

Pulmonary hypertension and home-based (PHAHB) exercise intervention: protocol for a feasibility study.

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BMJ Open Pulmonary hypertension and home-based (PHAHB) exercise intervention: protocol for a feasibility study

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ABSTRACT

Introduction Novel therapies for pulmonary hypertension (PH) have improved survival and slowed disease progression. However, patients still present with symptoms of exertional dyspnoea and fatigue, which impacts their ability to perform activities of daily living, reduces exercise tolerance and impairs their quality of life (QoL). Exercise training has shown to be safe and effective at enhancing QoL and physical function in PH patients, yet it remains an underused adjunct therapy. Most exercise training for PH patients has been offered through hospital-based programmes. Home-based exercise programmes provide an alternative model that has the potential to increase the availability and accessibility of exercise training as an adjunct therapy in PH. The purpose of this study is to investigate the feasibility, acceptability, utility and safety of a novel remotely supervised home-based PH exercise programme.

Methods Single arm intervention with a pre/post comparisons design and a follow-up maintenance phase will be employed. Eligible participants (n=25) will be recruited from the Mater Misericordiae University Hospital PH Unit. Participants will undergo a 10-week home-based exercise programme, with induction training, support materials, telecommunication support and health coaching sessions followed by a 10-week maintenance phase. The primary outcomes are feasibility, acceptability, utility and safety of the intervention. Secondary outcomes will include the impact of the intervention on exercise capacity, physical activity, strength, health-related QoL and exercise self-efficacy.

Ethics and dissemination Ethics approval has been obtained from the Mater Misericordiae Institutional Review Board REF:1/378/2032 and Dublin City University Research Ethics DCUREC/2018/246. A manuscript of the results will be submitted to a peer-reviewed journal and results will be presented at conferences, community and consumer forums and hospital research conferences.

Trial registration number ISRCTN83783446; Pre-results.

INTRODUCTION

Despite earlier diagnosis and improved pharmaceutical therapies, many pulmonary hypertension (PH) participants continue to experience exertional symptoms of dyspnoea and fatigue, which leads to a reduction in functional capacity and in turn, quality of

Strengths and limitations of this study

- This is the first study to assess the feasibility, utility, safety and acceptability of a novel distance-based exercise intervention for pulmonary hypertension (PH) patients.
- The intervention is pragmatic and scalable and could be integrated into existing healthcare pathways.
- As PH is a rare disease with a small population size within Ireland, there is a lack of a usual care control group which is a limitation of the study.

life (QoL). Consequently, there is greater recognition for a more holistic approach to PH treatment beyond pharmacological therapies.¹

Exercise rehabilitation and physical activity (PA) interventions have continuously demonstrated effectiveness as adjuvant therapies for improving exercise capacity and QoL in a spectrum of cardiopulmonary disorders.²⁻⁵ Although research investigating exercise in PH is an emerging field of study, the body of evidence regarding its efficacy continues to grow. Recent systematic reviews and meta-analyses have reported improvements in exercise capacity and QoL in PH,⁶⁻¹¹ which has prompted a renewed focus on exercise training and pulmonary rehabilitation for PH patients.

In the 2015, the European Society of Cardiology/European Respiratory Society recommended that exercise training should be implemented by specialist PH centres as an adjunct to medical therapy for stable PH participants.¹² Currently, the optimal mode, intensity and duration of exercise training, and the characteristics of participants most likely to benefit from exercise training are poorly understood.¹³ To date, the centre-based Heidelberg rehabilitation programme remains the gold-standard exercise programme in PH. It involves an intensive 3-week in-patient induction phase, with a

continued multimodality, monitored outpatient period.¹⁴ Despite improvements in exercise capacity, muscle function, QoL and pulmonary haemodynamics, the initial inpatient phase is resource intensive to operate and roll out.¹⁵

An alternative and pragmatic approach, found to be as effective as a supervised exercise programme in cardiac rehabilitation, is a home-based model of delivery.¹⁶ Home-based interventions also provide solutions to common barriers to participation in centre-based programmes such as access and transport issues, and are less expensive.¹⁷ Further, patient populations including PH¹⁸ express a preference for unsupervised, self-paced, low-to-moderate intensity PA, specifically walking.^{19 20} Through the use of telehealth, distance-based programmes could potentially offer an alternative mode of delivery for exercise training to increase adherence, availability and affordability for PH patients.

