et al., 2014; Ehlken et al., 2016; Fukui et al., 2016).

Table 1.3: Study Characteristics (in chronological order)

Author, year and country	*Study design*	*Study population (type of PH and where intervention was based)*	*Number of participants*	*Age (years)* ±SD	*Gender (% Female)*
Mereles et al. 2006 Germany	RCT	Any PH type. Inpatient 3 weeks then community dwelling 12 weeks	30	50 ±13	10 male, 20 female (67%)
Fox et al. 2011 Israel	Non-R CT	PAH. Community dwelling	22	52 ±12	7 male, 15 female (68%)
Nagel et al. 2012 Germany	Prospective single arm	CTEPH. Inpatient first 3 weeks Community dwelling 12 weeks	35	61 ±15	19 male,16 female (46%)
Becker-Grunig et al. 2013 Germany	Prospective single arm	PAH. community dwelling	20	48 ±11	4 male,16 female (80%)
Chan et al. 2013 USA	RCT	Any PH type. Community dwelling	26	54 (SD not presented)	26 female (100%)
Kabitz et al. 2013 Germany	Prospective single arm	PAH. Inpatient first 3 weeks then community dwelling for 12 weeks	7	60 ±11	3 male, 4 female (57%)
Ehlken et al. 2016 Germany	RCT	PAH, CTEPH. Inpatient first 3 weeks then community dwelling	87	56 ±15	40 male, 47 female (54%)
Fukui et al. 2016 Japan	Non-R CT	CTEPH. Inpatient hospital 1 week then community dwelling	41	68 ±33	11 male, 30 female (73%)
Grunig et al. 2020 multiple European sites	RCT	PAH OR CTEPH. Community dwelling	129	54 ±12	35 male, 94 female (73%)
Hemnes et al. 2021 USA	RCT	PAH. Community dwelling	42	47 ±18	6 male, 36 female (86%)
Butane et al. 2022 Latvia	RCT	PAH. Community dwelling	21	67 (SD not presented)	2 male, 19 female (90%)
Chia et al. 2022 Australia	RCT	PAH. Community dwelling	16	54 ±15	3 male, 13 female (81%)

SD = Standard deviation, PH = pulmonary hypertension, PAH = Pulmonary arterial hypertension, CTEPH = Chronic thromboembolic pulmonary hypertension

Quality Assessment

The quality of each study was assessed using the Mixed Methods Appraisal Tool (MMAT; Hong et al., 2018) due to heterogeneous methods and designs. Table 1.4 summarises the quality assessment results for RCTs and table 1.5 for non-randomised studies. Overall, eleven of the twelve papers were deemed to be of good quality and the remaining one (Ehlken et al., 2016) of moderate quality.

Quantitative randomised control trials

Six of the seven RCTs were deemed to be of good quality and one of moderate quality. Of the good quality, three papers (Butane et al., 2022; Hemnes et al., 2021 and Mereles et al., 2006) scored 14 (maximum score), with randomisation appropriately performed and fully detailed. These papers also had comparable groups at baseline, completed outcome data, successful blinding of assessors to the intervention and participants adhering to the intervention. Of the remaining three good quality studies (Chan et al., 2013; Chia et al., 2022 and Grunig et al., 2020), similar strengths were found, with some differences. Grunig et al's study did not blind assessors to the intervention due to its complex set-up across multiple sites. Chia et al (2022) did not discuss in any detail whether groups were comparable at baseline (it was also a pilot study, with difficulties in recruitment, highlighting the need for further research), and Chan et al. (2013) did not discuss the randomisation of participants in any detail and therefore, it was unclear if it was appropriately performed.

The only study that was rated as moderate in quality was by Ehlken et al. (2016). The authors did not discuss the randomisation of participants in enough detail, only stating they were randomly assigned to a control group and a training group and were also unable to blind assessors to the primary outcomes (changes in peak oxygen consumption). It should be noted however, that assessors were blinded for secondary outcomes (6-minute walk test, HRQoL, cardiac index and WHO functional class).

Quantitative non-randomised studies

All five of the non-randomised studies were deemed to be of good quality. Two were non-randomised control trials (Fox et al., 2011 and Fukui et al., 2016) and three were prospective, single arm studies (Becker-Grunig et al., 2013; Kabitz et al., 2013 and Nagel et al., 2012). Only

Fox et al. (2011) was judged to have met all the criteria, including (1) participants being representative of the target population, (2) having appropriate measurements for the intervention and outcomes, (3) having complete outcome data, (4) accounting for confounding variables in the design and analysis, and (5) administering the intervention as intended. The remaining four papers met most of these criteria, with the exception of explicitly discussing if or how confounders were accounted for in the design and analysis.

Table 1.4: Results for Quality Appraising of Randomised Control Trials using the MMAT (in chronological order)

Author and Year	*Screening questions: Are there clear research questions? Do the collected data allow to address the research question?*	*Is randomisation appropriately performed?*	*Are the groups comparable at baseline?*	*Are there complete outcome data?*	*Are outcome assessors blinded to the intervention provided?*	*Did the participants adhere to the assigned intervention?*	*Rating (/14)*
Mereles et al. (2006)	YY	Y	Y	Y	Y	Y	14 Good
Chan et al. (2013)	YY	CT	Y	Y	Y	Y	13 Good
Ehlken et al. (2016)	YY	CT	Y	Y	N	Y	11 Moderate
Grunig et al. (2020)	YY	Y	Y	Y	N	Y	12 Good
Hemnes et al. (2021)	YY	Y	Y	Y	Y	Y	14 Good
Butane et al. (2022)	YY	Y	Y	Y	Y	Y	14 Good
Chia et al. (2022)	YY	Y	CT	Y	Y	Y	13 Good

Y = Yes (2 points), CT = Can't tell (1 point), N = No (0 points)

Table 1.5: Results for Quality Appraising of Non-Randomised Studies using the MMAT (in chronological order)

Author and Year	*Screening questions: Are there clear research questions/Do the collected data allow to address the research question?*	*Are the Participants representative of the target population?*	*Are measurements appropriate regarding both the outcome and intervention?*	*Are there complete outcome data?*	*Are the confounders accounted for in the design and analysis?*	*During the study period, is the intervention administered as intended?*	*Rating (/14)*
Fox et al. (2011)	YY	Y	Y	Y	Y	Y	14 Good
Nagel et al. (2012)	YY	Y	Y	Y	N	Y	12 Good
Becker-Grunig et al. (2013)	YY	Y	Y	Y	N	Y	12 Good
Kabitz et al. (2013)	YY	Y	Y	Y	N	Y	12 Good
Fukui et al. (2016)	YY	Y	Y	Y	N	Y	12 Good

Y = Yes (2 points), CT = Can't tell (1 point), N = No (0 points)

Synthesis of Results

Key findings are presented in table 1.6.

What psychoeducation is incorporated in exercise-based interventions for individuals with PH?

There was a range of psychoeducation used within the included studies, with the majority of papers only briefly mentioning its inclusion.

Butane et al. (2022) and Nagel et al. (2012) discussed psychoeducation in the greatest detail. Butane et al's. (2022) intervention included relaxation techniques (such as breathing exercises and progressive muscle relaxation), body awareness training (noticing possible warning signals from the body and skills to manage these) and ways to manage stress and setbacks. In a previous study, which Butane et al. (2022) paper was a continuation of, authors reported that these components were incorporated into the program to offer encouragement and to improve how well participants can manage disease symptoms and daily life (Butane et al., 2021). Nagel et al. (2012) stated that 'psychological interviews' were offered to all study participants. These interviews could be attended twice a week with the option of participants involving their partners if they wished. Interviews covered a range of topics to better understand the impact PH can have on families, partners and careers. The goal of these interviews was to develop more positive approaches to coping with PH. In addition to this, group 'relaxation sessions' were offered to all participants up to twice a week, which involved progressive muscle relaxation.

Five of the twelve studies (Becker-Grunig et al., 2013; Ehlken et al., 2016; Grunig et al., 2020; Kabitz et al., 2013; Mereles et al., 2006) used the same exercise-based intervention and therefore presumably the same psychoeducation. All stated that 'mental training' was given to improve participants' perception of their abilities and limits. In addition to this, participants were offered psychological support if required. No further information could be obtained to identify specifically what type of 'mental training' and psychological support was offered.

Chia et al. (2022) stated that participants received three semi-structured psychology sessions with a qualified psychologist. These sessions lasted 20 minutes each and included education

on how to manage hyperventilation and anxiety during breathlessness. Cognitive Behavioural Therapy (CBT) was also given to support participants with dyspnoea as well as progressive muscle relaxation.

Chan et al. (2013) had limited information on psychoeducation used. It was reported that participants in both the intervention group (education plus exercise) and control group (just education) received weekly one-hour education sessions for ten weeks. These sessions covered a range of topics, including relaxation techniques, panic control, social well-being and breathing re-training. No information could be identified to further explore what specific techniques were used.

Very little information regarding psychoeducation was given in Fox et al.'s (2011) study, beyond stating that "participants were supported medically and psychologically as required and given encouragement throughout the program" (p.197).

In the online supplementary materials, Fukui et al. (2016) reported that in addition to the exercise training, participants received education, lifestyle guidance, counselling and psychological support by the multidisciplinary team throughout the study period. No further details were disclosed to suggest what these supports were specifically.

Hemnes et al. (2021) stated that their automated exercise-based intervention (where participants received text-based updates with the aim of improving their daily step count) was rooted in the behavioural change theory. Messages received by participants were described as encouraging, aiming to improve participants' motivation and compliance with the intervention. No details were provided on the aspects of behavioural change theory used and the contents of these text-based updates.

Who delivered the psychoeducation?

Psychoeducation was delivered by a psychologist in one study (Chia et al., 2022), an automated system in another study (Hemnes et al., 2021), and a mix of physiotherapists and/or physicians in the remaining ten studies (Mereles et al., 2006; fox et al., 2011; Nagel et

al., 2012; Becker-Grunig et al., 2013; Chan et al., 2013; Kabitz et al., 2013; Ehlken et al., 2016; Fukui et al., 2016; Grunig et al., 2020; Butane et al., 2022). No papers described the training or qualifications these clinicians have received to deliver psychoeducation, other than Nagel et al (2021) who stated that the physicians were specialised in rehabilitation medicine.

How effective were the interventions?

To answer this question, results have been separated into 'physical', 'HRQoL' and 'psychological' outcomes. The attrition rates of the included studies have also been included in table 7. The mean attrition rate for all studies was 17%, ranging between 37% (Nagel et al., 2021) to 0% (Kabitz et al., 2013).

