Pilot and Feasibility Studies

STUDY PROTOCOL

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Investigating the feasibility of an 8-week mindful breathing programme on breathlessness and self-efficacy in chronic obstructive pulmonary disease: an open-label study

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Abstract

Background High prevalences of anxiety and depression have been found in those with COPD which can exacerbate physically related impacts of increased levels of disability, and reduced enjoyment of life. Of particular concern is the anxiety-breathlessness cycle and reduced self-efficacy, which both adversely affect self-management of symptoms. Recognition of the need to address these issues has led to use of adjunctive psychologically based therapies including mindfulness. Standard mindfulness programmes have been found to be helpful in promoting a less distressing view of breathlessness and increasing self-efficacy in self-management; however, they can be difficult to access due to significant time commitments and need to travel for groups. This study examines a novel, portable, flexible mindfulness intervention for breathlessness that can be self-delivered in the person's home, enabling access to a potentially effective intervention to improve self-efficacy in COPD self-management. The primary aim of this study is to establish the feasibility of delivery of this intervention in terms of uptake and retention in the study, adherence to, and acceptability of the MBI. The secondary aim is to obtain preliminary estimates regarding change in self-efficacy in managing COPD.

Methods This mixed method pre-post-study with 3-month follow-up will assess feasibility of recruitment, acceptability, and report preliminary descriptive data regarding this novel mindful breathing intervention (MBI) in up to 30 adults with COPD.

A secondary outcome measure is change in the COPD self-efficacy scale. Other self-report measures include the St. Georges Chronic Respiratory Disease Questionnaire, Five Facet Mindfulness Questionnaire, Hospital Anxiety and Depression Scale, the EQ-5D-5L, and a daily diary recording breathlessness and mindfulness practice. Descriptive statistics and pre-post-change scores will be reported for quantitative data. A qualitative interview exploring participant experiences of the MBI will be undertaken at the 3-month follow-up point with 10 participants. Qualitative data will be analysed using thematic analysis. Data collection is ongoing at the time of submitting this manuscript.

Discussion This study is the first to assess feasibility of a self-delivered MBI for those with COPD in New Zealand. This study will also establish preliminary estimates of change on self-efficacy and other measures of health outcomes. If

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feasible, with preliminary evidence of positive impact on functioning, this will support the development of a larger clinical trial. Provision of self-delivered in-home mindfulness-based interventions for people with COPD may not only contribute to improved health, but potentially a reduction in resources, costs, and the time required for travel to group treatments), reducing barriers to treatment for people with COPD.

Trial registration Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12623000560695. Date registered: 24 May 2023.

Keywords Feasibility study, COPD, Breathlessness, Mindfulness, Self-efficacy, Physiological, Psychological

Background

Chronic obstructive pulmonary disease (COPD) is the diagnosis given to people with chronic lung disease including emphysema, chronic bronchitis, and chronic airflow obstruction which is not fully reversible. COPD affects up to 15% of New Zealanders over 45 and the usual cause is smoking. Damage to lungs leads to breathlessness, cough, and fatigue leading to severe impacts on activities of daily living, productivity, mobility, and physical and mental quality of life. Internationally, in 1990, COPD was the second most common cause of death; however, by 2019, it had dropped to the third most common [1]. Māori and Pacific populations in New Zealand have an increased COPD burden due to increased exposures to particulate matter through smoking, with the onset of COPD 15–20 years earlier than the European population [2].

In addition to the physical impacts of COPD increased levels of anxiety and depression associated with COPD contribute to increased levels of disability, reduced enjoyment and quality of life and poorer coping. The high prevalence of anxiety in those with COPD has the potential to establish and maintain the anxiety-breathlessness cycle [3]. People with COPD may experience a perception of increased oxygen needs which are not being met by breathing and this in turn creates hyperventilation which further exacerbates the level of anxiety. There has been recognition of the need to offer interventions to help people with COPD manage their anxiety to help break the anxiety-breathlessness cycle as well as lessening the impacts of COPD on quality of life and coping [4].

