An Intervention for Pulmonary Rehabilitators to Develop a Social Identity for Patients Attending Exercise Rehabilitation: A Feasibility and Pilot Randomised Control Trial Protocol

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) is a degenerative condition that can impair health related quality of life (HRQoL). A number of self-management interventions, employing a variety of behavioural change techniques (BCTs), have been adopted to improve HRQoL for COPD patients. However, a lack of attention has been given to group management interventions with an emphasis on incorporating BCTs into rehabilitators practice. This study aims to pilot and feasibly explore a social identity group-management intervention, delivered by COPD rehabilitation staff to patients attending exercise pulmonary rehabilitation. Doing so will help inform the plausibility of the intervention before conducting a full trial to evaluate its effectiveness to improve HRQoL.

Methods: This is a two center, randomized cross-over controlled trial. Two pulmonary rehabilitation centres based in the UK will be randomly allocated to two treatment arms (standard care and intervention). Outcome measurements relating to HRQoL and social identity will be completed pre and post exercise rehabilitation. Focus group interviews will be conducted at the end of exercise rehabilitation to capture participants' contextualised experiences of the intervention. COPD rehabilitators will undertake semi-structured interviews at the end of the trial to garner their holistic perspectives of intervention fidelity and implementation.

Discussion: This is the first study to adopt a social identity approach to develop a rehabilitator-led, group management intervention for COPD patients attending exercise pulmonary rehabilitation. The results of this study will provide evidence for the feasibility and sample size requirements to inform a larger study, which can ascertain the intervention's effectiveness for improving HRQoL for COPD patients.

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Keywords: COPD, group intervention, identity, quality of life

Background

COPD is a chronic debilitating condition and it is estimated that by 2020, COPD will be the fifth most burdensome disease and the third leading cause of mortality worldwide [1]. In view of the fact that COPD is a progressive disability, many individuals will experience the slow development of functional impairment and subsequently a deterioration of HRQoL. Therefore, HRQoL in COPD sufferers has become an important treatment outcome [2].

Since there is currently no cure for COPD, self-management of the disease is essential for reducing symptoms and improving the HRQoL. The goal of self-management is for patients to acquire the skills needed to carry out disease specific medical regimes, to guide changes in health behaviour and to provide emotional support to enable patients to adjust their roles for optimal function and control of their disease [3]. A plethora of self-management interventions to improve HRQoL among COPD patients have been developed and empirically tested. A meta-analysis of randomised controlled trials (RCTs) and non RCTs revealed self-management-based interventions improve HRQoL in COPD populations over and above standard care provision [4]. More recently, Newham and colleagues [5] concluded self-management interventions can be more effective than usual care for improving HRQoL, however their effectiveness was variable.

A number of recent reviews have attempted to explore the content underpinning self-management interventions [5,6]. Notably, the content of self-management interventions has comprised of a number of behavioural change techniques such as patient education, action planning, goal setting and biofeedback. The delivery of these techniques were largely conducted by non-clinical staff through individual sessions either face to face or telephone conversations, or through the individual distribution of booklet information. Based on the aforementioned reviews, two eminent issues arise. First, it is not surprising that self-management interventions have largely taken an individualistic approach given that sufferers

of COPD are diagnosed and treated as individuals in hospital, or when visiting the doctor. Group contexts, however, such as exercise rehabilitation, can provide an additional opportunity to improve the HRQoL for COPD sufferers through the group management of COPD treatment. To date, the utilisation of group contexts to facilitate group management interventions has largely remained unexplored. Given that COPD sufferers can be stigmatised [7], they may consequently experience impaired social interactions and isolation [8]. Group-management interventions, therefore, have the potential to promote positive social relationships and mutual social support for fellow COPD sufferers, providing an alternative contribution towards their HRQoL. Second, there is a notable lack of clinical staff involved in the delivery of group management interventions within the COPD literature. In the context of pulmonary exercise rehabilitation, COPD rehabilitators are uniquely positioned to make an important contribution to the delivery of behaviour change techniques given their active engagement in exercise rehabilitation. Nurse-led self-management interventions have been found to reduce symptoms and improve HRQoL among COPD patients [9]. However, to date no research has explored the feasibility for involving COPD rehabilitators in the delivery of group-management interventions in the context of pulmonary exercise rehabilitation.