Physical outcomes

All twelve papers identified significant findings in elements of physical outcomes. The most common outcome measure used to identify improved aerobic capacity was the 6 minute walk test (6MWT), with nine of the studies finding significant improvements for those who completed the exercise-based intervention (Becker-Gruing et al., 2013; Ehlken et al., 2016; Butane et al., 2022; Chan et al., 2013; Fox et al., 2011; Grunig et al., 2020; Kabitz et al., 2013; Mereles et al., 2006; Nagel et al., 2012). Two studies did not find a significant improvement on the 6MWT (Hemnes et al., 2021; Fukui et al., 2016), and one study (Chia et al., 2022) did not include this outcome. Six studies also measured the maximum amount of oxygen absorbed and used during exercise (peak oxygen consumption). Five studies found significant improvements in oxygen consumption post-intervention (Becker-Grunig et al., 2013; Ehlken et al., 2016; Fox et al., 2011; Fukui et al., 2016; Nagel et al., 2012) and one did not (Chan et al., 2013). Haemodynamic measures (assessing how well blood can flow through arteries and veins) were recorded in two papers, with one finding positive results following the exercise-based intervention (Ehlken et al., 2016) while the other did not (Fukui et al., 2016).

HRQoL outcomes

Two studies did not include measures relating to HRQoL outcomes (Fox et al., 2011; Kabitz et al., 2013;). Nine Papers incorporated a variety of HRQoL measures, including the Short Form-

36 (Mereles et al., 2006; Nagel et al., 2012; Becker-Grunig et al., 2013; Chan et al., 2013; Ehlken et al., 2016; Fukui et al., 2016; Grunig et al., 2020; Hemnes et al., 2021), emPHasis-10 (Hemnes et al., 2021), and CAMPHOR (Chia et al., 2022). Eight studies found significant improvements in HRQoL following the exercise-based intervention (Becker-Gruing et al., 2013; Ehlken et al., 2016; Chan et al., 2013; Chia et al., 2022; Grunig et al., 2020; Hemnes et al., 2021; Mereles et al., 2006; Nagel et al., 2012) and one did not (Fukui et al., 2016). Although not described specifically as a HRQoL measure, Butane et al. (2022) incorporated the 'Impact on Participation and Autonomy Questionnaire (IPA; Cardol et al., 2001) in their study and found significant improvements in participants who completed the exercise-based intervention. The IPA measures participation and autonomy by assessing five main domains: 1) autonomy indoors, 2) family role, 3) autonomy outdoors, 4) social relations, and 5) work and education opportunities. (Cardol et al., 2001). The measure was included to its similarity to other HRQoL measures described above.

Psychological outcomes

Only two studies measured specific psychological components (anxiety and depression) using standardised questionnaires (DASS, Chia et al., 2022; PHQ-9, Fukui et al., 2016). Chia et al. (2022) found significant improvements in symptoms of anxiety and depression in participants who completed the exercise-based intervention. Fukui et al. (2016) found no significant improvements in depression scores between the intervention and the control group.

Table 1.7: Key findings (in chronological order)

Author and year?	*Psychoeducation used*	*Clinician who delivered psychoeducation*	*Comparator*	*Attrition rate (%)*	*Summary of main findings*
Mereles et al. 2006	Mental training to improve perception of abilities and limits. Psychological support (unspecified)	Physical therapists and physicians	Control (TAU)	17%	Participants training groups significantly improved 6MWT (mean difference between groups was 111m; *p*= .001). WHO functioning class improved from 2.8±0.6 to 2.3±0.4 after 15 weeks, with no change in the control group (*p*=.001). Peak oxygen consumption at anaerobic threshold significantly improved when compared to control (*p*<.050) and achieved workload (*p*<.050). Compared to control group, training group also significantly improved physical (p=.003) and mental (*p*=.027) components of HRQoL measure (SF-36) as well as subscale scores of physical functioning (*p*=.018), role-physical (*p*=.003), social functioning (*p*=.002), mental health (*p*=.017) and vitality (*p*=.001). No Psychological measures presented.
Fox et al. 2011	Psychological support and encouragement given (unspecified)	Physiotherapist	Control (TAU)	32%	Participants in the training group significantly improved 6MWT (mean increase = 32m) when compared to the control group (mean decreased by 26m; *p*= .003). Peak oxygen consumption also significantly improved when compared to the control group (*p*<.050) No HRQoL or psychological measures presented.

Nagel et al. 2012	Twice weekly psychological interviews, Progressive muscle relaxation.	Physicians	N/A	37%	Participants significantly improved 6MWT after 15 weeks (mean increase 61±54; *p*= .001) when compared to pre interventions scores. Peak oxygen consumption also significantly improved (*p*= .003). HRQoL significantly improved for SF-36 sub scores of physical functioning (*p*= .041) and vitality (*p*= .03). No psychological measures presented.
Becker-Grunig et al. 2013	Mental training to improve perception of abilities and limits. Psychological support (unspecified)	Physical therapists and physicians	N/A	25%	Participants significantly improved 6MWT after 15 weeks (mean increase 67±59, *p*= .001). Peak oxygen consumption also significantly increased (*p*=.002). HRQoL significantly improved for SF-36 sub score bodily pain (*p*= .050) No psychological measure presented.
Chan et al. 2013	Panic control. Relaxation. Breathing retraining. Pacing and social well-being	Unknown	Education only (without exercise)	12%	Participants in exercise and education group significantly improved in 6MWT (mean increase 56±45m; *p*= .002) and increased time to exercise intolerance 1.9±1.3 min; *p*= .001). HRQoL significantly improved for the exercise and education group in six SF-36 subscales: physical functioning (p= .009), role-physical (p= .023), general health (p= .002), vitality (p= .002), social functioning (p= .016) and mental health (p= .028). Five scales on the CAMPHOR also significantly improved: Quality of life (p= .003), symptoms (p= .005), energy (p= .008). breathlessness (p=.041) and mood (p=.032). No improvements in education only group and no psychological measures presented.

Kabitz et al. 2013	Mental training to improve perception of abilities and limits. Psychological support (unspecified).	Physical therapists and physicians	N/A	0%	Participants significantly improved 6MWT (mean increase 81±30m, *p*= .012) as well as respiratory muscle strength (*p*=.037). No HRQoL or psychological measures presented.
Ehlken et al. 2016	Mental training to improve perception of abilities and limits. Psychological support (unspecified)	Physical therapists and physicians	Control (TAU)	18%	Participants in the intervention group significantly improved 6MWT (mean increase 29±53m, *p*= .002). Peak oxygen consumptions (*p*= .001) and cardiac index during exercise (*p*= .002) also significantly improved. HRQoL significantly improved for SF-36 sub score vitality (*p*= .036). No psychological measure was presented.
Fukui et al. 2016	Counselling and psychological support (unspecified)	Physical therapists and cardiologists	Control (TAU)	27%	Participants significantly improved peak oxygen consumption (*p*= .010) and heart failure symptoms (*p*= .010). No significant changes in HRQoL as assessed using SF-36. No changes in depression symptoms as assessed using PHQ-9.
Grunig et al. 2020	Mental training to improve perception of abilities and limits. Psychological support (unspecified)	Physical therapist	Control (TAU)	10%	Participants in training group significantly improved 6MWT (mean increase 34.1±8.3m, *p*= .001) and peak oxygen consumption (*p*= .048) when compared with the control group. Compared to the control group, the training group also significantly improved mental health (*p*=.001) component of a HRQoL measure (SF-36). No Psychological measure was presented.

Hemnes et al. 2021	Text message-based encouragement	Automated text message	Control (TAU)	5%	Participants in the exercise group significantly improved step count (mean = 1409 steps) compared to the control group (mean = 149, *p*=.020). No significant difference found in 6MWT between groups. Compared to control group, exercise group also scored significantly higher in HRQoL using the EmPHasis-10 measure (*p*= .046), however not in the SF-36. No psychological measure was presented.
Butane et al. 2022	Relaxation techniques including breathing and progressive muscle relaxation. Body awareness training. Self-control, managing stress and Improving motivation	Physiotherapists	Control (TAU)	5%	Participants in training group significantly improved 6MWT (mean increase 94.7±8.3m, *p*= .001). No specific HRQoL measure used, however similar measure (IPA) found significantly positive results. No psychological measures were presented.
Chia et al. 2022	3x 20-minute counselling sessions	Psychologist	Home walking programme	19%	Significant improvements in handgrip strength (*p*= .032) and peak oxygen consumption (*p*= .050). no significant different in 6MWT. Significant improvements in exercise group for HRQoL measured by CAMPHOR (*p*= .040). Significant improvement in depression (*p*= .011) and anxiety symptoms (*p*= .043) measured by DASS-21.

6MWT = six-minute walk test, SF-36 = Short Form-36, IPA = Impact on participation and autonomy questionnaire, CAMPHOR = Cambridge pulmonary hypertension outcome review, DASS-21 = Depression anxiety stress scale-21, N/A = Not applicable, TAU = Treatment as usual, WHO = World health organisation, M = meters, PHQ-9 = patient health questionnaire-9, IPA = Impact on Participation and Autonomy Questionnaire

Discussion

This review presents the first systematic synthesis of studies exploring the psychoeducation within exercise-based interventions for PH. Across the included studies, the average age (56 years) and gender-split (73% female) were generally similar to epidemiological studies in PH (50-65 years, Orem., 2017; 75% female, Mair et al., 2014). The most common type of PH included in the studies was PAH, which is also the most common type overall (50-60% of all cases; Hoeper et al., 2016). These factors which suggest that the sample was representative of the larger population. Results also indicate that exercise-based interventions with psychoeducation are safe within a community setting. The average attrition rate for all included studies was 17%, which is lower than some exercise-based interventions in similar areas (chronic obstructive pulmonary disease; 26% Ryrso et al., 2018).

Psychoeducation is a core component of exercise-based interventions for many cardiopulmonary conditions (Wiles et al., 2014) and has been broadly defined as education-based and self-help strategies, including information-based and cognitive-behavioural strategies, aimed at promoting behavioural change (Aldcroft et al., 2011). The current review indicated that there is no consistent definition of psychoeducation used as part of PH studies. Future research including psychoeducation as part of exercise-based interventions in PH may wish to specifically define this term to improve consistency of its use and inform the development of clinical practice in this area. Overall, the available studies show a great variability with regards to what psychoeducation is incorporated in these interventions, often lacking sufficient detail to standardise this approach and to inform the current clinical practice. Psychoeducation ranged from text-based encouragement (Hemnes et al., 2021) to evidence-based psychological interventions, such as CBT (Chia et al., 2022). Most studies included unspecified support in regard to elements of relaxation as well and improving motivation to engage in the intervention (Mereles et al., 2006; Nagel et al., 2012; Becker-Grunig et al., 2013; Chan et al., 2013; Kabitz et al., 2013; Ehlken et al., 2016; Grunig et al., 2020; Hemnes et al., 2021; Butane et al., 2022). Although it is positive that interventions are beginning to incorporate psychoeducation, more research is needed to fully understand specifically what is useful and how best to incorporate them. Due to the lack of current literature in this area, it is important that psychoeducation is recorded in more detail in future studies so that an evidence base can be created and, with time, expanded. This is particularly

important as existing literature in other areas (coronary artery disease; Aldcroft et al., 2011 and acute coronary syndrome; Cojocariu et al., 2021) supports the view that by incorporating psychoeducation, improvements in adherence to physical activity can be made due to increased motivation and ability to overcome barriers (Knittle et al., 2018). The included papers appear to give limited attention to defining the components of psychoeducation delivered as part of exercise-based interventions in PH. Future studies may benefit from incorporating existing checklists and guidelines, e.g. TIDieR, to comprehensibly describe the intended psychoeducation and the remaining contents of the proposed interventions (Hoffman et al., 2016). Behavioural change is the intended outcome for the exercise-based interventions in PH and other cardiopulmonary conditions. Future research can therefore also incorporate recognised and explicitly defined behaviour change techniques from existing taxonomies, e.g. the Behaviour Change Technique Taxonomy (Michie et al., 2013).