Furthermore, patients with COPD, and other long-term conditions, report low self-efficacy, which negatively affects their quality of life and ability to self-manage their illness and its symptoms [5]. Simpson and Jones found that COPD patients with higher self-efficacy experienced less breathlessness and decreased levels of depression and anxiety, and improved quality of life compared to those with lower self-efficacy [3].

Mindfulness has long been utilised in chronic conditions as a non-pharmacological therapy augmenting usual care. In 1982, Jon Kabat-Zinn implemented a 10-week mindfulness programme for 51 patients with intractable pain which had not responded to traditional pharmacotherapy. The findings demonstrated a marked decrease in pain reports and psychological distress [6]. Mindfulness has been found to increase self-awareness and self-efficacy, promoting a less emotionally problematic impact of breathlessness which enables greater symptom control [7]. Mindfulness based breathing therapy (MBBT) is a mindfulness-based complementary and alternative medicine which focusses on alleviating the symptoms of breathlessness by relaxation and enabling a less distressing and anxiety-inducing interpretation of the physiological symptoms of breathlessness [8]. Two studies have found that mindfulness increased coping by decreasing the psychological impacts of COPD, along with decreased levels of breathlessness and a lowered respiratory rate [4, 8]. Tan et al. undertook a randomised controlled trial which demonstrated a single 20-min mindfulness intervention resulted in clinical and statistically significant improvements in breathlessness [9].

Although these preliminary studies of MBBT show promise in assisting those with COPD, this existing research regarding the effectiveness of MBBT is limited and hence there are a number of issues in the management of breathlessness which require further exploration [4]. For example, Harrison et al. identified high dropout rates and sex and age-biased participant groups [10]. Mindfulness-based stress reduction (MBSR), as usually delivered, consists of eight 2.5-h group sessions and a 1-day mindfulness retreat; however, given this treatment intensity, attending all these sessions may be very difficult for those with COPD. There are feasibility issues for those with COPD in accessing treatment, related to the considerable time commitment and duration of group mindfulness sessions, and attendance requires travel which incurs financial costs. Finally, most studies lack follow-up, so it is unclear whether participants continue to use the intervention and whether benefits persist [10].

Study aims

This study aims to address the previously identified issues by establishing the feasibility and acceptability of providing a self-delivered in-home MBI for those with COPD. The aims of this study are to (1) establish the feasibility

of delivery of this intervention in terms of uptake and retention in the study, adherence to, and acceptability of, the MBI; and (2) obtain preliminary estimates regarding change in self-efficacy in managing COPD.

Methods

Study design

Mixed methods study: open-label pre-post-intervention study, with qualitative interview at 3-month follow-up.

The MBI in this current study will be self-managed; hence, the research participants will be able to choose a time which suits them each day, enabling a personalised delivery which aims to limit participant fatigue. The sessions are much shorter than the weekly group sessions employed in the MBSR studies reviewed [10] and there is no travel commitment. It is envisaged that these considerations may make the MBI more feasible for participants and will maximise adherence and enhance retention.

A planned qualitative interview regarding the acceptability of the MBI at the 3-month point will offer important additional information. Pre-post-measures assess physiological status and also self-efficacy which may contribute to improved management of breathlessness. This study will provide preliminary evidence regarding change in self-efficacy in managing COPD to inform power calculations for a larger trial. This MBI has significant potential to be beneficial for participants with COPD; however, a feasibility study is required as the important point of difference is that the intervention is self-managed in the participant's own home.

