UNIVERSITY OF BIRMINGHAM

BREATHE WELL

EXPLORING THE VALUE OF A COMMUNITY-BASED PHYSICAL ACTIVITY INTERVENTION FOR COPD PATIENTS WITH VARYING NEEDS IN BRAZIL (BW2).

UNIVERSITY OF BIRMINGHAM

BREATHE WELL BRAZIL GROUP

BREATHE WELL PROJECT

TITLE:

- Exploring the Value of a Community-Based Physical Activity Intervention for COPD Patients with varying needs in Brazil (BW2).

Protocol Version

- Version 024 (16/10/2019)

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Positions and Responsibilities: Names, Affiliations and Responsibilities

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- Nadine Cristina Machado (NCM): Physiotherapist; Pulmonary Rehabilitation specialist; researcher; will act as an observer.
- Talita Cepas Lobo (TCL): Psychologist; researcher; will act as an observer.
- Eduardo Magalhães (EM): Researcher at the Federal University of ABC; specialist in Qualitative Research; will provide specialised support to the team.
- Vânia Barbosa Nascimento (VBN): Researcher; head of the Collective Health discipline of the ABC School of Medicine, will act as advisor of the SMM doctoral course.
- Dr. Rachel Adams (RA) from the University of Birmingham; will oversee the study in conjunction with other UoB contributors.

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ACRONYMS

AFTL	lowest score lower
BHU	Basic health Unit
BW1	Breathe Well 1
BW2	Breathe Well 2
GHQ-12	General Health Questionnaire
CanCOLD	Canadian Cohort Obstructive Lung Disease
CHA	Community Health Agent
CAT	COPD Assessment Test
CBT	Cognitive Behavior Therapy
CKD	chronic kidney disease
COPD	Chronic obstructive pulmonary disease
DOB	Date of Birthday
DLPA	Double step
FEV1	Forced expiratory volume in one second
FG	Focus group
GERD	Gastroesophageal reflux disease
GAD-7	Generalized Anxiety Disorder Screener
GLI	Global Lung Function Initiative
IHD	ischemic heart disease
PA	Physical activity
PR	Pulmonary Rehabilitation
PHT	Pulmonary Hypertension
PHQ-9	Patient Health Questionnaire -9
QOL	Quality of life
MET	Expenditure in metabolic equivalents

PRP	Programs pulmonary rehabilitation
SMM	Skeletal muscle mass

SUMMARY

Research Question:

Aim:

- To explore the barriers and enablers to physical activity and exercise programmes amongst COPD patients in Brazil with and without mood disorders (anxiety and / or depression).

Population

- Patients with newly diagnosed COPD from the Breathe Well 1 (BW1) project with and without mood disorders.
- Patients with and without mood disorders who have established COPD and are being treated at the Basic Health Units in São Bernardo do Campo, São Paulo, Brazil.

Inclusion Criteria

- Patients diagnosed with COPD as part of BW1
- Patients being treated for COPD at the Basic Health Units in São Bernardo do Campo, São Paulo, Brazil.

Exclusion Criteria

- Patient unable to give valid consent
- Patients with moderate / severe cognitive impairment
- Patients with a diagnosis of asthma

Methods

This study follows is known as BW2 and will follow on from BW1. Eligible patients will be invited to a screening appointment where the study will be explained and consent obtained. Eligible patients will then be invited to one of 7 focus groups (FGs) each containing 6-10 participants. The first group will be a pilot. Followed by 2 sets of FGs – one containing COPD patients with anxiety and / or depression, the other set containing COPD patients without anxiety or depression. In each set one FG will be conducted with newly diagnosed COPD patients, another with patients who have established COPD and a third with a mix of newly diagnosed and established COPD patients. During screening FEV1 and CAT scores will be recorded from patient notes and sampling questionnaires completed. Sampling will enable researchers to identify those with anxiety and /or depression and those with newly diagnosed or established COPD. It will also enable inclusion of participants with a range of disease severity, a range of ages, gender, levels of exercise / activity and education.