A theoretical approach not yet considered for the group management of COPD is social identity theory [10]. The key premise of social identity theory is that group membership (e.g., exercise group) to which a person belongs, can provide an individual with a sense of who they are in terms of a defined group identity (i.e., 'we' and 'us' rather than 'I' and 'me'). That is, the way a person feels and thinks about self is derived from their social groupings. According to social identity theorising, a group identity is formed on the basis of three contextually salient social processes: 1) *categorisation*: awareness of similarities that connect group members as a team; 2) *identification*: positively valuing the importance of belonging to a group membership; and 3) *inter-group comparison*: group membership

perceived as more favourable in comparison with other out-groups. In group contexts, the social processes underpinning social identity theorising can serve to enhance group members' self-esteem, sense of connectedness to others, and provide a basis for receiving social support [11]. Furthermore, identifying with activities that are congruent to the group can facilitate adaptive cognitive, emotional and physical well-being within individuals as a result of favourable social group exchanges [11]. Therefore, the development of social identity within a group- setting can be adaptive for one's well-being and achieving desirable health outcomes.

In the context of health and well-being there is emerging evidence for interventions that draw upon the social identity approach [12,13,14, 15, 16]. Collectively these findings suggest that social identity has benefits for well-being among older adults, in part because groups facilitate communication and engagement with information, alongside providing a basis for providing social support and positive social integration. In view that COPD mainly affects older adults, it is possible that group contexts that develop a social identity can make an important contribution to their HRQoL. Therefore, the purpose of the present study is to feasibly examine a pilot RCT rehabilitator-led social identity intervention, in order to obtain data for a future effectiveness trial to improve the HRQoL for COPD patients attending exercise pulmonary rehabilitation. Specifically, the feasibility and pilot RCT will determine:

1. The required sample size for a larger RCT trial to establish effectiveness.
2. Recruitment, retention and adherence rates, alongside identifying the practicalities and strategies to facilitate these rates for COPD patients.
3. The appropriateness of outcome measures and randomization in terms of:
    a. Patient willingness to complete outcome measures (e.g., percentage of completed data and missing data).

b. Rehabilitator willingness for collecting outcome data (e.g., percentage of completed and missing case report forms).

c. Rehabilitator and patient willingness to be randomized across centres.

4. The acceptability of the intervention for patients, with respect to:

a. Engagement and compliance to the intervention protocol.

b. Perceptions of barriers and facilitators for COPD patients.

c. The degree of patient satisfaction.

d. The perceived relevance of the intervention.

5. The acceptability for rehabilitators delivering the intervention, in terms of:

a. Intervention fidelity (e.g., compliance with training protocol, monitoring of intervention delivery competency).

b. Provision of resources for intervention implementation.

c. Perceptions of barriers and facilitators for practice change.

Methods

Study design and setting

We propose a pilot, two center, randomized cross-over controlled trial. Two pulmonary rehabilitation centres based in the UK will be randomly allocated to two treatment arms (centres are units of randomisation, not the patients). A total of 42 consecutive eligible participants undergoing the an 8-week pulmonary exercise rehabilitation at two centres will be consented as the first trial cohort. The participants in one centre will be given standard care (n = 21) and the participants in the second centre will be given the intervention (n = 21). The standard care arm will consist of participants receiving their standard pulmonary exercise rehabilitation program (the control group), and the intervention arm will consist of patients receiving the standard pulmonary rehabilitation program plus a rehabilitator-led intervention

aimed at developing a social identity (the intervention group). After the first cohort completes their 8-week rehabilitation program, the centres will switch study arms and a second cohort of 42 new eligible participants will be recruited. This cross-over design aims to achieve symmetry of any confounders relating to rehabilitation centre location. Quantitative outcome measures will be determined at two time points: before rehabilitation (week 0) and at the last week of rehabilitation (week 8). Participants will also be invited to attend focus groups at the end of the rehabilitation period (week 9) to obtain a qualitative evaluation of the intervention. Obtaining both quantitative and qualitative information will help establish a clear and comprehensive plan for progression into a future full RCT trial. See Figure 1 for an overview of the study design.

Sample size estimation

As this is a feasibility and pilot study, in conjunction with adopting a novel intervention that has not been tested with COPD patients, no formal sample size calculation will be conducted. We aim to recruit sixty COPD patients within 6 months. This sample size is in accordance with recommendations for parameter estimation from pilot studies in order to determine an appropriate sample size for a full clinical trial [17]. However, in order to mitigate the known high dropout rate due to high incidences of acute exacerbations for COPD patients during pulmonary rehabilitation, an additional 24 patients (40%) will be recruited.