Although the few studies examining the beneficial effects of home-based exercise training in PH are promising^{21 22} none included strategies to maximise adherence. An evidence-based approach to implement lifestyle changes requires the implementation of health behavioural change strategies grounded in behaviour change theory.²³ Evidence-based behaviour change techniques (BCT's) can be used to improve intervention effectiveness.²⁴ For example, the combination of the following BCT's: self-monitoring; goal setting; providing feedback on performance; and, review of behaviour goals, is associated with increased intervention effectiveness in PA interventions.²⁵ Interventions that meet the support needs and offer opportunities for self-monitoring have been found to be effective for improving PA in other chronic disease groups.²⁶ Wearable technology holds great potential as an easy to use, low cost self-monitoring tool with continuous feedback²⁷ and are perceived as acceptable and useful for individuals with chronic diseases.²⁸ Through the use of telehealth, distance-based programmes could potentially offer an alternative mode of delivery for exercise training to increase adherence, availability and affordability for PH patients. The aim of this study is to assess the feasibility, acceptability, utility and safety of a novel home-based exercise training programme for PH patients.

METHODS AND ANALYSIS

Study design

The study will employ a single group preintervention and postintervention design with a follow-up maintenance phase. The purpose of the maintenance phase is to assess if the intervention facilitates the adoption of independent exercise in participants when formal support is removed. The study will adhere to the Standard Protocol Items: Recommendations for Interventional Trials Reporting Template.²⁹ Participants will complete assessments at baseline (T1), after the 10-week intervention (T2) and at 20 weeks follow-up (T3).

Eligibility criteria

Inclusion criteria are male or female >18 years, with a diagnosis of PH (WHO groups I and IV) by right heart catheterisation showing baseline mean pulmonary arterial pressure ≥ 25 mm Hg, pulmonary vascular resistance ≥ 240 dyne s/cm⁵, pulmonary capillary wedge pressure ≤ 15 mm Hg and receiving optimised conventional PH therapy. Participants must be clinically stable with no medication changes in the 2 months prior to enrolment.

Exclusion criteria include PH of any cause other than outlined in the inclusion criteria such as PH from left heart disease or lung disease/hypoxia (WHO groups II and III), pregnancy, signs of right heart decompensation, acute infection and fever, change in disease-targeted therapy within the last 2 months, scheduled to receive an investigational drug during the course of the study, forced expiratory volume in 1 s/forced vital capacity <0.5, total lung capacity <70% of the normal value, active liver disease, porphyria, elevations of serum transaminases $>3 \times$ upper limit of normal (ULN), bilirubin $>1.5 \times$ ULN, haemoglobin concentration <75% of the lower limit of normal, systolic blood pressure <85 mm Hg, active myocarditis, unstable angina pectoris, exercise induced ventricular arrhythmias, decompensated heart failure, hypertrophic obstructive cardiomyopathy or impaired left ventricular function.

Participant recruitment

Participants will be recruited from the PH Unit at the Mater Misericordiae University Hospital, Dublin, Ireland. Eligible participants will be invited to participate during their routine 3–6 months clinic visit. They will be given a verbal explanation of the study and provided with an information sheet by their PH specialist (SG/BM) or a member of their clinical team. After receiving the information, potential participants will have the option to speak on the day to a member of the research team or to receive a follow-up phone call within 1–2 days. Participants will have the opportunity to ask questions and will have time to consider their participation. Written consent will be obtained by mail (online supplemental file 1)

Sample size

Pilot study sample size typically ranges from 24 to 50.^{30–32} We estimate a target sample size of 25 to be sufficient for this feasibility study.³¹

Primary outcomes

Feasibility

Assessed by participant recruitment (enrolment as a proportion of eligible participants) and retention (proportion that completed all assessments); (1) engagement with the intervention measured according to attendance at induction sessions and health coaching sessions and adherence, defined as the percentage of home-based exercise sessions recorded by participants who complete the intervention assessed via log books and weekly calls) and 2) by examining delivery as intended (as per

protocol) and health coach perceptions concerning how patients' received the intervention components. This will be captured immediately after each session in order to keep a record of how delivery was received in relation to the planned delivery (eg, if a participants required extra time or further support following the induction training session).