FGs will be audio recorded and transcribed. A selection of transcripts will be translated into English.

Analysis

- FG data will be analysed thematically using framework analysis to identify barriers and facilitators to the introduction of a PA program appropriate to the primary care setting in Brazil.

CONTENTS

BACKGROUND

Chronic obstructive pulmonary disease (COPD) is recognized as a worldwide public health problem [1,2] imposing an economic and social burden on patients and the health system.[3] Although it is a preventable and treatable disease, it is the fourth leading cause of death worldwide[2], while in Brazil it is the third leading cause of death among non-communicable chronic diseases.[3] It is estimated that in Brazil the prevalence of individuals with COPD is 7.3 million.[4] It is a debilitating disease [5] which is often underdiagnosed in the early stages.[3,6] Often found in smokers[5] but environmental pollutants, particulates and gases (biomass burning) are also involved in the genesis of COPD[3] as well as aging.[7,8] It is a highly disabling disease[9,10] marked by severe social and economic impairment as well as a high frequency of physical inactivity and immobility.[2]

1.1. Impact of COPD

COPD is characterized by airflow obstruction.[3,11] Airflow limitation causes exertional dyspnea and exercise intolerance[12] making physical conditioning difficult[13] leading to functional disability in the patient, reduced quality of life, physical inactivity, psychological distress [6,12] socioeconomic deprivation and stigma.[14] Individuals in the mild or moderate stages of the disease already present an altered exercise capacity and daily activities, even when pulmonary function measured by spirometry has little or no change.[15]

1.2. Benefits of physical activity in COPD

Studies show that exercise is the basis of a comprehensive pulmonary rehabilitation (PR) program in COPD patients.[11,16] PR consists of a comprehensive multidisciplinary intervention based on a complete patient assessment, followed by tailored therapies that include, but are not limited to: physical training, education and behaviour change, improving physical and psychological condition and promoting long-term adherence and health improvement behaviours.[17]Increased physical capacity promotes improvement of dyspnea,

psycho-emotional aspects and quality of life, decreasing the demand for emergency services and reducing the risk of exacerbation[11,16,17] and should be a goal to be pursued in the treatment of COPD patients. However, greater awareness is needed from health professionals in educating patients about the importance of the content and benefits of physical training as part of treatment.[16]

1.3. Comorbities in COPD

Comorbidities are frequent in chronic obstructive pulmonary disease (COPD) and significantly impact on patients' quality of life, exacerbation frequency and survival.[18,19] More than 80% of patients with COPD are estimated to have at least one comorbid chronic condition. As a result, COPD treatment guidelines are incorporating comorbidities into their COPD management recommendations, as it is becoming increasingly clear that multimorbidity and specific comorbidities are strongly associated with mortality and clinical outcomes in COPD, including dyspnea, exercise capacity, quality of life, use of health services and risk of exacerbation.[19]

Studies clearly demonstrate that comorbidities are universal problem in patients with COPD. Around 86 to 98% of individuals with COPD have at least 1 comorbid condition, and that the average number of comorbidities per individual is 1.2 to 4.3. In addition to, it seems clear that the burden of comorbidities is more substantial in individuals with more severe COPD.[19]

Most studies state that the most prevalent comorbidities include anxiety/ depression,[9,10,20,21] heart failure, ischemic heart disease (IHD), pulmonary hypertension (PHT), metabolic syndrome, diabetes, osteoporosis, and gastroesophageal reflux disease (GERD).[22] Smith et al[18] also included lung cancer, pulmonary fibrosis and chronic kidney

disease (CKD) in this review, because of their clinical significance in COPD.[18] Comorbidities increase exacerbations and hospitalizations in COPD.[18,21]