There was also a lack of detail provided by all papers within this review in regard to who delivered psychoeducation as part of exercise-based interventions in PH. Only one study included a psychologist to deliver the psychoeducational component (Chia et al., 2022). One study used an automated text-system rather than a clinician (Hemnes et al., 2021). The remaining ten studies included either a physiotherapist and/or unspecified physician, which is in line with previous suggestions that psychoeducation should be delivered by appropriately trained professionals within a particular medical area (Palli, 2017). Given the limited information included in the studies, it is unknown what, if any, specialist training physiotherapists and physicians received to deliver psychoeducation. Ensuring that staff are appropriately trained has been shown to improve treatment fidelity and outcomes (Wiltsey-Stirman, 2022), therefore it would be important for future studies to record training/qualifications of the clinicians who deliver psychoeducation as part of exercise-based interventions. This can also highlight future training needs and requirements for staff within clinical settings.

All studies included in this review recorded significant improvements in a wide range of physical outcomes, including 6MWT and peak oxygen consumption. Nine of the twelve studies also measured HRQoL, with eight finding significant improvements in at least some domains (Becker-Gruing et al., 2013; Ehlken et al., 2016; Chan et al., 2013; Chia et al., 2022; Grunig et al., 2020; Hemnes et al., 2021; Mereles et al., 2006; Nagel et al., 2012) and one did

not (Fukui et al., 2016). Only two studies (Fukui et al., 2016; Chia et al., 2022) explored specific psychological outcomes, with only one showing significant improvements in anxiety and depression (Chia et al., 2022).

These results suggest that the interventions had a positive influence on participants, however, it is currently unknown what, if any, specific contribution psychoeducation had to these outcomes. Existing exercise-based interventions for individuals with PH that do not include specific psychological components show similar positive results in regard to physical, QoL, psychological outcomes (Pandey et al., 2015; Kagioglou et al., 2021) as well as attrition rate (Gonzalez-Saiz et al., 2017). Literature in other cardiopulmonary conditions, such as acute coronary syndrome indicates, however, that adding psychoeducation to exercise-based interventions improves physical, QoL and psychological outcomes. Future studies comparing exercise-based interventions with and without psychoeducation for individuals with PH would shed further light on the usefulness of this approach

Limitations

The major limitation of this review, which has already been discussed, is that it was not possible to compare exercise-based interventions including psychoeducation with exercise-based interventions without psychoeducation. Due to this, authors are unable to further explore the specific impact psychoeducation may have on these interventions. Future research should specify in more detail whether or not exercise-based interventions incorporated psychoeducation so that this can be further explored.

Another limitation was the variable, often scarce, detail on the specific psychoeducation used as part of the studies and the clinicians involved in the delivery of these interventions. These prevented any conclusions on what aspects of psychoeducation should be included as part of exercise-based interventions in PH, how they should be delivered and what training should be available for staff involved. Future studies aiming to clarify these issues would be useful in further informing the current clinical practice and expanding the available evidence base.

Also, due to the large heterogeneity of psychoeducation and measures used within the included papers, a meta-analysis could not be performed and instead, a narrative synthesis

was adopted. It is hoped that the growing evidence base within this field will allow a more detailed and in-depth analysis in the future.

The representativeness of the findings may have been impacted by the review's inclusion criteria, specifically its focus on studies written in English, with most studies being from western countries. This precluded any exploration of socio-cultural factors from other cultures.

Finally, a limitation was the significantly reduced time the lead researcher had in carrying out the review. A different topic was planned to be reviewed, with the review proposal and initial search terms developed. Four months before the deadline, a review with similar aims was published, without first being published on PROSPERO and so a new topic was required. Time pressures therefore may have impacted this review and influenced overall results. Future reviews should, to the best of their ability, ensure that there is sufficient time to complete each stage fully and, in enough depth, to ensure the best possible search and analysis.

Conclusion

The current review is the first of its kind to examine what psychoeducation is incorporated into exercise-based interventions for individuals with PH. The current findings point to a small number of studies including this component, with large variability in the delivery methods. The specific details of psychoeducation are often not discussed in full therefore at present it is unclear what components of psychoeducation might be useful to these interventions and how they can inform the current clinical guidelines. Due to lack of information, the current review has also been unable to make any definitive conclusions in regard to the effect psychoeducation has on outcomes of exercise-based interventions for PH, although these interventions have shown positive improvements in physical, psychological and HRQoL outcomes. It is hoped that future studies will build on the current evidence base by adding more detailed accounts of psychoeducation and its delivery within the exercise-based interventions for this population, allowing to standardise these interventions with time and better examine their impact on symptom management

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Chapter 2

The Relationship Between Interoception and Psychological Outcomes: A Randomised Controlled Feasibility Trial Exploring a Mind-Body Intervention in Patients with Pulmonary Hypertension

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Plain Language Summary

Title

The Relationship Between Interoception and Psychological Outcomes: A Randomised Controlled Feasibility Trial Exploring a Mind-Body Intervention in Patients with Pulmonary Hypertension.

Background

Pulmonary Hypertension (PH) is a rare and life-limiting disorder which can negatively impact individuals' anxiety, depression, and health-related quality of life (HRQoL). Interoception is the ability to perceive the internal state of the body and there is an emerging area of research that suggests interoceptive interventions can improve the ability to interpret signals within the body, which in turn can improve psychological outcomes.

Aims and Questions

This project aimed to develop a new interoceptive-based intervention and explore the feasibility and acceptability of it. Additional aims included identifying attrition rate and rate of completed measures whilst also examining preliminary effectiveness of the intervention for improving interoception and the impact of this on participant's anxiety, depression, and HRQoL.

Methods

Participants

Participants were patients under the care of the Scottish Pulmonary Vascular Unit (SPVU) at the Golden Jubilee University National Hospital, Scotland, who were diagnosed with any form of PH of any severity.

Recruitment

Participants were informed of the study by posters in the hospital and staff in the SPVU. Online information was also available.

Consent

Participants gained access to study information and digitally consented via an online survey website (Microsoft Forms) to be contacted by the lead researcher. Once participants had been contacted and agreed to participate, another online consent form was completed. Participants were reminded throughout the study that they could withdraw at any time.

Design of Study

The study was a randomised controlled feasibility study with participants being randomly allocated to either the intervention or waitlist (control) group.

Data Collection

Participants virtually completed standardised measures to self-report on their levels of interoception, anxiety, depression, and HRQoL before the first group began their intervention and repeated these again after their intervention was complete. At this point, the intervention group also completed a feasibility and acceptability questionnaire developed by researchers.

Main findings and Conclusions

An eight-week, online group intervention was developed using existing literature and support from an expert clinical psychologist in the area. The intervention was well-received by all participants. All participants were likely to recommend the intervention to others with PH and felt that it was useful to them overall. The majority of participants also felt that the intervention improved their mind-body connection (88.8%), HRQoL (88.8%), symptoms of anxiety (77.7%) and depression (66.6%). The attrition rate was found to be 37.5%, with 100% completed measures. Self-report measures suggested that interoception increased after the intervention, however, there was no change in mood or HRQoL. An increase in anxiety was

found, although this was within the mild clinical range. Due to the higher-than-expected drop-out rate, results should be read with caution.

The intervention was found to be safe, acceptable and feasible with the preliminary results suggesting that a positive impact to the participants' interoceptive ability may have occurred. However, as this is a very early piece of research, a much larger trial is needed to further examine the impact this intervention may have.

Abstract

Introduction

People with Pulmonary Hypertension (PH) are at an increased risk of hypervigilance and fatigue, which can impact emotional well-being and health-related quality of life (HRQoL). Existing research has shown that interoceptive-based interventions (IBIs) have improved emotional wellbeing and quality of life within those with long term health conditions. Therefore, current researchers developed and tested the acceptability, feasibility and preliminary effectiveness of a novel IBI for adults with PH.

Methods

Participants were randomised into an intervention (n=16) or waitlist (n=16) group. Interoception, anxiety, mood and HRQoL were measured pre- and post-intervention and a feasibility and acceptability questionnaire was completed post-intervention. Feasibility and acceptability data was mostly descriptive, and t-tests were carried out to answer additional research questions.

Results

An eight-week IBI was developed, with all (100%) participants finding it helpful and were likely to recommend it. The majority of participants felt that the intervention improved mind-body connection (88.8%), HRQoL (88.8%), symptoms of anxiety (77.7%) and depression (66.6%). Improvements in interoception was found in the intervention group, however no changes in mood or HRQoL. Anxiety was found to have increased, however fell within the 'mild' clinical range. A higher-than-expected attrition rate (37.5%) was found and therefore analysis was underpowered, and results should be interpreted with caution.

Conclusions

The intervention was found to be safe, acceptable and feasible. The results of this study will hopefully inspire larger scale studies on the effectiveness of IBIs in PH and build on the growing evidence base of these interventions in chronic physical health conditions.

Introduction

Pulmonary Hypertension (PH) is a rare and life-limiting disorder, affecting 15-50 people per million (NHS England., 2013). It is characterised by increased blood pressure in the pulmonary arteries, which, if left untreated, can cause right heart failure (Ruopp & Cockrill., 2022). PH is most frequently diagnosed in patients aged between 50 and 65 years (Orem, 2017), with a female to male ratio of four to one (Mair et al., 2014). Life expectancy varies depending on the type and severity of PH, with an average of two to six years (NHS Digital, 2023). Although there are five types of PH (Mandras et al., 2020), symptoms across all variants of the disease remain the same, with breathing difficulties and fatigue being most prominent (Rawlings et al., 2022). Currently, there is no cure for PH with medication only alleviating symptoms and often having side effects, such as headaches and generalised pain (e.g., Yaghi et al., 2020). The condition and side effects from treatment can negatively affect individuals' health-related quality of life (HRQoL; Armstrong et al., 2019).