The MBI being utilised in this study was developed by Dr. Roberto Benzo, a pulmonologist and the founder of the Mindful Breathing Laboratories and associate professor at the Mayo Clinic College of Medicine and Science [11]. Dr. Benzo's MBI has shown promise in clinical practice but has yet to be formally evaluated. The MBI is nine sessions over an 8-week timeframe in a format which enables the participant to self-manage the intervention. It utilises fundamental elements of MBSR adapted for COPD. Strategies include the body scan, focussing attention on the breath, awareness of body sensations, seated or standing yoga stretching exercises, and non-reactive awareness, using the breath as the anchor [12]. The mindful breathing recordings are freely available from the Mindful Breathing laboratory https://www.mayo.edu/research/labs/mindful-breathing/audio-files.

Inclusion criteria

- Males and females aged 18 years and above with a diagnosis of COPD.
- Able to provide informed consent.
- Refractory breathlessness at rest (Medical Research Council [MRC] dyspnoea scale ≥ 2) at any time in the preceding 4 weeks.
- Anxiety and depression.
- Can be on long-term oxygen therapy.
- Capable of writing/maintaining a diary and able to converse in English, for interviews.
- Patients of the Health New Zealand-Canterbury (Te Whatu Ora-Waitaha) respiratory outpatient service.
- Access to a device to play mindfulness recordings (via Podcasts/CD's/USB). If the participant does not have access to a suitable device, they will be loaned a device for the duration of the study.

Exclusion criteria

- Breathlessness of unknown origin, including a primary diagnosis of chronic hyperventilation syndrome.
- Within 2 weeks of an acute exacerbation requiring hospitalisation.
- Life expectancy of < 3 months.
- Severe comorbidities which would limit the participant's ability to participate in the study.
- Acute psychiatric disorder including schizophrenia, bipolar disorder, substance use disorder, or suicidality.
- Cancer diagnosis.
- Neurological disease and/or cognitive impairment, including dementia.
- Residing in the Chatham Islands due to travel logistics for the pre- and post-intervention home visits.

Recruitment timeline: November 2023–December 2023. Enrolment will be continuous until a sample of 30 participants is obtained.

Recruitment

This study seeks to recruit adults (18 years of age and older) with refractory breathlessness (Medical Research Council [MRC] ≥ 2) and moderate to advanced COPD via the Health New Zealand Canterbury respiratory outpatient department who will contact potential study participants (by email/post). To maximise recruitment, at the invitation of the group leaders, the researcher will attend the community-based Canterbury Community Respiratory Support and Exercise Groups to present the study and seek potential participants. The researcher will engage with Māori health workers to enlist their help in recruiting Māori participants and to ensure this research is ethically and culturally responsive.

Procedure

Consent: potential participants will contact the researcher directly or will indicate to Health New Zealand Te Whatu Ora staff that they are interested in the study. The researcher will then contact the person to provide information about the study, go through the information sheet and if they are willing to proceed, will obtain written informed consent (Additional file 1).

The research study is registered with the Australian and New Zealand Clinical Trials registry (37723) (Additional file 2).

Locality approval was provided by Health New Zealand (RO23012). Ethics was approved by the Health and Disability Ethics Committees, Ministry of Health, New Zealand (15152) (Additional file 3).

There is no cost to participants to take part in this study and no payment is made to participants. The researchers include registered health professionals (SH, JJ, AW, PS) and the research team have processes for dealing with any clinical matters arising during the treatment. This research is investigator-devised and led with the expertise of the supervision team.

Setting

The MBI will be undertaken within the province of Canterbury, in the South Island of New Zealand. The setting for the data collection and pre-treatment assessment will be determined by participant's choice (clinic or home or other setting). The MBI study will include up to three home/clinic/other contact assessment visits; pre-treatment assessment (physiological measurements and clinician-assessed or self-report measures), at end of treatment (9–10 weeks) and 3-month follow-up. Ten semi-structured qualitative interviews will be undertaken at the 3-month follow-up point.

Intervention

The MBI is provided for participants to self-deliver in their own home, or another place of their choice, for their comfort and convenience. The intervention is added to optimal pharmacological and non-pharmacological management already included within usual care (treatment as usual) for patients with moderate to advanced COPD and refractory breathlessness.