1.4. Anxiety and depression in COPD

Anxiety and depression are common comorbidities in COPD and they have a considerable impact on patients in terms of associations with mortality, exacerbations and quality of life.[9,10,18,20,21,23,24]

There is variation in prevalence according to the study, population and definition of these psychiatric comorbidities (self-reported, questionnaire, or clinical review, according to Diagnostic and Statistical Manual of Mental Disorders criteria).[18,20]These conditions are commonly untreated or incompletely treated and may have significant implications for patient adherence to medical treatment as a result of cognitive functioning and decreased effectiveness of coping and self-management by patients. Depression is considered a predictor of mortality after hospitalization for acute exacerbation.[20]

According to Puma et al[24] , the risk factors for increased rates of depression include living alone and gender. Females have rate both anxiety and depression higher. Rates of depression are more strongly correlated with severity of dyspnoea as compared with males. Increasing severity of COPD is associated with higher rates of depression and anxiety, for example, in patients requiring long-term oxygenterapy, 57% were found to have depressive symptoms and 18% had depression classified as severe. End-stage COPD patients undergoing palliative care also have high rates of anxiety and depression. Other considerable risk factors are patients that have been hospitalized for an exacerbation of COPD or recovering from an exacerbation, severity of respiratory symptoms especially dyspnoea and serious impairment of physical functioning. [24]

In Brazil the prevalence of anxiety and depression in COPD patients ranges from 21% to 96% and 27% to 79%, respectively[9] and is similar to studies in the United Kingdom, Denmark, Canada and New Zealand, which showed 28% to 80% and 50% to 74% [21]respectively. There is a complex interaction between anxiety and shortness of breath, occurring as a vicious cycle of worsening symptoms.[21] Depression and anxiety in COPD are associated with a disproportionate increase in health care utilization rates and costs[17,20,25]

and depression is a strong predictor of mortality.[17]The effects of COPD are permanently felt as the disease progresses[9] with progressive worsening of dyspnea, imposing the need for patients to change their lifestyle, as they feel unable to maintain their routine of life before the manifestation of the disease.[9]

Evidence suggests that there is a high prevalence of anxiety and depression among COPD patients, much of which is underdiagnosed and therefore untreated. More timely diagnosis is required[(24)] Self-reported screening instruments are useful as an initial approach; however validated tools should then be utilized to minimize false positives and standardize care. When and in whom screening should be done is still not clear for patients with COPD. The application in all patients is not yet clear and if it should be carried out with all COPD patients or just to those at higher risk of these comorbidities.

To Alexopoulos et al[26] due to the negative impact of depressive and anxiety disorders and symptoms associated to COPD patients, it is important that a better treatment integrated approach is required, and that it enhances the benefits between mental and physical health most effectively. There is extensive evidence of the benefits of pulmonary rehabilitation (RP) for patients with COPD and it has shown to significantly reduce symptoms of both anxiety and depression in COPD patients, possibly through improved physical capacity . Adding a depression or anxiety targeted treatment to the pulmonary rehabilitation program may have additive therapeutic benefits. This synergistic effect has been alluded to in a study where marked improvement in depression symptoms was shown when brief inpatient pulmonary rehabilitation plus antidepressants were used with COPD patients with major depression.[26] Similarly, another study showed a significant improvement in anxiety and depression with improvement of physical capacity, when Cognitive Behavior Therapy (CBT) was provided within a pulmonary rehabilitation program.[9]

Future studies should aim to fill the current gaps in knowledge about treatment of psychological symptoms in COPD. There are not any significant studies that have definitively assessed the true benefits of psychological, pharmacological or combined treatment modalities in the COPD population.[22] Focusing on determining the best treatment for specific groups e.g., based on gender, severity of COPD and frequency of exacerbations. There is also uncertainty regarding the cost-effectiveness of targeted treatment of anxiety and

depression, and feasibility of restructuring health-care delivery to incorporate care for mood and anxiety disorders as an integral part of high quality, comprehensive chronic disease management of patients with COPD.[22]