Pulmonary Hypertension is often reported to be a 'hidden' disease, and as a result, misdiagnosis and delays are not uncommon. Many patients in the UK can wait two years from first experiencing a symptom to diagnosis; and, on average, more than four doctors are seen before the PH diagnosis is made (Armstrong et al., 2019). Following diagnosis, individuals report a reduction in quality of life and physical functioning, and many express confusion, uncertainty, and frustration regarding their physical health (Rawlings et al., 2020). Patients can face additional stressors, such as financial difficulties (due to being unable to work), social withdrawal and reduced activities (Rawlings et al., 2020). Given these difficulties, people diagnosed with PH are more likely to have higher levels of depression (28%; Mai et al., 2022) and anxiety (37.1%; Mai et al., 2022) than the general population (depression 11.3%; Arias de la Torre et al., 2021; anxiety 6%; The Priory Group, 2025). The prevalence of depression and anxiety in PH patients is similar to other life-limiting conditions, such as cancer (depression 27.9% and anxiety 35.2%; Zeilinger et al., 2022) and epilepsy (depression 23.6% and anxiety 27.4%; Kanner et al., 2023). Individuals with PH who report higher levels of anxiety and depression tend to have lower HRQoL (Liao et al., 2021).

Specialised psychological support for PH offers the potential to improve emotional well-being and HRQoL (e.g., Shields et al., 2020), however, despite high rates of depression and anxiety

in this population, less than one in four individuals receive psychological treatment (Bussotti &Sommaruga., 2018) and the research in this area remains limited (Rawlings, Novakova, Armstrong and Thompson., 2023). This highlights the need to further develop psychological interventions that can help individuals with PH improve their emotional well-being and HRQoL.

Interoception

Interoception is broadly defined as the ability to perceive the internal states of the body, more specifically, the process of sensing, interpreting, integrating and regulating. This process is complex and relies on bidirectional communication between the brain and internal organs (Chen et al., 2021). Interoception is important in maintaining homeostasis to ensure that the body is able to survive and function correctly (Mulder et al., 2024). This varies from simple processes, such as perceiving and acting on feelings of thirst, to more complex interactions that can inform our decision-making process, often described as 'a gut feeling' (Dunn et al., 2010).

Impaired interoception has been linked to a number of mental and physical health conditions. Existing literature has suggested that changes in brain networks involved in interoception have been found in conditions, such as heart failure, chronic pain and diabetes (Locatelli et al., 2023) as well as mental health conditions, such as anxiety, depression, PTSD, OCD and eating disorders (Heim et al., 2023; Brewer, Murphy and Bird., 2021; Khalsa et al., 2018).

Interoceptive interventions

Interoceptive-based interventions (IBIs) have emerged with the aim of improving interoceptive abilities. These can involve exposing individuals to potentially uncomfortable bodily sensations, with the goal of reappraising and regulating them (interoceptive exposure; Boettcher & Barlow., 2019). Other interventions may train people to increase their accuracy to notice the internal states within the body with techniques such as mindfulness (Fischer et al., 2017).

Heim et al (2023), conducted the first systematic review of IBIs, finding evidence for the use of these treatments in many disorders, including physical health conditions, such as irritable bowel syndrome, fibromyalgia and chronic pain. Although there is currently no specific

evidence base for IBI in PH, research has indicated impaired processing of internal bodily signals for those diagnosed with the condition. For example, a thematic synthesis of qualitative studies on adults' experiences of living with pulmonary hypertension has found that uncertainty around bodily sensations is often associated with perceptions of threat leading to increased hypervigilance and fear of bodily sensations (Rawling et al., 2020). This in turn can precipitate and perpetuate both psychological and physiological distress which can lead to a development of unhelpful coping behaviours, such as reassurance seeking and increased worry (Rawlings et al., 2020). Additionally, fatigue, which is a common symptom in PH (Rawlings et al., 2020), has been shown to be associated with impairments in interoception (Eggart, Valdes-Stauber and Heinze., 2023). Increased fatigue in PH can lead to a loss of meaningful activities, which in turn trigger and maintain symptoms of depression (Rawling et al., 2020). Finally, interventions focused on the regulation of internal states, such as slow breathing, have been shown to improve physical symptoms in other respiratory conditions, such as chronic obstructive pulmonary disease (COPD; Raupach et al., 2008) and when used with those with PH have improved depression, sleep disturbances and HRQoL (Matura et al., 2017).

Aims and Research Questions

The primary aim of this study was to develop an IBI for those with PH. A secondary aim was to deliver the IBI, examining its feasibility and acceptability. Additional questions can be seen below:

Additional Research Questions

- What was the overall attrition rate for the intervention?
- What was the rate of completed measures?
- Were there changes in interoception when comparing patient scores pre- and post-intervention
- Were there changes in interoception when comparing intervention and waitlist group?
- Were there changes in anxiety, depression and HRQoL when comparing patient scores pre- and post-intervention,

- Were there changes in anxiety, depression and HRQoL when comparing intervention and waitlist group?
- What sample size would be required for future studies based on current effect-sizes?

Method

Design

The design of the study was a randomised controlled feasibility trial and was conducted in accordance with CONSORT guidelines (Appendix 2:1; Elridge et al, 2016). Data was collected between August-December 2024, with recruitment running from June-October 2024. The lead researcher randomised the participants to either the intervention or the waitlist group using an online randomiser (RANDOM.ORG - List Randomizer). All participants were asked to complete a series of measures at baseline and after the intervention group completed their intervention. Neither the participants nor the researchers were blinded to group allocation.

Ethical approval was obtained from the London-Westminster Research Ethics Committee (Appendix 2.3) and the NHS Golden Jubilee (Appendix 2.3). The study was also registered at clinicaltrials.gov: NCT06443580.

Development of the interoceptive based intervention

Due to time constraints, the researchers were unable to adapt a specific framework to developing the current IBI. However, in line with the existing guidelines, e.g. the medical research council framework (Skivington et al., 2021), the following steps have been considered: (1) the identification, contextualisation and deepened understanding of the problem, mainly via review of clinical experience and existing literature (Rawlings et al., 2020), (2) the review of published studies (e.g. Heim et al., 2023) to identify the effectiveness of previously developed IBIs and techniques that may be useful for the planned intervention, and (3) the synthesis of available evidence and theories to identify useful techniques for the PH population and develop an overarching model for the proposed intervention, (as evidenced by the intervention topic guide and resource pack) and (4) the feedback sought

from participants as part of the intervention to inform future developments, its usefulness to participants and applicability outside of the clinical context.

Participants

Participants for the study were recruited from the Scottish Pulmonary Vascular Unit (SPVU) at the Golden Jubilee University National Hospital, Scotland. To be eligible, participants were required to: be aged over 18 years; have a diagnosis of any form of PH; be fluent in English; and be able to commit to the study period. Participants were excluded from the study if they: had current thoughts of self-harm and suicide; presented with comorbid alcohol or substance misuse; and/or were receiving psychological interventions at the time of the study.

Procedure

Participants were recruited from the SPVU clinics using convenience sampling to ensure the sample number was achieved. Study posters were displayed in SPVU waiting areas, and paper copies of participant information sheets were freely available in these areas. SPVU clinicians outlined the study to potential participants and directed them to the study materials if they expressed interest. Individuals could then scan a QR code from the participant information sheet, which took them to an online form (Microsoft Forms) where they would consent to being contacted by the lead researcher and leave their contact information. The lead researcher then contacted the potential participants to answer any questions about the study and complete a screening questionnaire, a demographic form and a consent form to participate in the study. Finally, they were emailed their participant number and a link to baseline measures, which they were asked to complete. Participants were emailed by the lead researcher again once they were randomised into either the intervention or the waitlist group to inform them of their allocation

It was decided that there would be two intervention groups and two waitlist groups. This was to appropriately balance the estimated samples size from power calculations as well as balance an appropriate number of participants in each group to encourage behaviour change and positive group cohesion, as found in previous online, group-based psychological interventions (Preuhs, Velderman and Empelen., 2023). Two cycles of recruitment were

performed due to time constraints, meaning that groups could begin whilst recruitment for the next cycle was ongoing.

Participants were informed of the start date and emailed a resource pack. The waitlist groups were informed that they would be contacted by the lead researcher once the intervention group is finished to arrange for the same intervention to be delivered to them.

Once the intervention group was finished, both the intervention and the waitlist groups repeated the measures, with the intervention group completing an additional feasibility and acceptability questionnaire developed by the researchers. The waitlist group was then informed of when their own start date for the intervention and emailed the same resource pack by the researcher.

Measures

To obtain clinical information, participants were asked to complete a demographic form, which included their date of birth, ethnicity, gender, highest academic qualification and GP details.

Feasibility and Acceptability Questionnaire. A questionnaire was developed by researchers to collect information regarding feasibility and acceptability of the intervention. Participants were asked about the online research forms, different aspects of the intervention including its format, setting and delivery; the usefulness of the shared materials and resources; the level of support received and the helpfulness of the intervention in improving their levels of interoception, anxiety, depression and HRQoL. The participants were also asked whether they would recommend this intervention to others with PH. Questions were structured as statements and participants were asked to rate how much they agree with each statement on a five-point Likert scale ('strongly agree', 'agree', 'neither agree nor disagree', 'disagree' and 'strongly disagree'). Participants also had an option to include additional comments at the end of the questionnaire.

Multidimensional Assessment of Interoceptive Awareness- Version 2 (MAIA-2; Mehling et al., 2018). This self-report measure includes 32-items split into eight subscales of interoception: (1) noticing, (2) not-distracting, (3) not-worrying, (4) attention regulation, (5) emotional awareness, (6) self-regulation, (7) body listening and (8) trust. Participants rate each item on

a six-point Likert scale (0= 'never' to 6= 'always'), with average scores for each subscales ranging from 0-5, where higher scores indicating more awareness of bodily sensations. This measure has been widely used in research and has been shown to be reliable, including for those with a long-term health condition (Mehling et al., 2018) and has been shown to detect effects of interventions aimed at interoception (Eggart et al.,2021).

The Generalised Anxiety Disorders Scale (GAD-7; Spitzer et al., 2006) is a self-report measure that has been widely used to assess symptoms of generalised anxiety in primary care settings. This scale has shown good reliability and construct validity (Johnson et al., 2019). It consists of seven items which are scored on a four-point Likert scale (0 = 'not at all' to 4 = 'nearly every day'). Scores range from 0-21, with 0-4 indicating minimal anxiety, 5-9 indicating mild anxiety, 10-14 indicating moderate anxiety and more than 15 indicating severe anxiety.