Acceptability and utility

Assessed through self-report questionnaires completed at T2 and interviews. The questionnaire will assess participant perceptions of intervention appropriateness, effectiveness, quality, accessibility/usability, intrusiveness and overall enjoyment and attitude towards the intervention. Semistructured interviews with a sub-set of participants (~n=12) will be conducted within 2 weeks of completing the T2 assessment. The interviews will further explore acceptability and utility of the intervention including perceptions concerning exercise prescription, adherence to different components of the intervention, in addition to the facilitating and hindering factors to participation. Participants will also be asked to offer suggestions for improvement and implementation. Interviews will be conducted via telephone or online platforms (ie, Zoom) and will be audiorecorded and transcribed.

Safety

Participants will be instructed to inform researchers immediately of any adverse advent. In addition, participants will be questioned about adverse events directly related to participation in the exercise intervention during a biweekly support call.

Secondary outcomes

Exercise capacity

Assessed using the 6 min walk test. The test will be administered according to the European Respiratory Society/American Thoracic Society technical standard Guidelines³³ and will be conducted at home using detailed step-by-step video and written instructions and remotely supervised via phone/teleconferencing by a researcher (CMC). A family member/friend will assist with conducting the test, including measuring blood pressure and oxygen saturation (SpO₂) with guidance from the researcher before and after the test. The Frontier X heart rate (HR) monitor will be worn during the test to provide real-time feedback. The assistant will ask the participant to call out their SpO₂ and HR at each minute of the test. Subjective symptoms of dyspnoea and fatigue will be recorded using the Modified Borg Scale (0–10)³⁴ before and after the test. Standard encouragement will be delivered by the assistant, with researcher prompting, if needed.

Muscular strength

Lower body muscle strength will be assessed using the 30 s sit-to-stand test (STS) from a seat height of 40–45 cm. The STS is a commonly used field-based measure of functional lower limb muscle strength, particularly in clinical

and elderly populations. The test will be conducted in each participant's home via teleconference. A researcher (CM) will provide a demonstration, time the test and count the repetitions. Each participant will perform two trials separated by 5 min, with the best score being recorded.

Physicalactivity behaviour

ActivPAL microactivity monitors (PAL Technologies, Glasgow, Scotland) will be used to assess free living activity behaviour. The device samples at 20 Hz for 15 s epochs and measures bodily accelerations using triaxial accelerometer. An inbuilt inclinometer measures thigh inclination. Proprietary algorithms classifies activities into sitting/lying time, standing time, stepping time, step count and activity counts. Participants will be mailed the accelerometer together with detailed wear instruction and provided with a prepaid postage envelope to return the device. They will be instructed to wear the device on the anterior aspect of their right thigh continuously for 7 days, except during water immersion activities (ie, swimming and bathing). The ActivPAL is a valid and reliable measure of activity and sedentary behaviour.^{35 36}

Psychological outcomes and mediators

Quality of life

The Medical Outcomes Study Short-Form 36-Item Survey is a well-validated, generic questionnaire³⁷ consisting of physical functioning, physical role functioning, bodily pain and general health and the four mental subscales of vitality, social functioning, emotional role functioning and mental health. The Cambridge Pulmonary Hypertension Outcome Review³⁸ was designed as a disease-specific health-related QoL measure for PH patients. It is widely used as a clinical and research tool in PH and assess symptoms (25 items) functioning (15 items) and quality life (25 items).

Fatigue

The Fatigue Severity Scale (FSS)³⁹ measures the patient's perception of the influence of fatigue on physical and social functioning through responses to nine different physical and social functioning situations. The FSS is a valid tool for assessing fatigue across various health conditions.⁴⁰

Self-regulatory self-efficacy for exercise

Assessed using a modified 11-item scale,^{41 42} which provide information on task, scheduling and recovery self-efficacy. Questions begin with the stem 'How confident are you that you can...' and include items such as 'plan exercise sessions that will be at least moderately difficult (eg, have you breathing a little hard, your heart rate increases)?'. Participants rate their confidence on a 0–10 Likert scale, with a higher score indicating greater self-efficacy for exercise (Cronbach alpha, $\alpha=0.951$).

Intentions to exercise

Two items will measure intention to engage in moderate-intensity PA for 150 min/week in the next 10 weeks, based on previously established measures.⁴³

Outcome expectations

Ten items will assess outcome expectations. Five-items are derived from the validated exercise pros subscale⁴⁴ and five items to assess outcomes related to common symptoms reported in PH, 'such as breathlessness'.⁴⁵

Social support

Social support for exercise from family and friends scale⁴⁶ uses a 20-item scale to assess support from family and friends respectively. Responses will be recorded on a Likert scale of 1–5, with higher scores representing greater social support. (Cronbach's alpha, family $\alpha=0.926$, friends $\alpha=0.921$).