1.5. Uptake of physical activity in COPD patients

COPD is a systemic disease that affects the cardiovascular, musculoskeletal systems and psychosocial aspects with its progression, leading to reduced quality of life and impact on health status.[23,24] Physical inactivity is common in patients with chronic obstructive pulmonary disease (COPD) compared with healthy control subjects , as well as in patients with other chronic diseases[27,28]Being identified in the early stages of the disease, before the onset of respiratory symptoms and not only in the advanced stages of the disease.[28,29] It considered an important predictor of COPD outcome. Lower levels of physical activity are associated with a higher risk of exacerbation and exacerbation-related hospitalization of mortality[29,35] as well as increased risk.[31] Studies show that maintaining physical activity over time results in a protective effect against disease exacerbation and hospitalization. However, as physical activity decreased over time, the risk of exacerbation reached that of individuals who entered the study with low levels of physical activity and who maintained these low levels.

Pulmonary inflammation and airway degeneration, chronic changes in lung mechanics promotes air trapping in the lungs. This pathophysiological process is believed to induce pulmonary hyperinflation, reducing physical capacity to diminishing physical efforts. With the progression of the disease, the pathophysiological changes in COPD tend to worsen triggering limiting symptoms in patients, such as dyspnea. As a result, the activities of the individual's daily life are reduced by setting up a vicious cycle in which he limits his activities to alleviate the symptoms. This excessive rest leads the individual with COPD to physical deconditioning, considered the main factor for loss of strength and muscle mass, leading to functional disability. Dyspnea is the main symptom associated with physical disability, reduced quality of life and poor prognosis, and is usually progressive with the evolution of the disease.[23]

Inability to engage in balanced physical activity is a common feature of COPD. Activity restriction can be evident even in mild cases.[36] Studies show that a regular exercise

program is associated with improvements in functional capacity and quality of life of people with COPD[13,23,37] being one a cost-effective intervention[13,37] However, studies show that PA in COPD patients is usually less frequent than in healthy participants, decreasing with disease progression.[6] Regular exercise promotes improvements reduction of respiratory symptoms, reduces the risk of mortality in individuals with COPD, in addition to improving physical, mental health and quality of life.

According to Van Remoortel et al[28] the physical inactivity is more strongly associated with the presence of comorbidities than was airflow limitation. However, no prospective study has objectively assessed the association between physical activity and the presence of comorbidities over time in COPD.[28] PA was only weakly associated with lung function. However, Chin related in a review that the daily physical activity in patients.[28,39] There exists an inverse association between daily physical activity and dynamic hyperinflation[31] which is closely correlated with the degree of exertional dyspnea.[28] Waschki and Singh et al,[40,41] believe that the pulmonary function, lower extremity strength and exercise tests are associated with lower levels of physical activity in COPD patients[28,40,41]and daily symptoms such as dyspnea and fatigue are associated with physical activity levels. [28,29,41] Self-efficacy, defined as an individual's belief in their ability to be successful in something, is weakly associated with daily physical activity.[28,42] Moreover, impaired health status is somewhat correlated with physical activity, as confirmed in a 5-year longitudinal observational study. [28]

In a study of elderly patients with chronic obstructive pulmonary disease (COPD), severe dyspnea and depression are independent risk factor for low-level physical activity (PA) although these clinical factors alone do not explain the reason why these patients do little PA.[28,43]

A recent prospective study demonstrated that depression affects the rate of reduction of physical activity after 6 months in COPD patients.[28,44] Physical activity is usually self-reported and unlike physical fitness, which is objectively measured, it tends to be overestimated. The 6-minute walk test is a widely used and validated test to measure

physical fitness in COPD. To identify the risk factors that affect physical activity in clinical settings, it is necessary to develop methods that can easily measure physical fitness. [28]

1.6. Physical activity in Brazilian COPD patients

Physical inactivity in COPD patients is considered as a factor directly related to increased risk of exacerbations and as the best predictor of early mortality in COPD.[13,45]