Patient Health Questionnaire 9 (PHQ-9; Kroenke et al., 2001) is a self-report measure that has been widely used to assess symptoms of depression in primary care settings. This scale has been shown to have good psychometric properties (Johnson et al., 2019). It consists of nine items which are scored on a four-point Likert scale (0 = 'not at all' to 4 = 'nearly every day'). Scores range from 0-27, with 0-4 indicating no depression, 5-9 indicating mild, 10-14 indicating moderate, 15-19 indicating moderately severe and 20-27 indicating severe.

emPHasis-10 (Lewis et al., 2021) is a ten item self-report questionnaire, which has been specifically designed to measures HRQoL in PH patients. This measure has been routinely used in clinical practices and in previous PH research (Rawling et al., 2022; Odevoglu et al., 2018). Items are scored on a six-point Likert scale. Scores range from 0-50, with higher scores indicating lower levels of HRQoL.

<u>Sample Size</u>

Various authors have suggested different rules of thumb for estimating sample sizes in feasibility and pilot studies. These have ranged from 10, (Kieser et al., 1996) to 35 participants per arm (Teare et al., 2014). A recent review (Totton et al., 2023) of 761 UK-based studies has found that 99% met the smaller recommended number of participants per arm (Kieser et al., 1996) but none met the larger one (Teare et al., 2104). Julious (2005) has suggested a minimum of 12 participants per arm based on the rationale of feasibility as well as the mean

and variance precision. The researchers decided to adopt this recommendation for the current study as the sample size of 24 seemed feasible given the time constraints and practicalities of the recruitment. This was true even after the decision was made to revise the number of participants to 32 to account for the average dropout rate of 31% found in online psychological interventions (Melville et al., 2010). As this is the first study of its kind in PH, it was also important to avoid over-recruitment in an already clinically vulnerable population, if, for whatever reason, the planned intervention was found not to be beneficial to the participants.

Data Analysis

For analysis, incomplete data from participants who dropped out of the study were removed.

Descriptive analysis was used to examine the acceptability and feasibility of the intervention.

Attrition rate and the rate of completed measures were calculated using percentages.

Dependent t-tests were used to explore pre- and post-intervention changes in interoception, anxiety, depression and HRQoL.

Independent t-tests were used to explore between-group changes in interoception, anxiety, depression and HRQoL.

Effect sizes were estimated using Cohen's *d* and classified as small (*d* = 0.2), medium (*d* = 0.5) and large (*d* ≥ 0.8; Sullivan and Feinn., 2012).

Results

Primary Research Question: Development of an IBI for individuals with PH

The intervention was developed by the lead researcher with support from a clinical psychologist with expert knowledge of PH, working within the SPVU. In the initial stages, the lead researcher reviewed existing literature on PH focusing on the links between the body

and mind. Two key themes emerged as a result of this: 1) that uncertainty around bodily sensations is associated with a sense of threat in PH and 2) that fatigue is associated with difficulties in balancing energy reserves, which may lead to loss of meaningful activities and negatively impact psychological outcomes (Rawlings et al., 2020). The second stage included reviewing existing IBIs in the literature. Despite not having access to full interventions, researchers were able to identify a number of interoceptive based techniques (e.g. Briggs & Holland., 2023; Heim et al., 2023) that were adapted for the present population. The final stage considered the way of introducing interoception to participants, emphasising its relevance in day-to-day life, including emotions and behaviours. After discussions with the expert clinical psychologist, the final agreed layout included the topics and session aims listed in table 2.1.

Online delivery was decided in an attempt to minimise potential barriers of engagement (Macdonell and Prinz., 2017). A group intervention was decided to allow participants to share and connect with others who may have similar challenges, as research has shown improved outcomes in regard to improved well-being and adherence when in this format. (American Psychological Association., 2019).

The intervention was delivered online (via Microsoft Teams) once a week for eight weeks and lasted 90 minutes per session. Due to the nature of PH two 10-minute breaks were allocated per session to give participant adequate time to attend to their needs and manage symptoms of fatigue. The number of weeks was chosen based on the only systematic review exploring IBIs, which identified the average intervention length as 8.5 weeks (Heim et al., 2023). All sessions were delivered by the lead researcher as well as the expert clinical psychologist within the SPVU. This was to manage technical problems or offer additional support in case of any unexpected distress or risk issues. Intervention materials are found in appendix 2.5.

Table 2.1: IBI session topic guide

Session	Session Aims
1 Welcome and introduction to interoception	To create feelings of safety, security and agreed ways of working. To build engagement, motivation and understanding of the purpose of the group. To introduce interoception and why it is important to connect with the body. To introduce body scan exercise to help participants begin to notice and understand different body sensations.
2 Interoception and its relevance to PH	To explore participants understanding of their interoceptive awareness before their diagnosis of PH and how this may have changed once their physical symptoms began. To discuss whether any changes in interoceptive awareness have impacted their daily functioning. To introduce an adapted breathing exercise to help participants manage body sensations associated with stress.
3 The relationship between interoception and emotions	To identify how bodily signals can influence emotional regulation and emotional well-being. To identify both positive and negative factors impacting participants' abilities to use interoception to regulate their emotions. To introduce a theoretical basis for why improved interoception may positively impact mood. To introduce exercises were making bodily changes (e.g. a small smile) can induce different emotions.
4 The relationship between interoception and behaviours	To identify how interoception can impact behaviours and decision making. To identify both positive and negative factors impacting participants' ability to use interoception to guide behaviours. To introduce a theoretical basis for why improving interoception may positively impact behaviours and decision making. To introduce a table for participants to complete, breaking down what body signals they feel and how these may impact their behaviours.
5 Understanding uncertainty of PH symptoms through the lens of interoception	To further understand the lived experiences of PH symptoms and uncertainty regarding varying changes to physical ability. To explore how uncertainty of physical symptoms impacts participants' emotions (e.g. hypervigilance) and behaviours (e.g. safety behaviours). To support participants to improve their tolerance of uncertainty safely through interoception. To use a traffic light system to categorise bodily sensations with the aim of aiding their decision-making process (e.g. when medical assistance may be required).
6 Understanding fatigue in PH through the lens of interoception	To identify why fatigue is common in PH. To explore the relationship between interoception and fatigue. To identify both positive and negative factors affecting participants' ability to use interoception to manage fatigue. To introduce the concept of 'pacing' based on participants' interoceptive skills. To introduce an activity planner with interoceptive elements (e.g. tracking bodily symptoms to aid decision making around pacing).
7 Practising and consolidating skills	To review previous sessions and practise interoceptive skills. To support participants to adapt interoceptive skills into their day to day lives. To introduce the importance of maintaining skills developed in this group. To engage in a fun quiz to summarise key points from each session.
8 Group reflections, maintaining skills and group endings	To continue to reflect on the group and participants' experiences of it. To discuss knowledge gained and celebrate achievements. To complete final measures and maintenance plan.

PH= Pulmonary hypertension

Secondary Research Question: Was the intervention acceptable and feasible?

Of the 16 participants allocated to the intervention group, nine (56.2%) completed the intervention and answered the 'Feasibility and Acceptability' Questionnaire. The sections below highlight the main findings. Full response details can be found in table 2.2.

Study Forms

The majority of participants (N=8, 88.8%) either strongly agreed or agreed that the study forms (such as the consent form and questionnaires) were easy to follow. All participants (N=9, 100%) either strongly agreed or agreed that the forms were easy to complete online.

Delivery and format of the intervention

All participants (N=9, 100%) either strongly agreed or agreed that delivering the intervention online was helpful and that they felt it is best delivered in a group format. All (N=9, 100%) strongly agreed or agreed that information provided in the group was useful to them and that each session had a clear plan, with specific learning outcomes.

Session resources and materials

All participants (N=9, 100%) either strongly agreed or agreed that the exercises discussed and practised in the sessions were useful and that they were all (N=9, 100%) confident in using these exercises in their daily life. All participants (N=9, 100%) also found the additional resources (found in the resource pack) helpful.

Support available during the intervention

All participants (N=9, 100%) either strongly agreed or agreed that the level of support received by facilitators was sufficient and that the sessions were delivered at an appropriate pace. All participants (N=9, 100%) also either strongly agreed or agreed that initial sessions created a supportive environment.

Expectations and engagement

The majority of participants (N=8, 88.8%) either strongly agreed or agreed that the intervention focused on what they were expecting it to and all (N=9, 100%) felt confident in what was expected of them as part of the intervention. The majority of participants (N=8, 88.8%) strongly agreed or agreed that they felt comfortable engaging in group discussions.

Perceived helpfulness of the intervention

The majority of participants (N=8, 88.8%) either strongly agreed or agreed that the intervention helped them to connect with their body.

The majority of participants (N=7, 77.7%). either strongly agreed or agreed that the intervention helped them with symptoms of anxiety.

The majority of participants (N=6, 66.6%). either strongly agreed or agreed that the intervention helped them with symptoms of low mood/depression.

The majority of participants (N=8, 88.8%) strongly agreed or agreed that the intervention helped their HRQoL.

All participants (N=9, 100%) either strongly agreed or agreed that overall, the intervention had been a help to them.

Perceived usefulness of the intervention to others

All participants (N=9, 100%) strongly agreed that they felt the intervention would benefit others with PH.

All participants (N=9, 100%) strongly agreed that they would recommend the intervention to other people diagnosed with the condition.

Table 2.2: Feasibility and Acceptability Questionnaire (n=9)

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree
The study forms (e.g. consent forms and questionnaires) were easy to follow	7 (77.7%)	1 (11.1%)	1 (11.1%)	0 (0%)	0 (0%)
The study forms were easy to complete online	8 (88.8%)	1 (11.1%)	0 (0%)	0 (0%)	0 (0%)
I found it helpful that the intervention was delivered online	5 (55.5%)	4 (44.4%)	0 (0%)	0 (0%)	0 (0%)
I feel that this intervention is best delivered within a group format	6 (66.6%)	3 (33.3%)	0 (0%)	0 (0%)	0 (0%)
Each session had a clear plan and learning outcomes	5 (55.5%)	4 (44.4%)	0 (0%)	0 (0%)	0 (0%)
The information provided in the group was useful to me	5 (55.5%)	4 (44.4%)	0 (0%)	0 (0%)	0 (0%)
I found the exercises in the sessions useful	6 (66.6%)	3 (33.3%)	0 (0%)	0 (0%)	0 (0%)
I feel confident in using the exercises from the group in my daily life	5 (55.5%)	4 (44.4%)	0 (0%)	0 (0%)	0 (0%)
I found the additional resources helpful	3 (33.3%)	6 (66.6%)	0 (0%)	0 (0%)	0 (0%)
The pace of the sessions was right for me	3 (33.3%)	6 (66.6%)	0 (0%)	0 (0%)	0 (0%)
The level of support I received from the facilitators was sufficient	7 (77.7%)	2 (22.2%)	0 (0%)	0 (0%)	0 (0%)
The initial sessions created a supportive environment	6 (66.6%)	3 (33.3%)	0 (0%)	0 (0%)	0 (0%)
I felt comfortable engaging in group discussions	7 (77.7%)	1 (11.1%)	0 (0%)	1 (11.1%)	0 (0%)
I felt confident in what was expected of me as part of the intervention	5 (55.5%)	4 (44.4%)	0 (0%)	0 (0%)	0 (0%)
The intervention had focused on what I was expecting it to	3 (33.3%)	5 (55.5%)	1 (11.1%)	0 (0%)	0 (0%)
The intervention has helped me to connect with my body	4 (44.4%)	4 (44.4%)	1 (11.1%)	0 (0%)	0 (0%)
The intervention has helped me with my symptoms of anxiety	1 (11.1%)	6 (66.6%)	2 (22.2%)	0 (0%)	0 (0%)
The intervention has helped me with my symptoms of low mood/depression	1 (11.1%)	5 (55.5%)	3 (33.3%)	0 (0%)	0 (0%)
The intervention has helped my health-related quality of life	1 (11.1%)	7 (77.7%)	1 (11.1%)	0 (0%)	0 (0%)
The intervention has overall been a help to me	6 (66.6%)	3 (33.3%)	0 (0%)	0 (0%)	0 (0%)
I feel that others with pulmonary hypertension would benefit from this intervention	9 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

I would recommend the intervention to another person with pulmonary hypertension	9 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Participant Characteristics

No significant difference in baseline characteristics was found between participants randomly allocated to the intervention and control group, with the exception of age. Control participants were significantly older (64.8 years) than the intervention group (56.8 years) t(30) =-1.7 , *p*= .036. See table 2.3 for more details.