Outcome assessments will take place at baseline (T1), after the 10-week intervention (T2) and at 20 weeks follow-up (T3). Semistructured interviews will be conducted at T2 to assess patient's perspective on programme acceptability and feasibility and at T3 to assess the follow-up phase. [Table 1](#) outlines the timeline of the assessments.

Procedure

Participants will complete all assessments, induction training and exercise training in their own home and will maintain in contact with researchers via telecommunication technologies (phone, videoconferencing and email). Following consent, a baseline assessment will be conducted (see [table 1](#)) and participants will be provided with an accelerometer to record their activity for the following week. The assessment procedure will be repeated at T2 (10 weeks) and T3 (20 weeks).

Participants will be provided with a home exercise bike (NordicTrack GX 2.7U), a wearable tracker watch (The Fitbit Charge 3), pulse oximeter (SafeHeart SpO₂ monitor), real time single lead ECG/HR/respiratory rate monitor (Frontier X), blood pressure monitor (Beurer BM44), a TheraBand, exercise manual, exercise diary and access to online videos. The exercise manual was partly based on the design of previous PA intervention in chronic disease—PPARCS²⁷ and WATTAP⁴⁷ trials and also our formative research with PH patients. The formative research highlighted the lack of understanding of the benefits of exercise, the importance of self-regulation strategies to support motivation and exercise engagement and the desire for visual picture and instruction of exercise. Concerns of breathlessness and energy management were also evident in interviews with PH patients and integrated into the exercise manual. The manual offers a comprehensive, patient-friendly resource detailing: (1) general information about the study; (2) useful links and contacts; (3) background information on PH; (4) education regarding exercise safety and the benefits of PA; (5) workbook style sections on motivation, goal

Table 1 Study outcome measures and time points

Assessments	Time		
	Baseline (T1)	Postintervention (T2)	Follow-up (T3)
Written informed consent and eligibility	X		
Demographics	X		
Medical history	X		
WHO functional class	X	X	X
Concomitant medication	X	X	X
Adverse events	X	X	X
Exercise capacity (6 MWT)	X	X	X
Muscle strength (Sit to Stand)	X	X	X
Physical activity (ActivPAL Micro)	X	X	X
Quality of life (CAMPHOR and SF-36)	X	X	X
Psychological constructs	X	X	X
Intervention debrief questionnaires/semistructured interviews		X	X

CAMPHOR, Cambridge Pulmonary Hypertension Outcome Review; 6 MWT, 6 min walk test; SF-36, Short-Form 36-Item Surve.

setting, overcoming barriers and psychosocial support; (6) managing breathlessness; (7) exercise intensity and limits; (8) guided home exercises with written and visual details and advice on progression and (9) advice on pacing and energy conservation. Participants will receive video clips of a qualified exercise specialist performing the exercises. Participants will be encouraged to refer to the video to ensure adherence to correct technique. Online videos will provide a visual demonstration of each exercise. Participants will be provided with an exercise diary as a tool to record their activity and effort perception. BCTs will be integrated in the intervention through wearable technology devices, the use of print and visual materials and health coaching and support calls.

The 10-week intervention consists of the following components: Three 60–90 min induction sessions (week 0 and 1), up to five 30 min support health coaching sessions (at week 2, 3, 5, 7, 9) and 3–5 weekly home-based exercise sessions. The intervention will end prior to T2 assessment. Participants will continue to have access to the exercise manual, bike and Fitbit during the maintenance phase.

Induction training

Induction training (1:1), via video conferencing, is a key component to ensure patients are confident to exercise at home and understand the appropriate exercise intensity and how to exercise safely. Participants will be encouraged to involve a family member, friend or carer in the induction training. The sessions will focus on the following topics:

Session 1: introduction

Education on PH and benefits of PA for PH. Familiarisation with intervention materials/equipment and self-monitoring.

Session 2: exercise safety and exercise demonstration

The session will focus on recognising exercise limits, warning signs and managing exercise intensity. Visual demonstrations of breathing techniques and aerobic, strength and respiratory training will be provided, with the opportunity for behavioural practice during the session to check technique and instil confidence.