Participant recruitment and eligibility

In this feasibility and pilot study we plan to recruit 84 consecutive eligible COPD patients attending pulmonary exercise rehabilitation. Rehabilitators will recruit participants who have been referred to pulmonary exercise rehabilitation. Prior to embarking upon exercise pulmonary rehabilitation, rehabilitators will provide each participant with an information sheet providing full details of the study. Those participants willing to take part

will be asked to complete a consent form. To be eligible to take part in this study participants must: 1) have been diagnosed as having COPD and enrolled on a pulmonary rehabilitation programme; 2) score between 1-4 on the modified medical research council dyspnoea scale; 3) have FEV_1 / FVC < 0.7 on spirometric recording, as per NICE guidance; 4) willingly provide written informed consent.

Description of the intervention

Based on a literature review and tenets of social identity theory, the intervention will train COPD rehabilitators to create a social identity for COPD patients attending exercise rehabilitation. Social identity will be operationalised based on the technique of group goal setting. There is an increasing body of research to support the theoretical integration of social identity principles and group goal setting [18,19]. In the context of the current intervention, for example, group-based goals will serve to 1) increase the likelihood that COPD patients will define themselves as members of the same exercise rehabilitation group, ''we'' or ''us'' (i.e., categorization); 2) provide a sense of common fate and collective group purpose and meaning (i.e., identification); and 3) define exercise rehabilitation as a distinct social in-group compared to other social out-groups (i.e., inter-group comparison).

COPD rehabilitators will be invited to attend two workshops, each lasting two hours. The first workshop will focus on knowledge dissemination of social identity principles in the context of exercise pulmonary rehabilitation. Its objective will be to ensure COPD rehabilitators understand social identity and how its principles relate to COPD patients attending exercise rehabilitation. The second workshop will be concerned with the practical application of social identity through collaborative SMART group goal setting, in exercise pulmonary rehabilitation. Its objective will be for COPD rehabilitators to understand how to develop social identity using the technique of group goal setting for COPD patients during exercise rehabilitation. Both workshops will be classroom-based and will be delivered using a

range of visual aids including PowerPoint slides and video clips. Group activities in the form of discussions, brainstorming, scenario problem solving and reflexivity will be incorporated into both workshops. Prior to each workshop, COPD rehabilitators will be provided with training packs that contain, PowerPoint Slides, workshop notes, planning sheets, and guides for monitoring and evaluating goal progress. The workshop instructor will be a member of the research team who is a qualified Practitioner Psychologist with the Health and Care Professions Council in the United Kingdom. The instructor will be available to provide immediate feedback and answer any questions the COPD rehabilitators may have over the course of the workshops.

Data collection

Baseline questionnaire data will be collected during participants' first pre-rehabilitation assessment visit (Week 0; Time 1), including demographic data, anthropometrics, smoking status, medical history. Outcome measures recorded during the assessment visit will be the COPD Assessment Test (CAT), Chronic Respiratory Questionnaire-Self Report (CRQ-SR), Lung Information Needs Questionnaire (LINQ) and the modified Medical Research Council (mMRC) scale. Objective data will be collected via a participant Six-Minute Walk Test (6MWT). Outcome measures will be re-administered during a follow up assessment, one-week post rehabilitation completion (Week 9; Time 2). Additionally, baseline data will be collected during the first rehabilitation session (Week 1; Time 1) that will include outcome measures pertaining to EuroQoL - 5 Dimensions – 5 Levels (EQ-5D-5L), Hospital Anxiety Depression Scale (HADS), In-Group Identification Scale (IGIS) and re-administered during the last rehabilitation session (Week 8; Time 2). Focus group interviews with participants from the intervention group will be conducted during their follow up assessment (Week 9) and individual interviews with the rehabilitators will happen immediately at the end of the trial period.

Outcome measures

   CAT. The CAT was designed to assess COPD-specific HRQoL and consists of eight items presented as a semantic 6-point differential scale. Items assess cough, production of phlegm, chest tightness, breathlessness, activity limitations, confidence, sleep and energy. The minimum score possible for each item is 0 and the maximum score is 5. As such, the overall score can range between 0-40. The CAT has demonstrated good reliability (cronbach's coefficient alpha = 0.88) and good test re-test reliability (intraclass correlation coefficient = 0.80) [20].