Hernandes et al[13] in Brazilian study evidenced that COPD patients are less active in their daily physical activities when compared to healthy elderly.[13] This reduction in physical activity can be attributed to the increased sedentary lifestyle adopted by COPD patients as a result of, or due to systemic changes in the disease. Already Amorin et al[46] in another study that objectified assessment of PA in sedentary COPD patients at different stages of disease severity in Brazil, compared through an accelerometer with sedentary elderly without COPD, evidenced that in the milder stages of the disease, COPD patients have reduced daily physical activity.[46] Despite physical inactivity in healthy elderly people, COPD patients in Brazil were more physically active when compared to patients in Europe [(27)]leading us to reflect that a lower socioeconomic condition and greater mixed ethnic origins may be related to a higher level of PA in COPD patients.[13,47]

Xavier R. et al.[48] in a cross-sectional study evaluated COPD patients in a tertiary outpatient clinic of a university hospital according to age, airflow obstruction (FEV 1), previous hospitalization, dyspnea (MRC scale), strength (maximal isometric quadriceps strength), body composition (skeletal muscle mass (% SMM) , octopolar bio impedance and DLPA (step counts per day) through of accelerometer (GT3X) and evidenced that older COPD patients with lower quadriceps strength, more dyspnea and previous hospitalization and worse airflow obstruction impaired the physical activity of daily living. Evaluating and improving these variables during clinical treatment of COPD patients can help to stay physically active. [48]

1.7. The role of anxiety and depression in engaging in physical activity and taking part in exercise interventions

Regular physical activity (PA) is consistently related to the reduction of the risk of hospitalisation and death.[38,44] Anxiety and depression are also factors potentially impacting

on PA in COPD patients, ones which are especially important because of their prevalence in COPD.[44] The barriers and enablers to PA in COPD patients need to be better understood. Anxiety has been reported in ~ 40% of COPD patients [27,44] and is associated with the occurrence of tachypnea, which in turn may lead to worsening pulmonary hyperinflation, dyspnea on exertion, reduced exercise capacity and worse quality of life. [44,49] Depression, in turn, was identified in 25% of COPD patients[25,44] and is also associated with worse exercise capacity and poorer health. [44,50]

Results from a large Canadian study (Canadian Cohort Obstructive Lung Disease - CanCOLD) reported that higher levels of anxiety and depression were related to lower levels of PA in patients with and without COPD, suggesting that psychological distress is similarly associated with poorer health behaviours in those with and without COPD.[50]

1.8. Pulmonary rehabilitation in COPD

The pharmacological and non-pharmacological treatment is very important for the patient with COPD. From this perspective, Pulmonary Rehabilitation (PR) is considered as a standard recommendation among non-pharmacological treatments.[51]

PR is a comprehensive intervention based on thorough assessment, followed by patient-adapted therapies that include, but are not limited to physical training, education, and behaviour change. It is designed to improve the physical and psychological condition of people with chronic respiratory diseases and to promote long-term adherence to health-enhancing behaviours.[11,33,51,52] Emphasizing behaviour change through collaborative self-management may result in greater participation in physical activities, which will in turn increase exercise capacity. Both increased exercise capacity and adaptive behaviour change are necessary to achieve significant and lasting increases in physical activity in patients with COPD.[33]

Successful completion of PR is associated with a reduction of symptoms, economic benefits to health, as well as exerting some effects on lung function, exacerbations and mortality and the ability of the family to adapt to the disease. [53,56] However, PR remains highly inaccessible due to lack of awareness of its benefits, poor referral and availability mostly in

hospitals. [53] Researchers point to a growing knowledge about rehabilitation, especially in the last decade, and it is worth noting that a PR program can be applied in various contexts. There are currently calls for institutions to implement community-based PR programme and assess its cost-benefit.[53]

