A home-based intervention to promote mindful breathing awareness through pursed-lip breathing training for COPD patients

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Hypothesis:
We hypothesize that providing COPD patients with a mindful breathing module that is easy-to-use, prompts them to complete daily mindful breathing practice, and provides feedback will improve their breathing mechanics, emotional awareness, increase the time that they spend in heart rate coherence, and improve their quality of life.

Aims, purpose, or objectives:
The primary outcomes of the study are changes in breathlessness and emotions. Changes from baseline to three months on the two primary outcomes will be compared between the study arms using two-sample, two-sided t-tests with 5% type I error rates. Means, SDs, medians, ranges, and frequency distributions will be reported and plotted over time by study arm. Linear models will be used to assess the impact of treatment arm on three-month outcomes after adjusting for the corresponding baseline measure and other variables related to the outcome (age, degree of breathlessness at baseline using the mMRC dyspnea, and FEV1).

Methods:
This project will involve two Phases: phase one in which mindful breathing by itself without any other device will be tested to make sure that it is acceptable to patients and makes a difference comparing to the usual protocol in use right now. Phase two will include a particular device that will guide the mindful breathing practice that we think will be more intuitive to practice and guide the mindful breathing and that device will be tested once we know that the acceptance to the mindful breathing practice, from phase one, is appropriate.

Phase 1: A total of 70 adults diagnosed with COPD will be enrolled in the study. Half of the participants will be randomized to receive the home-based PR with the Pursed Lipped Breathing Application (intervention) and half will receive the home-based PR (control). Randomization will take place in a REDCap database and will be in equal proportion.

Phase 2: A total of 70 adults diagnosed with COPD will be enrolled in the study. Half of the participants will be randomized to receive the home-based PR with the mindful breathing module which consists of the Pursed Lipped Breathing Application and the Spire Health Tags (intervention) and half will receive the home-based PR (control). Randomization will be take place in a REDCap database and will be in equal proportion.

Both groups entail one week of baseline where the participants wear an ActiGraph activity tracker and answer questionnaires. Baseline is followed by 12 weeks of home-based PR plus health coaching. The Intervention group also has the mindful breathing module loaded on the Android tablet. Both groups will also complete questionnaires and wear an ActiGraph activity monitor at 3 and 6 months.

Questionnaires:
Quality of Life will be assessed three times (baseline, 3 and 6 months) by the Medical Research Council (mMCR) questionnaire, the Chronic Respiratory Disease Questionnaire (CRQ), the Self-Management Ability Scale (SMAS30) and the Mindful Attention and Awareness Scale (MAAS). The questionnaires take about 20 minutes to complete.
At baseline additional health data will be collected from the medical record (chart review) to complete the Charlson comorbidity index, including lung function, demographics, living condition (living alone or not), GOLD stage, and comorbidities.

ActiGraph:
Physical activity will be measured three times (baseline, 3 and 6 months) by the ActiGraph activity monitor. The ActiGraph activity monitor has tri-axial accelerometers and will be wrist worn for seven days. Important measures to be analyzed are daily number of steps, activity counts, minutes per day spent in daily physical activities of at least moderate intensity, and sedentary time (<2 metabolic equivalents).

The questionnaires and Acti Graphs will be mailed to the participant with pre-paid shipping materials to send back.

Health Coaching:
All participants will receive a weekly coaching call to discuss their rehabilitation and health process. The calls are structured using motivational interviewing. The coach will review with the patient the data from the health coach system. Collaboratively, goals for rehabilitation for the following week will be set, based on information gathered and the patients' personal preferences. Each call lasts about 20 minutes. All calls will be taped to ensure compliance with the protocol.

Target accrual: 140
Subject population (children, adults, groups): Adults 40 years of age or older
Inclusion Criteria:
- Clinical diagnosis of COPD
- At least 10 pack years of smoking

Exclusion Criteria:
- Unable to do mild exercise (orthopedic-neurologic problems or confined to a bed)
- Unable to follow commands (cognitive impairment)
- Have a high likelihood of being lost to follow-up (active alcohol or drug abuse)
- Live in an area that does not have cellular service (Verizon)

Potential participants will have the option of meeting a study coordinator in person (if they are on campus for a clinical appointment), meeting via Video Anywhere through Epic, or meeting over the phone. If the patient desires, their consent can be digitally obtained and documented through PTRAX. The patient also has the option of receiving the consent via mail and mailing back the consent in a provided postage paid envelope. Documentation of informed consent/HIPAA authorization will involve the use of the Research Participant Tracking (PTrax) Digital Signature Capture technology for research informed consent/HIPAA authorization forms. This is an institutionally approved process for documenting consent/HIPAA authorization only while the subject, and/or the subject's representative, is in the physical presence of the person authorized to obtain consent/HIPAA authorization. The study team may print a copy of the signed consent form/HIPAA authorization form for the subject or their representative. The consent form/HIPAA authorization form will also be available to the subject via the patient portal. Note: If the subject or their representative prefers not to use the Digital Signature Capture technology, the study team will provide a paper consent form/HIPAA authorization form for signature.

Statistica Analysis Plan

Sample Size
We calculated that sixty two participants will provide 80% power to detect 1 point of change in the two co primary outcomes (breathlessness and emotion as measured by the CRQ) with an alpha of 0.025. A 1 point change represents a clinically meaningful change.95 We expect about a 20 percent attrition rate (withdraw, not able to complete the 12 weeks of home-based rehab) and will therefore enroll 70 participants in each phase.

Analysis Plan
The primary outcomes of the study are changes in breathlessness and emotions. Changes from baseline to three months on the two primary outcomes will be compared between the study arms using two-sample, two-sided t-tests with 5% type I error rates. Means, SDs, medians, ranges, and frequency distributions will be reported and plotted over time by study arm. Linear models will be used to assess the impact of treatment arm on three-month outcomes after adjusting for the corresponding baseline measure and other variables related to the outcome (age, degree of breathlessness at baseline using the mMRC dyspnea, and FEV1).
The Chronic Respiratory Disease Questionnaire (CRQ) is a 20-question inventory assessing the areas of dyspnea, fatigue, emotion, and feelings of mastery. The fatigue, emotion, and mastery subscales ask patients to rate how often in the last two weeks they have been afflicted with a particular feeling or experience on a scale of 1 to 7, with higher ratings indicating less symptom impairment. The CRQ has shown to be valid and has high internal consistency reliability. Test-retest reliability is adequate in all subscales, but is particularly high in the subscales of fatigue (r=0.90), emotion (r=0.93), and mastery (r=0.91). The minimal clinically important difference for this instrument of 0.5 points is universally recognized. The Domains Dyspnea (breathlessness) and Emotions are the two co primary outcomes.

Physical activity will be measured at baseline, 3, and 6 months by the ActiGraph GX6 activity monitor, which has been used to assess physical activity in COPD populations. (92) The number of daily steps at baseline, 3, and 6 months and across the two groups will be compared. Emotional Intelligence will be measured by the Trait Emotional Intelligence questionnaire at baseline, 3, and 6 months .(84) Mindfulness will be measured by the Mindful Attention and Awareness Scale at baseline, 3, and 6 months.(93) The participants HRC and respiratory rate will be tracked for the entire intervention period using the Spire Health Tags. At baseline additional health data will be collected from each participant's medical record to complete the Charlson comorbidity index, including lung function, demographics, living condition (living alone or not), GOLD stage, and comorbidities.