   CRQ-SR. The CRQ-SR measures HRQoL in patients with COPD. It contains 20-items that assesses dyspnoea (5-items), fatigue (4-items), emotional function (7-items) and mastery (4-items). Patients select, rank and score five everyday activities that make them breathless on a 7 point-likert scale from 1 (extremely short of breath) to 7 (not at all short of breath). Scores are calculated by dividing the total score per domain by the corresponding number of items. Therefore, overall scores can range, per domain, between 1-7 with lower scores indicating a greater degree of dysfunction. The CRQ-SR has demonstrated good reliability across all domains with cronbach coefficient alphas ranging between 0.75-0.91 [21]. The CRQ-SR intraclass correlation coefficient ranges between 0.83-0.90 [22], demonstrating very good test re-test reliability.

   LINQ. The LINQ is an information needs patient-centred instrument, assessing COPD disease specific knowledge and management. It contains 16-items and is composed of 6 subscales including disease knowledge, medication, self-management, smoking, exercise and diet. Each item is multiple choice and scored where 0 = no information need and 1-3 = an informational need. Scores are summed for each subscale and can range from 0-4 (disease knowledge), 0-5 (medication), 0-6 (self-management), 0-3 (smoking), 0-5 (exercise) and 0-2 (diet). Higher scores reflect a greater informational need. The LINQ has been found to have

good test-retest reliability (interclass correlation coefficient 0.66-0.98) and an overall total score cronbach alpha coefficient of 0.62 [23].

mMRC. The mMRC is a measure of perceived respiratory disability for daily activities. It consists of five descriptive breathlessness statements graded 0 (not troubled by breathlessness) to grade 4 (being too breathless) and is used extensively as an evaluation rating for dyspnoea [24] and a valid tool to assess disability in patients with COPD [25]. Furthermore, Hsu and colleagues [26] have concluded that the mMRC is a concise and practical tool to assess the HRQoL of COPD patients in daily clinical practice.

EQ-5D-5L. The EQ-5D-5L is a generic measure of HRQoL. It consists of five dimensions, mobility, self-care, usual activities, pain/ discomfort and anxiety/depression. Each dimension has a five-level response option ranging from 1 (no problems) to 5 (extreme problems). Scores across the 5-level responses are combined to produce a five-digit number that is converted to a utility index based on the EQ-5D-5L value set for England [27]. The utility index ranges from -0.208 (worst possible health) to 1.000 (best possible health). The EQ-5D-5L also includes a 20cm visual analogue scale that records patient's self-rated health with end points ranging from 0 (the worst health you can imagine) to 100 (the best health you can imagine). A recent study by [28] validated the use of the EQ-5D-5L as a measure for HRQoL with COPD patients.

HADS. The HADS was developed to detect states of depression and anxiety amongst patients in clinical settings. It contains 14-items and consists of two subscales, anxiety and depression. The items are rated on a four-point likert scale ranging from 0 (not present) to 3 (considerable). Item scores are summed giving separate scores for anxiety and depression ranging from 0 to 21. The psychometric properties for the use of the HADS among COPD patients have previously been successfully established [29]. Previous research has indicated

anxiety and depression, as measured by HADS, to be associated with HRQoL for respiratory conditions [30, 31].

IGIS. The IGIS is a 14-item multidimensional measure of social identity related processes. Specifically, it measures social processes of identification towards a group membership across five domains, solidarity (3-items), satisfaction (4-items), centrality (3-items), individual stereotyping (2-items) and in-group homogeneity (2-items). In this study, group membership will be associated with the COPD exercise rehabilitation group and will be referred to as such in all items. Each item will be rated on a 7-point likert scale anchored at 1(strongly disagree) to 7 (strongly agree). Scores will be calculated by dividing the total score per domain by the corresponding number of items. Therefore, scores can range between 1-7 with higher scores indicating greater group identification. Leach and colleagues [32] have shown the IGIS to be reliable and valid.

6MWT. The 6MWT is a functional exercise capacity test approved by the American Thoracic Society for use with COPD patients. The objective of this test is for patients to walk as far as possible during six minutes over a 30 metre marked stretch. Upon test completion, the total distance covered will be calculated. Previous research has identified that exercise capacity, as determined by the 6MWT, is an important physiological factor that can determine HRQoL [33].

Interviews

At the end of each 8-week exercise rehabilitation programme, the intervention group will undertake a focus group interview. The group interviews will primarily focus on the acceptability of the intervention from COPD patients' perspectives. In addition, to ascertain COPD rehabilitator perspectives of intervention acceptability, individual semi-structured interviews will be conducted once the entire rehabilitation period has been completed.