The MBI will be delivered by the researcher (SH), who is a Nurse Practitioner with a special interest in respiratory diseases and under the guidance of a supervisor (JJ) with expertise in mindfulness.

At weeks 2, 4, and 6 of the research study, participants will be contacted by telephone, text or email whichever is their preference. The purpose of this contact is to offer encouragement to continue the daily diary documentation and daily use of the MBI.

At the first meeting with the participants (pre MBI) the researcher will introduce the MBI and provide the participants with access to the online website, or if preferred recordings of the MBI on CDs or another suitable media.

There are nine mindfulness sessions to be undertaken for 8 weeks. The content of the sessions is listed in Table 1. Apart from week 6 which has two audios, all weeks have only one audio. Audios range from three to 26 min in duration.

The tasks and timeframes for the study are presented in Table 2. This study will employ pre and post-quantitative measurements and semi structured qualitative interviews conducted at the 3-month follow-up point. The post-intervention quantitative assessments will be undertaken at the 9–10-week point as the measures are designed to assess functioning over the past one to 2 weeks hence need to be undertaken after the intervention is complete. The 3-month follow-up qualitative assessments will add

Table 1 Mindful breathing intervention

Week #	Audio duration	Audio description
Week 1	3 min	Focus on the breath
Week 2	26 min	Body scan
Week 3	17 min	Seated meditation on the body which includes a body scan
Week 4	20 min	Meditation on the breath It also focuses on suspending judgement.
Week 5	20 min	Meditation on sounds, thoughts and emotions. The focus is on the hearing, watching difficult thoughts and emotions and just recognising them and being present. Accepting with no judgement of what comes.
Week 6	6 min total	An introduction to the Ten Breath Practice—introduction (3 min) and provides an explanation and then a brief practice. The Ten Breath Practice, (3 min) is more of a practice—it focuses on the breath while counting after the out-breaths and noticing how one feels. In consultation with Dr. Benzo and Dr. Zimmerman the researcher has decided to include both these audios in week 6 as they both focus on the breath and counting.
Week 7	20 min	Mindful standing Yoga. The standing yoga could also be done in a seated position if desired. It includes relaxing movements with gentle stretches.
Week 8	3 min	Review of mindfulness. This recording reinforces mindfulness and how to practice it. Tips-for-the journey. This audio also provides a conclusion to the MBI and promotes ongoing mindfulness practice.

Table 2 Spirit diagram [13]. Tasks, timeframes, and measures

		Data collection				
Tasks and measures	**Recruitment**	**Baseline**			**Follow-up**	**End of study**
Timepoint	**-T**	**Week 1**	**Week 8**	**Weeks 9–10**	**3 months**	
Recruitment	November 2023–December 2023					
Eligibility screen	x					
Informed consent	x					
Intervention		x	x			
Outcomes						
Quantitative data collection		x		x		
Physiological measures						
Respiratory rate, heart rate, blood pressure, and saturated percentage of oxygen		x				
Self-report measures		X		X		
COPD Self-efficacy scale		X		X		
St. George's Respiratory Questionnaire-C		X		X		
Medical Research Council Severity of Breathlessness Scale		X		X		
Hospital Anxiety and Depression Scale		X		X		
Five-facet Mindfulness questionnaire (Short-Form)		X		X		
EQ-SD-SL		x		x		
Semi-structured interviews					x	
Feasibility and acceptability data					x	
Daily diary throughout treatment		x	x			
Evaluation						x
Dissemination						x

valuable information regarding the participants continued use of the MBI and the extent to which benefits persist.

Outcomes

1) Feasibility will be established by assessing.

   a) Uptake (percentage of participants accepting, of those offered the intervention)
   b) Adherence (as recorded in the daily diary)
   c) Retention (percentage of participants completing at least 6/9 sessions)
   d) Acceptability of the MBI, assessed at the 3-month follow-up point through semi structured qualitative interviews.
   e) Levels of baseline mindfulness
   f) The MBI demonstrates increased mindfulness in those with low mindfulness at baseline.