No significant differences were found between those that completed final measures compared with those that did not, with the exception of anxiety (GAD-7). Non-completers scored significantly higher (9.75) than the completers (4.45); t(30) =-2.4, *p*= .011. See table 2.4 for more details.

Table 2.3: Baseline data for participants randomised to the intervention or control group. Means and (standard deviations) unless otherwise stated. p values of independent t-tests are included.

Characteristics	Intervention Group	Control Group	*p* value
Number of participants	16	16	
Mean age (years)	56.8	64.8	.036*
Gender			.241
Male	7 (44%)	5 (31%)	
Female	9 (56%)	11 (69%)	
Other	0 (0%)	0 (0%)	
Prefer not to say	0 (0%)	0 (0%)	
Ethnicity			.163
White	15 (94%)	16 (100%)	
Asian	1 (6%)	0 (0%)	
Black	0 (0%)	0 (0%)	
Multiple ethnic groups	0 (0%)	0 (0%)	
Other	0 (0%)	0 (0%)	
Highest Qualification			.160
School	6 (38%)	5 (31%)	
College	4 (25%)	2 (13%)	
University	3 (19%)	5 (31%)	
Apprenticeship or professional training	3 (19%)	4 (25%)	
MAIA-2			
Noticing	2.91 (0.6)	2.86 (1.3)	.449
Not-distracting	2.62 (1.3)	2.39 (1.6)	.317
Not-worrying	2.94 (1.2)	2.66 (1.0)	.246
Attention regulation	2.94 (1.4)	2.84 (1.4)	.421
Emotional awareness	2.45 (1.3)	3.00 (1.4)	.121
Self-regulation	2.73 (1.4)	2.92 (1.2)	.341
Body listening	2.01 (1.3)	1.73 (1.4)	.278
Trust	2.99 (1.4)	3.13 (1.5)	.401
GAD-7	4.81 (5.7)	5.43 (5.8)	.380
PHQ-9	8.13 (6.3)	7.44 (5.9)	.376
emPHasis-10	24.00 (13.5)	23.68 (11.9)	.472

MAIA-2 = Multidimensional Assessment of Interoceptive Awareness - Version 2; GAD-7 = Generalised Anxiety Disorder – 7; PHQ-9 = Patient Health Questionnaire – 9. * $p \leq 0.05$.

Table 2.4: Baseline data for participants who completed final measures and those that did not. Means and (standard deviations) unless otherwise stated. p values of independent t-tests are included.

Characteristics	Completers	Non-completers	*p* value
Number of participants	20	12	
Mean age (years)	62.2 (12.6)	57.6 (12.6)	.163
Gender			.463
Male	8 (40%)	4 (33%)	
Female	12 (60%)	8 (67%)	
Other	0 (0%)	0 (0%)	
Prefer not to say	0 (0%)	0 (0%)	
Ethnicity			.224
White	19 (95%)	12 (100%)	
Asian	1 (5%)	0 (0%)	
Black	0 (0%)	0 (0%)	
Multiple ethnic groups	0 (0%)	0 (0%)	
Other	0 (0%)	0 (0%)	
Highest Qualification			.171
School	7 (35%)	4 (33%)	
College	1 (5%)	4 (33%)	
University	7 (35%)	2 (17%)	
Apprenticeship or professional training	5 (25%)	2 (17%)	
MAIA-2			
Noticing	2.75 (1.0)	3.10 (1.0)	.172
Not-distracting	2.54 (1.2)	2.47 (1.2)	.447
Not-worrying	2.86 (1.3)	2.73 (0.8)	.379
Attention regulation	2.77 (1.6)	3.02 (0.9)	.308
Emotional awareness	2.56 (1.4)	2.93 (1.1)	.219
Self-regulation	2.80 (1.4)	2.83 (1.1)	.472
Body listening	1.84 (1.6)	1.86 (0.9)	.482
Trust	3.05 (1.6)	3.09 (1.2)	.470
GAD-7	4.45 (5.6)	9.75 (6.7)	.011*
PHQ-9	6.65 (5.4)	9.66 (6.8)	.087
emPHasis-10	21.95 (12.6)	27.00 (12.2)	.137

MAIA-2 = Multidimensional Assessment of Interoceptive Awareness - Version 2; GAD-7 = Generalised Anxiety Disorder – 7; PHQ-9 = Patient Health Questionnaire – 9. * $p \leq 0.05$.

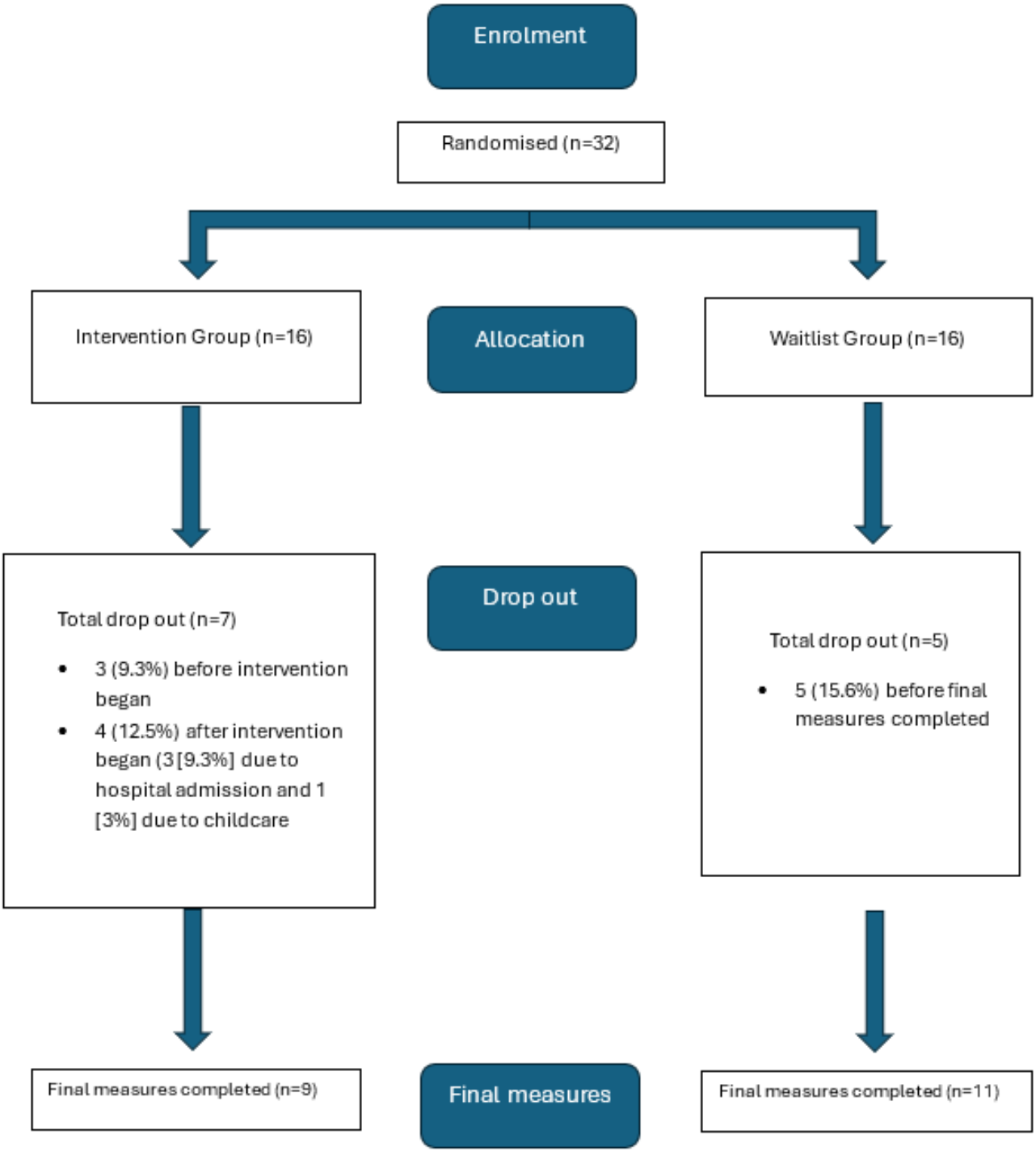
Additional Research Questions

What was the overall attrition rate for the intervention?

Overall, 71 individuals gave their details to be contacted regarding the study after reading the participant information sheet. Thirty-two (45.1%) then consented to taking part in the study and completed the baseline measures. A total of 20 participants (62.5%) repeated the measures at the end of the intervention from both groups. Of the 12 that did not complete the study, eight (25%) withdrew prior to the start of the intervention and one (3%) no longer met the study criteria. Of the remaining four participants, three (9%) withdrew from the intervention once it had begun due to a decline in their physical health, requiring hospital admission. One (3%) participant withdrew from the intervention due to childcare responsibilities.

No adverse events were found during or after the intervention. A total attrition rate in both groups for repeated measures was 37.5%. For the intervention group, an attrition rate of 43.7% was observed. After adjusting calculations for those who began the intervention (13 participants), the attrition rate was found to be 30.8%. See Figure 2.1 for more details.

Figure 2.1: CONSORT Flow Diagram



What was the rate of completed measures?

An overall completion rate of measures was 100% for participants who completed the intervention.

Were there changes in interoception when comparing patient scores pre- and post-intervention?