Data analyses

Prior to data analyses, quantitative data will be screened for data entry accuracy (approximately 10% of the sample), out of range values and missing data. The mean and standard deviation (median and interquartile range for non-normally distributed data) and percentages will be used to calculate participant recruitment, outcome measure completion, rates of retention and adherence, and pre and post intervention values for all outcome values. Since this is a pilot study, treatment comparisons will focus on effect size estimation and associated 95% confidence intervals rather than hypothesis testing, as recommended [17]. A systematic inductive thematic approach [34] will be used to analyse patient focus group interviews and rehabilitator individual semi-structured interviews.

Discussion

Involving COPD rehabilitators in the delivery of group management interventions can potentially offer an alternative way for improving HRQoL for COPD patients. This feasibility and pilot RCT will examine a social identity derived group-based intervention, which is rehabilitator led and delivered to COPD patients attending exercise pulmonary rehabilitation.

The proposed intervention is informed by a prominent theory (social identity) for understanding interpersonal relations. This is a key strength of the intervention as theoretical underpinning is essential for understanding the processes informing how and why the intervention may or may not work [35]. Furthermore, contextual factors may shape theoretical processes and therefore need to be fully understood to determine how interventions will work in real world settings [35]. According to MRC guidance [35], interventions can be undermined by a lack of understanding concerning the context that interventions take place. As such, it is essential that the proposed intervention is developed with both theoretical and contextualised consideration in order to build an evidence base that informs COPD rehabilitator practice. The feasibility and pilot study proposed, therefore, is

innovative as it will explore the compatibility of social identity theory in the context of pulmonary exercise rehabilitation for incorporating into rehabilitator-led practice. This information is paramount to determine if the proposed intervention can be feasibly done and if so how. As previously recommended [36], the pilot element will extend the feasibility component by conducting a small scale study to determine randomization and required sample size for a future larger scale RCT.

There have been an increasing number of attempts to develop social identity-based interventions [11], however, such advances have not feed through to COPD rehabilitators working in pulmonary exercise rehabilitation. At present, there is no information available about social-identity derived behaviour change techniques to educate COPD rehabilitators. In order to bridge the gap between theory and practice, behaviour change techniques need to be feasibly developed and evaluated in order to empower COPD rehabilitators to operationalise social identity-based processes that can be implemented into group exercise rehabilitation. To this end, our protocol has described and rationalised the design of a study to pilot a new group-based intervention that integrates the social identity approach with group goal setting. The findings will inform a future RCT to test the effectiveness of a rehabilitator-led social identity-based intervention for improving the HRQoL of COPD patients attending exercise rehabilitation.

Abbreviations

COPD: Chronic Obstructive Pulmonary Disease; HRQoL: Health Related Quality of Life; BCT: Behaviour Change Technique; RCT: Randomized Control Trial; SMART: Specific, Measurable, Attainable, Realistic, Timely; CAT: COPD Assessment Test; CRQ-SR: Chronic Respiratory Questionnaire-Self Report; LINQ: Lung Information Needs Questionnaire; mMRC: modified Medical Research Council; 6MWT: 6 Minute Walk Test; EQ-5D-5L:

EuroQoL-5 Dimensions- 5 Levels; HADS: Hospital Anxiety Depression Scale; IGIS: In-Group Identification Scale; MRC: Medical Research Council

Availability of data and materials

Not applicable.

Authors contributions

AL is the chief investigator and drafted the manuscript. AL, AM and BM are responsible for the development of the protocol and its ethical approval. All authors contributed to the conception and production of the study procedures and materials. AW, BM and AL are responsible for quantitative and qualitative analysis. All authors contributed to the editing and revising of the manuscript.

Ethics approval and consent to participate

Ethical approval for this study has been granted by the National Research Ethics Service established by the Health Research Authority (National Health Service, UK), ref: 15/NW/0023. During recruitment, participants will be provided with an information sheet about the study and will need to provide written consent to take part. Participation in the study will be voluntary and participants have the right to withdraw at any time without incurring any form of penalty. Data collected will be confidential and stored in a secure

research unit. Hard copy data will remain in a locked cabinet in a key pad protect room and electronic data will be secure on password protected computer. All data will remain anonymous and not identifiable to any participants. Quantitative data will be coded with identification codes and qualitative data will use pseudonyms and identifiable information redacted.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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