2) Preliminary evidence of efficacy will be established by pre-post-change in self-efficacy of breathlessness control as measured by the COPD self-efficacy scale.

Pre-post-quantitative measures

The *COPD self-efficacy sale (CSES)* is a 34-item self-efficacy self-report scale for patients with COPD. The five factors included in the scale are: negative affect, intense emotional arousal, physical exertion, weather/environment. Scores range from 1 to 5, with higher scores indicating better levels of self-efficacy. This scale is well validated and widely used [14]. The CSES questionnaire is the primary quantitative measure in this study.

The *St. George's Respiratory Questionnaire (SGRQ-C)* is a 40-item validated health- related quality of life questionnaire. The SGRQ-C measures health impairment in patients with COPD. Part 1 produces a symptom score and part 2 produces activity and impact scores. Scores are calculated from a unique empirically derived weighting and the lowest possible weight is zero and the highest is 100. A total and three component scores are calculated (symptoms, activity, impacts). Each component of the questionnaire is scored separately [15].

The *Medical Research Council (MRC) Breathlessness Scale* is a 1 to 5 numeric rating scale and is a widely used and validated method of assessing breathlessness. The self-rated scale grades the degree of breathlessness in relation to activity. Grade 1—not troubled by

breathlessness except on strenuous exercise to grade 5—too breathless to leave the house or breathlessness when dressing or undressing [16].

The *Hospital Anxiety and Depression Scale (HADS)* is a 14-item of psychological distress (anxiety/depression subscales). It is a widely used and validated screening tool for anxiety and depression in non-psychiatric clinical populations. The self-rated scale consists of 14 items (7 each for anxiety HADS-A and depression HADS-D). Each item is rated on a four-point scale ranging from 0 (not at all) to 3 (very often). Responses are based on the relative frequency of symptoms over the preceding week [17].

The *Five Facet Mindfulness Questionnaire-Short Form (FFMQ-SF)* is a 24 item self-report questionnaire which measures five areas which describe experiences, non-reactivity, self-compassion, observing inner events, and acting mindfully. Scores are "never or very rarely true = 1, not often true = 2 sometimes true sometimes not true = 3 often true = 4 very often or always true" = 5, with 12 questions reversed scored (6-) [18].

The *EQ-5D-5L health related quality of life questionnaire* consists of the EQ-5D-5L descriptive system and the EQ Visual Analogue scale (EQ VAS). The EQ-5D-5L questionnaire is a validated and widely used self-report instrument to measure quality of health across a broad range of diseases and is frequently used in research. The descriptive system comprises the same 5 dimensions as the EQ5D-3L (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). However, each dimension now has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. Levels of perceived issues are coded from 1 to 5 and health status is summarised using the resultant 5-digit code (e.g. 12345). Status 11111 indicates no problems on any of the five levels. The VAS is coded as the exact number scored [19].

Daily diary

Participants will be asked to complete a daily diary (electronic or paper) throughout the duration of the MBI which will be collected by the researcher at the conclusion of the study at the post-MBI home/clinic/other setting visit. The daily diary will collect information on medication/mindfulness use, exercise or physical activity, breathlessness (MRC), and social/supportive interactions. The daily diary (yes/no) will also include a free text section to include other ways/techniques which the participant may have used to alleviate breathlessness. The diary may also be a monitoring tool, and it is hoped will provide important additional information including concordance with daily mindfulness.

Physiological measures (baseline only)

Physiological measures of breathlessness will be undertaken by the researcher (who is a Nurse Practitioner). These measures include the participants' respiratory rate, heart rate, blood pressure, and saturated percentage of oxygen. These measures will be taken prior to commencing the MBI.