For the intervention group, four subscales showed statistically significant improvements following the intervention: 1) noticing, $t(8) = -2.9$, $p = .009$, 2) emotional awareness, $t(8) = -3.8$, $p = .003$, 3) body listening, $t(8) = -3.3$, $p = .005$ and 4) trust, t=(8) -2.1, $p = .034$. Large effect sizes were observed for three of the subscales (noticing, $d = -0.99$; emotional awareness, $d = -1.27$ and body listening, $d = -1.12$) with one having a medium effect size (trust, $d = -0.71$).

In the control group, one subscale (not-worrying) showed significant improvements when participants repeated the measures, $t(10) = -2.7$, $p = .011$, with a large effect size ($d = -0.82$) there were no significant changes in seven of the eight subscales

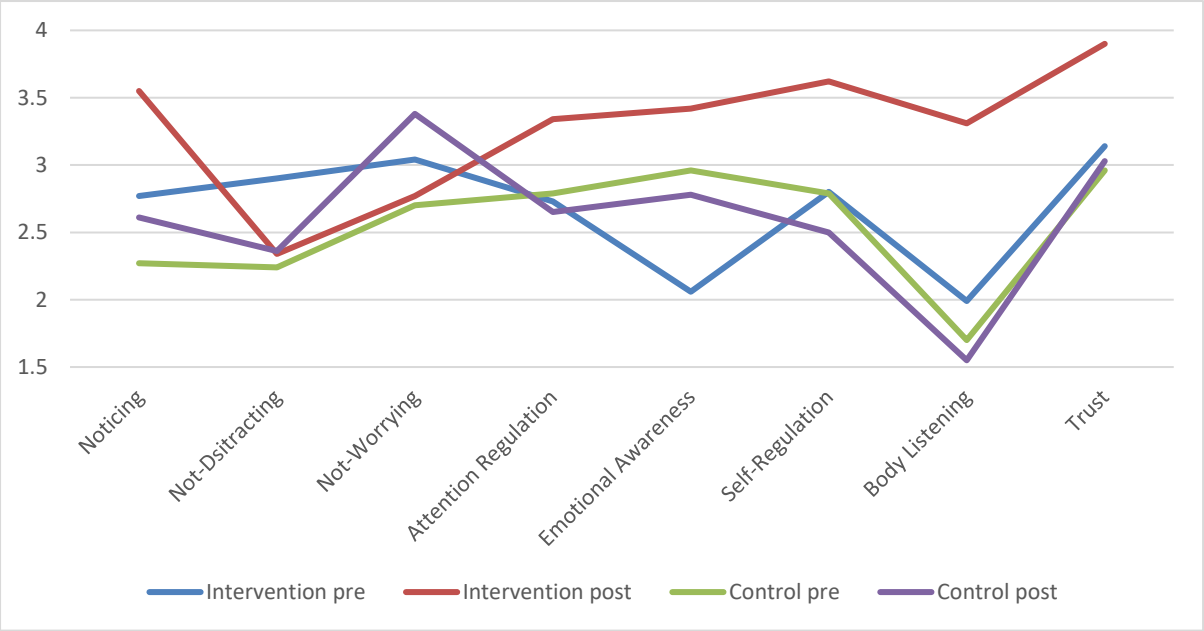
Full details are provided in Table 2.5. Figure 2.2 illustrates changes in MAIA-2 scores pre-and post-intervention.

Were there changes in interoception when comparing intervention and waitlist group?

When the measures were repeated, the intervention group showed significantly higher scores on two subscales: 1) self-regulation, $t(18) = 2.1$, $p = .024$ and 2) body listening, $t(18) = 2.6$, $p = .010$ as compared to the waitlist group. Large effect sizes were observed for these two subscales (self-regulation, $d = 0.95$ and body listening, $d = 1.14$).

Full details are provided in Table 2.6.

Figure 2.2: Mean subscale scores for MAIA-2 pre- and post-intervention for both groups



MAIA-2 = Multidimensional Assessment of Interoceptive Awareness - Version 2

Were there changes in anxiety, depression and HRQoL when comparing participant scores pre- and post-intervention?

The intervention group showed significantly higher scores on anxiety, $t(8) = -1.9$, $p = .050$ following the intervention, with a medium effect size (d = -0.61). No significant changes were found for depression and HRQoL.

When the measures were repeated, the waitlist group showed significantly lower HRQoL, $t(10) = -1.9$, $p = .045$ as compared to the intervention group, with a medium effect size (d = -0.56). No significant changes were found for anxiety or depression.

Further details are provided in Table 2.5.

Were there changes in anxiety, depression and HRQoL when comparing intervention and waitlist groups?

No significant changes were found between groups for anxiety, depression and HRQoL.

Further details are available in Table 2.6.

What sample size would be required for future studies based on current effect-sizes?

Due to a higher-than-anticipated attrition rate, calculating a reliable sample size for future studies was not feasible.

Table 2.5: Differences in mean scores for interoception, anxiety, low mood and HRQoL pre- and post-intervention for participants in the intervention (n=9) and control groups (n=11). p-values of dependent t-tests are also included.

Measure	Group	Pre-	Post-	Standard Deviation	Effect size (Cohen's *d*)	Confidence Interval (95%)	*p*-value
MAIA-2	Intervention						
Noticing		2.77	3.55	0.78	-0.99	-0.17 – 2.97	.009*
Not-distracting		2.90	2.34	1.39	0.40	-0.50 – 1.64	.128
Not-worrying		3.04	2.77	1.28	0.20	-0.72 – 1.26	.274
Attention regulation		2.73	3.34	1.47	-0.41	-1.74 – 0.51	.123
Emotional awareness		2.06	3.42	1.06	-1.27	-2.17 – 0.53	.003*
Self-regulation		2.80	3.62	1.36	-0.59	-1.86 – 0.23	.056
Body listening		1.99	3.31	1.17	-1.12	-2.21 – -0.41	.005*
Trust		3.14	3.90	1.07	-0.71	-1.57 – 0.06	.034*
MAIA-2	Control						
Noticing		2.72	2.61	0.81	0.13	-0.43 – 0.66	.654
Not-distracting		2.24	2.36	0.57	-0.20	-0.50 – 0.26	.252
Not-worrying		2.70	3.38	0.81	-0.82	-1.22 – -0.12	.011*
Attention regulation		2.79	2.65	0.77	0.17	-0.38 – 0.65	.288
Emotional awareness		2.96	2.78	0.67	0.26	-0.27 – 0.63	.197
Self-regulation		2.79	2.50	0.56	0.52	0.08 – 0.67	.058
Body listening		1.70	1.55	0.64	0.23	-0.27 – 0.58	.266
Trust		2.96	3.03	0.29	-0.21	-0.26 – 0.13	.247
GAD-7	Intervention	3.11	4.77	2.69	-0.61	-3.73 – 0.40	.050*
	Control	5.54	5.36	0.98	0.18	-0.47 – 0.84	.276
PHQ-9	Intervention	7.00	5.22	3.23	0.55	-0.70 – 4.26	.069
	Control	6.36	6.90	1.69	-0.32	-1.68 – 1.06	.155
emPHasis-10	Intervention	20.22	20.00	6.99	.03	-5.15 – 5.59	.463
	Control	23.36	27.00	6.40	-.56	-7.94 – .66	.045*

MAIA-2 = Multidimensional Assessment of Interoceptive Awareness - Version 2; GAD-7 = Generalised Anxiety Disorder – 7; PHQ-9 = Patient Health Questionnaire – 9. * $p \leq 0.05$.

Table 2.6: Differences in mean scores for interoception, anxiety, low mood and HRQoL between the intervention (n=9) and control groups (n=11). p values of independent t-tests are included.

Measure	Intervention Group	Control Group	Effect size (Cohen's *d*)	*p* value
MAIA-2				
Noticing	3.55	2.61	0.76	.054
Not-distracting	2.34	2.36	-0.02	.483
Not-worrying	2.77	3.38	-0.72	.062
Attention regulation	3.34	2.65	0.55	.118
Emotional awareness	3.42	2.78	0.53	.125
Self-regulation	3.62	2.50	0.95	.024*
Body listening	3.31	1.55	1.14	.010*
Trust	3.90	3.03	0.62	.090
GAD-7	4.77	5.36	-0.10	.405
PHQ-9	5.22	6.90	-0.31	.243
emPHasis-10	20.00	27.00	-0.52	.130

MAIA-2 = Multidimensional Assessment of Interoceptive Awareness - Version 2; GAD-7 = Generalised Anxiety Disorder – 7; PHQ-9 = Patient Health Questionnaire – 9. * $p \leq 0.05$.

Discussion

This is the first study investigating a newly created interoceptive based intervention for individuals with PH. Despite advances in medicine, PH remains incurable and available treatments focus on symptom management (Yaghi et al., 2020). Individuals living with PH continue to experience physical limitations and side-effects from treatment, which often affect HRQoL (Rawlings et al., 2020) and may explain high rates of anxiety and depression reported in this population (Mai et al., 2017). Previous research has shown that IBIs can improve an individual's ability to reappraise and regulate uncomfortable bodily sensations (Boettcher & Barlow., 2019), which in turn can positively impact anxiety, low mood and QoL (Heim et al., 2023). The most common physical symptoms of PH are breathlessness and fatigue (Rawlings et al., 2023) and therefore the intervention was developed with these in mind. When designing any intervention with participants diagnosed with a chronic, incurable physical health condition, such as PH, ethical considerations are important to consider. This

is to minimise any negative impact that the research study may instil. For the current intervention, researchers attempted to balance recruiting enough participants to gain sufficient statistical power with ensuring that a particularly vulnerable group is not over-recruited to an intervention that may not be beneficial to them. Given the progressive nature of PH, with possible exacerbations in physical symptoms and physical health decline despite treatment, it was decided to stagger the recruitment to minimise participant wait times of the intervention, regardless of which group they were randomly allocated to. Future research should continue to consider and evaluate the potential ethical issues within this population when developing next stages for the intervention. Given the rarity of PH, we designed an online group intervention to facilitate access for participants and ensure that the sample accurately represents the characteristics of this population. The majority of participants in the study were female (63%) with the average age of 60.5 years, which is generally representative of the larger population (Hoeper & Gibbs, 2014). Participants in the intervention group were significantly younger (56.8 years) than the control group (64.8 years), however still in the expected age range for this condition (50-65 years; Orem., 2017). Those that completed the final measures scored significantly lower in anxiety (GAD-7; 4.45) than those that did not (9.75), and the most common reported reason for drop out was a decline in physical health. Research has shown no significant differences between participants that score higher in anxiety and worsening clinical outcomes for PH (Takita et al., 2021), and therefore it is unclear why this may have occurred. One possibility could be that individuals with PH who have higher levels of anxiety have reported greater vigilance to their symptoms and their impact on their daily activities (Rawlings et al., 2020). Some discussed avoiding illness reminders as a consequence (Muntingh, Gerritsen, Batelaan & Bogaard et al., 2017), which could have contributed to them being less likely to engage with the current intervention. It would be useful for future research to clarify possible barriers to engagement in this population.