Session 3: recap

Exercise demonstrations and key safety points will be reviewed. Any issues regarding intervention materials/equipment will be addressed and participant goals will be reviewed, alongside additional tips for family/friend support and motivation.

Health coaching sessions

The health coaching sessions (via videoconferencing) will use BCTs to foster exercise adherence, motivate and provide support. Over the five sessions the topics will include; benefits of exercise, goal setting, action planning, self-monitoring, identification and management of barriers to exercise, problem solving and feedback on behaviour, with the option for participants to complete formal paperwork in the intervention manual. If required, additional support will be available outside of scheduled sessions.

Participants will be encouraged to wear the Fitbit Charge 3 daily during the intervention. The Fitbit data will be used to guide individually tailored goals, assess adherence to exercise and overall daily PA and as tool to provide feedback to the researcher and participants.

Exercise programme

Participants will complete a 10-week individualised, home-based exercise programme. The programme will be prescribed using the Frequency, Intensity, Time and Type and will employ a multimodal approach that integrates aerobic, resistance and respiratory training. The goals for each component are outlined in the sections below. These are aspirational goals that may not be realistic for all participants. Exercise prescription will be individualised based on their baseline PA levels, 6 min walk test distance and physical capabilities. The modified Borg rating of perceived exertion (RPE) scale⁴⁸ will be used to help prescribe exercise intensity. The RPE scale is a

psychophysiological measurement that translates physical stimuli to a psychological construct of perceived exertion and has been validated in other clinical groups.⁴⁹ Participants will aim to achieve an RPE of 3 (moderate) initially. Based on individual progress an RPE of 4 (somewhat hard) may be advised for some participants. The exercise programme will include:

Aerobic training

Participants will initially aim to undertake a minimum of 10 min of structured aerobic exercise involving walking, cycling or a combination on ≥ 3 days/week. Participants will be allowed to perform this exercise in a single bout, or accumulate it in bouts of at least 5 min in duration. The duration will be progressively increased, with the goal of accumulating ≥ 30 min on ≥ 5 days/week.

Resistance training

Participants will initially undertake resistance training on 2 days/week, involving a single set of 6–8 repetitions of upper and lower extremity and whole body exercises. Training volume will progressively increase with the goal of completing 2–3 sets of 10–12 reps of 4–6 exercises on three non-consecutive days. Participants will use pursed lip breathing to help airways stay open during exhalation. Bodyweight resistance will be used initially and based on individual ability, TheraBands, water bottles or light dumbbells will be introduced.

Respiratory training

Participants will initially perform 10 min of respiratory training at least twice a week, which will follow the protocol established by the Heidelberg PH research group.⁵⁰ This involves a combination breathing techniques (eg, pursed lip, diaphragmic and slow breathing) emphasising control over their rate of inspiration to expiration and to strengthen the diaphragm, stretching of the chest and thoracic muscles (eg, cat-to-cow) and respiratory muscle strengthening exercises. Training volume will progressively increase with the goal of completing 15/20 min of accumulated respiratory training on ≥ 3 d/week. The intensity of the respiratory muscle strengthening exercises can be progressed using a TheraBand.

Participants will wear a Frontier X device (receiver attached to a strap place around the chest) during exercise sessions. The first 2 weeks will be monitored by researchers and then periodically monitored. This will allow access to real time ECG, HR, respiratory rate and cadence. Oxygen saturation will be monitored and participants will be instructed to stop exercising if the SpO₂ value drops below 88%, as per guidelines.⁵¹ Participants will document any adverse events and report to the research team immediately.

Data management and timeline

The trial will be overseen by the trial management group, consisting the principal investigator, the trial-coordinator and health coach. They will meet every 4 weeks and will oversee all aspects of the conduct of the trial including

performing safety oversight activities. Individual data will be deidentified, coded and entered. Each participant will be assigned a personal identification code, which will be used on all case report forms and in all electronic databases. Prior to any statistical analysis, all variables will be checked for missing, impossible and improbable values. Impossible and improbable values will be defined by clinical opinion and will include values that are outside three SD of the mean value. Study recruitment began at the end of September 2020 and the study is expected to be completed in July 2021.