Qualitative interviews

At the 3-month follow-up, 10 participants will be purposively chosen for the qualitative interviews. This selection process will include a mix of ages and gender, ethnicity, body mass index, and severity of disease. The interviews will be semi-structured, open-ended questions to elicit the participant's experiences, expectations and views about the acceptability and value of the MBI. An example of an interview question is "what aspects of the intervention have you found most helpful/unhelpful". Interviews will be no longer than 60 min in duration and can be undertaken face to face or via video/telephone or zoom conferencing if the participant desires.

Data management

Study data will be collected on paper-based case record forms (daily diary and questionnaires) and then entered into SPSS. SPSS files will be backed up on University of Otago servers. The daily diary and questionnaire booklets will be stored under lock and key in a filing cabinet at the University of Otago. The participants will each have a coded folder within the locked filing cabinet. The principal investigator will be the gatekeeper, and access will only be permitted to the research team (SH, MW, PS, JJ) and only as necessary.

De-identified (coded) information

To ensure the participant's personal information is kept confidential, information that identifies them will not be included in any report generated by the research team. Instead, the participants will be identified by a code. The research team will keep a list linking this code with the participants name so that they can be identified by their coded data if needed. The study's results may be published or presented, but not in a form that would reasonably be expected to identify any of the participants.

Security and storage of the information

The identifiable information will be held at Otago University–Christchurch during the study. After the study, it is transferred to a secure archiving site, stored for at least

10 years, and then destroyed. All storage will comply with local and/or international data security guidelines.

Rights to access information

The participants will have the right to request access to the information held by the research team. They also have the right to request that any information they disagree with is corrected.

Māori data sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

- We have consulted with the Māori research advisor Otago University–Christchurch, about the collection, ownership, and use of study data.

Risks

Although every effort will be made to protect the data privacy, absolute confidentiality of the information cannot be guaranteed. Even with coded and anonymised data, there is no guarantee that the participant cannot be identified. The risk of people accessing and misusing the information is currently very small but may increase in the future as people find new ways of tracing information. Data collected in the field will be transferred by the researcher immediately to the University of Otago and placed in the file under lock and key.

Please see the attached data management plan for additional information (Additional file 4).

Monitoring

Data monitoring

This study does not have external funding and hence there are no competing interests with a sponsor. A data monitoring committee has not been employed for this feasibility trial. If the results of this study suggest the need for a randomised controlled trial a data monitoring committee will be employed to provide study oversight. As this is a small feasibility study interim analyses during the study will not be undertaken. Data analyses will begin after the final study participant completes their follow-up questionnaires.

Harms

The Health and Disability Ethics Committees, Ministry of Health, New Zealand has reporting mechanisms for expected, and unexpected, adverse events and serious adverse events. As noted previously all the researchers are registered health professionals (SH, AW, PS, JJ) and the research team have processes for dealing with any clinical matters arising during the treatment.

Audit

The supervision team are all skilled researchers experienced in research processes, Fortnightly supervision (SH, AW, PS, JJ) meetings will ensure the study adheres to the agreed procedures and protocols and upholds ethical standards.

Statistical methodology

Given the scope of the feasibility study the aim is to recruit 30 participants. A sample size of 30 will allow the researcher to determine if there are likely to be problems in uptake, adherence, retention, and/or acceptability of the MBI. A sample size of 30 will provide a 90% power to detect a change in efficacy (or other continuous outcomes) with an effect size magnitude 0.62 or above (considered a medium to large change). The justification for this sample size is based on authoritative literature [20].

Quantitative analyses

Data analyses will be performed using the Statistical Package for the Social Sciences (SPSS) (version 27.0: SPSS Inc., Chicago, IL, USA). As a feasibility study, analysis will be exploratory and focused upon feasibility outcomes. Descriptive data will be reported in percentages, mean (standard deviations) and/or medians (ranges). Those participants who did not complete the MBI will be included in the main analysis but will be removed from the 'as treated' analysis. Pre-post-change scores for the self-report measures and Cohen's *d* effect sizes will be reported with 95% confidence intervals.