Preliminary results indicate that the intervention was feasible, acceptable, and safe, with no adverse effects reported throughout its duration. The target sample size was successfully achieved, suggesting that the recruitment method is appropriate for a larger-scale trial. However, the higher-than-expected attrition rate (37.5%) should be accounted for in future studies. All participants found the intervention generally helpful with the majority feeling that it has it has helped their HRQoL, symptoms of anxiety, low mood and connecting with their

body. All participants felt that others with PH would benefit from it and indicated that they would recommend it to them. Participants also found that the methodology of completing questionnaires (via MS forms), being an online group, resources available and support received by facilitators was also helpful, as well as participants feeling clear on what their roles were within the group. These results suggest that future interventions should utilise similar approaches as they appear suitable to this population.

Additional research questions aimed to specify overall attrition rate and rate of overall completed measures, explore the preliminary effectiveness of the intervention on improving interoception, anxiety, depression and HRQoL. Although the sample size was successfully achieved, a larger than expected attrition rate was found (37.5%). This reduces the study's statistical power, limiting the ability to detect between- and within- group differences. As such, results should be interpreted with the caveat that lack of significance does not necessarily indicate no effects. The primary reason for participant dropout was a decline in physical health, resulting in hospital admissions. When comparing attrition rates to existing psychological interventions for PH, this study exhibited a higher rate. Rawlings et al. (2022) developed a self-help CBT resource for individuals with PH and reported a lower attrition rate (15.6%). This difference may be attributed to variations in methodology. For example, the current interventions length was double (8 weeks) that of Rawlings' intervention (4 weeks) and a larger time commitment was required for the current intervention (90 minutes per week plus additional time to practice exercises at home). Existing literature suggests that self-help interventions generally show lower attrition rates due to their convenience and flexibility (Al-Asadi, Klein, and Meyer et al., 2014). It is, however, worth noting that attrition rate was lower when only including participants who began the intervention (30.8%). This is similar to the rates typically observed in online psychological interventions, such as CBT (29.5%; Fanous & Daniels, 2020). All participants (100%) who completed the intervention also completed all final measures, suggesting adherence to the intervention itself.

Participants who completed the intervention showed improved scores in four interoceptive domains: 1) improved awareness of body sensations (noticing), 2) greater awareness of the connection between body sensations and emotional states (Emotional awareness), 3) better active listening to the body for insight (body listening) and 4) trusting body sensations (trust). It is not unsurprising that these domains have shown improvements, as the intervention

focussed on these areas. Topics included why it is important to listen to bodily sensations and exercises were encouraged such as body scans to support these developments. Interestingly, in contrast with perceived benefits to anxiety post intervention, significant rises in anxiety were found in the GAD-7, where an increase from minimal to mild clinical cut offs occurred. Possible explanations of this may be that initial uncertainty around bodily sensations detected often leads to increased hypervigilance (Rawlings et al., 2020) and that as participants may previously have been unaware of particular sensations, were now noticing them for the first time, creating some levels of increased anxiety. Over time, the control group showed less of the tendency to worry/experience emotional distress with sensations of pain and discomfort while also experiencing lower HRQoL. Researchers are unsure why significant improvements were found in regard to worrying for the waitlist group, however, can speculate that as they were waiting for the intervention, this may have reduced short term concerns. However, contradictory to this, the waitlist group also showed significant reduction in their HRQoL over time. No changes were found in depression and HRQoL for the intervention group when comparing pre- and post-intervention. At baseline, PHQ-9 scores (7.00) were in the 'mild' clinical category (5-9) and this category did not change. EmPHasis-10 scores also indicated no significant issues related to HRQoL. A possible reason for these findings may be that as participants did not report any particular issues with their mood or HRQoL pre-intervention, this limits its ability to potentially impact these areas.

When comparing between groups at the end of the intervention, significant improvements were found in two interoceptive domains for the intervention group including 1) better ability to regulate distress by attending to body sensations (self-regulation) and 2) better active listening to the body for insight (body listening). Potential reasons for why improvements in these domains when comparing groups may be that in addition to possible reasons described in pre vs post results, topics and exercises within the intervention also focus on techniques to better manage uncomfortable sensations (e.g. breathing techniques and thought challenging) which may have improved participants ability to regulate their distress by better controlling their bodies.

Limitations

The results of this preliminary study must be interpreted in light of its limitations. A limitation of the current study is that although researchers did consider intervention development frameworks (e.g. the Medical Research Council Framework; Skivington et al., 2021) when creating the IBI, due to logistical constraints, it was not feasible to follow specific frameworks thoroughly. In line with this framework, researchers did review current literature, discuss with clinical experts and those with direct experience of the condition, review the impact of previous IBI's and consider useful techniques for those with PH. However, due to time constraints, this process could not be done in the depth that the framework suggests. It is recommended therefore that future research adapt this intervention in line with appropriate frameworks.

A major limitation was the higher-than-expected attrition rate (37.5%) which has already been discussed in detail. For future studies, it is recommended to increase the sample size to better assess the impact of this intervention, however, to continue to consider the ethical impact previously discussed in regard to over recruitment.

Another limitation of this study was the inability to follow-up participants over time after the completion of the intervention. Many studies investigating IBIs have included follow-up assessments (Quadt et al., 2021; Bravo et al., 2019), which are valuable for evaluating the longer-term effects. Follow-up measures also provide insight into any changes that may not have been evident at the time of the final assessment but could become noticeable later. Including follow-up measures in future studies would be beneficial to better understand the sustained impact of the intervention.

As this was a preliminary study, recruitment was intentionally broad to ensure the inclusion of appropriate participants. However, this approach may have influenced who agreed to participate. Research suggests that individuals with higher levels of agreeableness are more likely to engage in research (Ingendahl, Woitzel, & Alves, 2023), which may have led to the inclusion of participants who experience lower levels of anxiety, mood disturbances, and better perceived quality of life. Individuals with PH are known to have higher levels of anxiety and depression as compared to the general population (Olsson et al., 2021). Future studies

might benefit from recruiting participants with higher anxiety and depression levels as well as poorer HRQoL to further explore the effects of IBIs on these factors.

Conclusions

This study provides preliminary evidence that an eight-week online interoception-based intervention for PH is safe, feasible, and well-accepted by participants. Although the results lack sufficient statistical power to draw significant conclusions, they suggest improvements in participants' interoceptive abilities and perceived benefits to overall well-being measured on the self-reported feasibility and acceptability questionnaire. However, no changes were found when using standardised measures, with the exception of slightly higher anxiety scores. While these are only preliminary findings, the study supports the rationale for a larger scale trial.

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Appendices

Appendix 1: PRISMA 2020 expanded checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	P. 8
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	P. 9
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	P.10-11
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	P. 12
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	P.14
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	P.12
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	P.12
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	P.13
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	P.13
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	P.13
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	P.13
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	P.14
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	P.14
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	P.13
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	N/A
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	N/A
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	N/A
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N/A
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A

Section and Topic	Item #	Checklist item	Location where item is reported
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	P.14
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	P.15
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	N/A
Study characteristics	17	Cite each included study and present its characteristics.	P.16-18
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	P.21-22
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	P27-30
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	P.19
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	P.27-30
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	P.31-32
	23b	Discuss any limitations of the evidence included in the review.	P.33
	23c	Discuss any limitations of the review processes used.	P.33
	23d	Discuss implications of the results for practice, policy, and future research.	P.33-34
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	P.12
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	N/A
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	N/A
Competing interests	26	Declare any competing interests of review authors.	N/A

Section and Topic	Item #	Checklist item	Location where item is reported
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	N/A

Appendix 2.1: CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	P. 43
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	P.47
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	P.47-50
	2b	Specific objectives or research questions for pilot trial	P.50
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	P.51
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	P.51
	4b	Settings and locations where the data were collected	P.51
	4c	How participants were identified and consented	P.51-52
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	P.52
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	P.52-54
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A

Sample size	7a	Rationale for numbers in the pilot trial	P.53
	7b	When applicable, explanation of any interim analyses and stopping guidelines	P.54
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	P.51
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	P.51
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	P.51
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	P.51
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	P.54
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	P.63
	13b	For each group, losses and exclusions after randomisation, together with reasons	P.64
Recruitment	14a	Dates defining the periods of recruitment and follow-up	P.51
	14b	Why the pilot trial ended or was stopped	N/A

Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	P.61
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	P.68-69
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	P.68-69
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	P.68-69
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	P.72
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	P.73
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	P.73
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	P.73
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	P.51
Protocol	24	Where the pilot trial protocol can be accessed, if available	P.88
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	N/A
	26	Ethical approval or approval by research review committee, confirmed with reference number	P.51

Appendix 2.2: Major Research Project Proposal

https://osf.io/ykj4a

Appendix 2.3: Approval letters

NHS Golden Jubilee approval for research project (with amendment)

NHS Golden Jubilee approval for research project letter removed due to confidentiality issues.

NHS REC letter favourable opinion on further information

NHS REC letter favourable opinion on further information removed due to confidentiality issues.

NHS REC letter favourable ethical opinion

NHS REC letter favourable ethical opinion removed due to confidentiality issues.

University of Glasgow Proceed to Ethics Letter

University of Glasgow
School of Health & Wellbeing

BC/LC

28th November 2023

Derick Moore
2021489m@student.gla.ac.uk

Dear Derick,

Major Research Project Proposal

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

The above project has been reviewed by your University Research Supervisor and by a member of staff not involved in your project and has now been deemed fit to proceed to ethics.

Congratulations and good luck with the study.

Yours sincerely

Dr Breda Cullen
Senior Lecturer in Clinical Psychology
DClinPsy Research Director

Appendix 2.4: Participant information sheet and consent form

Participant information sheet: https://osf.io/qukvz

Consent form: https://osf.io/xf6gu

Appendix 2.5: Nonstandard research materials

Feasibility and acceptability questionnaire:	https://osf.io/32wy7/
Demographic form:	https://osf.io/exv6g
Expression of interest form:	https://osf.io/w6qh9/
Screening questionnaire:	https://osf.io/wscrv
Study recruitment poster:	https://osf.io/nce5h
Intervention topic guide:	https://osf.io/n8t6x
Intervention resource pack:	https://osf.io/5ruvd
Week 1 – 8 session slides:	https://osf.io/r4maf/files/osfstorage
Week 1 – 8 delivery manuals:	https://osf.io/r4maf/files/osfstorage

Appendix 2.6: Data analysis plan

https://osf.io/x2sve?mode=&revisionId=&view_only=

Appendices 2.7: Records of data analysis

SPSS syntax file: https://osf.io/uvgm2

SPSS data output https://osf.io/a3jye

Appendices 2.8: Data availability statement

Anonymised data will be stored on the secure NHS share drive, where it was originally collected. As agreed by participants, this data can be shared with other researchers to aid future research projects. Any identifiable data (e.g. consent forms) will be deleted within three months of the study completion.