Statistical analysis

Statistical analysis of quantitative data will be performed using SPSS V.24. Prior to statistical analysis, the Shapiro-Wilks test will be applied to check for normality. Continuous variables will be reported as mean (range), mean (SD) or median and IQR, depending on distribution, and categorical variables as frequency (%). Descriptive analyses will be undertaken to summarise participant characteristics and the quantitative data of the intervention feasibility, acceptability and utility. Qualitative data from post-trial interviews and researcher field notes will be analysed using inductive thematic analysis to identify common themes.⁵² A linear mixed model analysis (MMA) will be used to examine the impact of time in this study. An MMA is a suitable approach to modelling time series data which contains repeated measures.⁵³ The MMA does not require complete data sets and does not exclude participants with missing data.⁵⁴ Furthermore, MMA has less stringent assumptions than other repeated measures models (such as analysis of variance) and also exhibits increased power to detect treatment effects. The data will adjust for confounding variables, such as age, baseline line fitness, gender and PH group.

Patient and public involvement

Formative qualitative research took place with PH patients during the intervention development stages. Semistructured phone interviews (N=19) were conducted providing insight into patient barriers and motivators to PA, and exercise preferences. The findings fed into the design of the intervention along with PH clinician input. A patient representative provided opinions on the study protocol, patient-facing documentation (eg, participants information sheet) and intervention material (eg, exercise manual) to ensure it was patient friendly.

DISCUSSION

The promise of exercise training in the treatment and management of PH has gained significant interest over the past two decades. The observed positive effects of exercise programmes on patients' exercise capacity, functional capacity and QoL⁵⁵ make a strong argument for the inclusion of exercise as an adjunctive therapy for stable PH patients.⁵⁶ Considering that structured and resource-intensive hospital-based exercise programmes are unlikely

to be scalable, it is an opportune time to assess the efficacy, safety and impact of home-based programmes as an alternative mode of delivery for PH patients.

A home-based exercise programme may eliminate many of the barriers associated with inpatients or outpatients setting such as transportation issues, location, long wait periods for availability and accessibility for patients. A recent review of exercise interventions in PH by Ozemek *et al*⁵⁶ highlighted the need for inclusion of home exercise programmes to allow patients achieve the optimal 5–6 days of structured exercise.

This study will use a remote delivery for exercise training with the use of telehealth methods, wearable technology, performance feedback and behavioural support to deliver and monitor the intervention. The aim is to eliminate the burden on patients to attend several times per week to an outpatient clinic, accommodate resource availability, make the programme achievable in a 'real-world' setting and improve the reach beyond the traditional healthcare facilities. The follow-up post intervention (T3) phase will provide insight into whether behavioural support is necessary in order for PH patients to remain physically active. Furthermore, it will allow us to assess resource needs in future home-based exercise programmes such as the provision of specific exercise equipment and the use of ubiquitous, low cost devices to monitor activity and safety (eg, bike, wearable activity tracker). Remote assessment of outcomes may remove threats to external validity and evaluation of the feasibility of such assessment will address the goals of implementation science to close the research-to-practice gap and support implementation and scale up of evidence-based interventions.⁵⁷

To our knowledge, this will be the first study to employ the use of evidence-based BCTs to examine the feasibility, utility and efficacy of a remote home-based approach to exercise training for medically stable PH patients. The secondary aims of this study are to evaluate whether this approach leads to improvement in selected indices of physical and psychological health.

PH is a rare, debilitating condition with most clinics centralised and limited community resources available. Telehealth holds significant potential to meet the growing support for exercise training to be included as an adjunct therapy by offering remote training and support, which is key to long-term implementation of exercise training for the PH population. It provides a service that is more accessible and may potentially offer a more affordable enhanced level of care. Our current understanding is limited concerning the acceptability, feasibility, safety and utility of a home-based programme for stable PH patients. This study will help gain a valuable insight into this gap in knowledge.

ETHICS AND DISSEMINATION

Ethics approval has been obtained from the Mater Misericordiae Institutional Review Board REF:1/378/2032 and Dublin City University Research Ethics

DCUREC/2018/246. A manuscript of the results will be submitted to a peer-reviewed journal and results will be presented at conferences, community and consumer forums and hospital research conferences.

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Contributors CM, BK, SJH, NMc, SG, BM and NMo were involved in study conceptualisation, development of intervention content and writing of the protocol. AM provided guidance on the statistical analysis. CM led the writing of the manuscript and all authors edited and reviewed the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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