Given the small sample size, it is unlikely that there will be statistically significant differences established on the outcome measures.

Qualitative analyses

Qualitative interviews and entries from the free text daily diary will be imported into Nvivo (version 11). Inductive thematic content analysis will be conducted utilising Braun and Clarke's naturalistic interpretive approach employing structured process steps to explore the participant's views and experiences of the MBI. This process will incorporate member checking to ensure accuracy of interpretation [21].

Success criteria

The success of the feasibility study will be measured against the Red-Amber-Green (RAG) criteria [22] and aligned with feasibility outcomes. The RAG criteria will be useful to identify potential barriers and facilitators to the execution of a larger trial. To enable an in-depth

assessment of the feasibility and change in self-efficacy of the MBI a high retention and adherence rate was considered important to inform any potential future pilot study.

	Red	Amber	Green
1. Response rates participant response	Uptake < 25% of eligible patients	Uptake 25–50% of eligible patients	Uptake > 50% of eligible patients
2. Adherence (completed 6/9 sessions of the MBI)	Adherence rate < 50%	Adherence rate 50–70%	Adherence rate > 70%
3. Retention rates (those participants who completed pre- and post-quantitative questionnaires)	< 30% patients	30–50% patients	> 50% patients

Discussion

This study seeks to explore the feasibility (uptake, adherence, retention, acceptability) and preliminary estimates of efficacy of a self-managed daily MBI in improving self-efficacy in management of COPD. Other outcomes measured include breathlessness, mood and anxiety, quality of life, and mindfulness. The 3-month follow-up interview to assess acceptability is a strength of this feasibility study and the results from these qualitative interviews will be used to inform and modify the MBI for future research. It is hoped that this self-delivered home-based intervention will overcome previously identified issues which have provided barriers to uptake and utilisation of mindful breathing to date. To the researcher's knowledge, mindful breathing delivered on a daily basis and self-managed by the participants in their own homes has not been done previously with COPD and hence a feasibility study is necessary to explore the acceptability and preliminary evidence of effectiveness of this MBI especially within the New Zealand context and to inform future research. This research is of significance to Māori (Indigenous people of New Zealand) who are three and a half times more likely to die from COPD-related causes than other ethnicities and are affected by COPD 15 to 20 years earlier than non-Māori [2]. It is important to assess the acceptability of the MBI for Māori given the increased burden of COPD for this group.

This research will be disseminated in journal articles in peer-reviewed publications.

Abbreviations

MBI Mindful breathing intervention
CSES COPD Self-efficacy Scale
SGRQ-C St. George's Respiratory Questionnaire-COPD
MRC Medical Research Council Severity of Breathlessness Scale
HADS Hospital Anxiety and Depression Scale
FFMQ-SF Five-Facet Mindfulness Questionnaire-Short Form

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40814-025-01649-x.

Additional file 1. Participant information and consent form.

Additional file 2. Data management plan.

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Trial sponsor

University of Otago, Christchurch. The trial sponsor is not involved in the design, analysis or interpretation of the findings.

Trial status

Participant recruitment commenced beginning of November 2023 and was completed by the end of December 2023. Data collection is ongoing at the time of writing this manuscript.

Authors' contributions

SH conceived the study. All authors assisted SH with the design of the research protocol. SH drafted the manuscript. Other authors made conceptual or design contributions to the study and critiqued the draft manuscript. JJ approved the final version for publication.

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This research is being undertaken as part of a PhD project and has received no external funding.

Data availability

The data sets to be generated or analysed during the study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Ethics reference: Health and Disability Ethics Committees, Ministry of Health, New Zealand.
2023 AM 15152, 9th October 2023.

Consent for publication

The study participants gave consent for publication of their de-identified qualitative and quantitative data.

Competing interests

The authors declare that they have no competing interests.

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