A primary care model focusing on recovery, prevention and health promotion favours the practice of physical activity, recommending a minimum intensity of 30 minutes per day, with the intention of developing or maintaining the patient's functional capacity, improving their quality of life (QOL). Walking is the most recommended physical activity, but the literature shows that many patients do not go for a walk.[32]

Rochester et al [54] reported that muscle strength training within PR may be more beneficial to quality of life when compared to aerobic exercise. Few scientific studies have highlighted the advantages of prescribing this type of activity performed in outpatient and home environments, with accessible equipment, since patients and public services in general do not have access to devices designed for this purpose, despite the recommendations of public health guidelines.[54]

Studies have shown that after the PR program there was an increase in physical activity levels in people with COPD who perform exercise maintenance and that PA is positively related to improvements in exercise capacity, quality of life and dyspnea.[21,52]

Barriers to participation in exercise maintenance programs include fear, lack of motivation, environmental factors such as social isolation and changes in physical health. There is some evidence that social support and appropriate training of the rehabilitation professionals themselves, can address these barriers, resulting in increased participation in PR.[52]

1.9. Need for this study

Pulmonary rehabilitation is one of the most effective treatments for the management of COPD symptoms. One intended outcome of PR is increased physical activity, which is shown to improve anxiety and depression. As approximately 55% of COPD patients suffer

from anxiety and depression, it is contended that PR may be particularly beneficial to this subgroup of COPD patients.

The benefits of exercise for COPD patients are well described, whether performed individually or as part of PR programmes. They have also been shown to have benefit among COPD patients with anxiety and depression. But engagement in physical activity and uptake of exercise programmes is generally poor.[55] In Brazil, there are few (if any) such exercise programmes organised for COPD patients, and given the cultural differences, it is not clear whether programmes designed for other countries would work well in Brazil. Furthermore, it is important to provide interventions for both newly diagnosed and existing COPD, and patients with mood disorders.[56]There is a lack of research exploring the attitudes and beliefs of Brazilian individuals with COPD, as well as their attitude towards initiating and maintaining daily PA as a lifestyle choice.[6] This research therefore aims to explore the enablers and barriers to participation in PA for This research therefore aims to explore the enablers and barriers to participation in PA for This research therefore aims to explore the enablers and barriers to participation in PA for COPD patients both with and without mood disorders (anxiety and /or depression) acting as a resource for the development of future, culturally appropriate programs.

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1. METHODS

2.1. Study Design

- Qualitative study using data from focus groups (FG).

2.2. Location and Timeframe

A. The population

- This study will be conducted in a primary care setting, in the city of São Bernardo do Campo, São Paulo.
- Patients with newly diagnosed COPD will be drawn from the BW1 project.
- Patients with existing COPD will be drawn from basic health units (BHUs).
- Participants will be sampled for a range of characteristics including: those with anxiety and /or depression, severity of symptoms/disease and recent or established diagnosis.
- We also aim to include participants from a range of ages, gender, levels of exercise/activity and education.

B. Procedure

- Patients with newly diagnosed COPD will be recruited by the BW1 team. The BW1 team will send information sheets about BW2 to potentially eligible patients when inviting them to their BW1 follow up appointments. If at their appointment they are eligible (COPD diagnosis is confirmed) the BW2 study will be explained to them. Patients who agree to participate will sign informed consent and complete a screening questionnaire.
- Patients with existing COPD will be recruited from the BHUs. Letters of invitations to BW2 will be sent to BHU patients known to have COPD. If interested they will be invited to attend the BHU to sign informed consent and complete a screening questionnaire. In addition, patients with existing COPD will be given an information sheet about BW2 when attending for appointments. Patients who agree to participate will sign informed consent and complete a screening questionnaire.

- Screening questionnaires will be evaluated and patients invited to participate in one of the 7 following FGs, each containing 6-10 participants(totaling 60 participants):
    - Prior to the formal collection of data there will be a pilot FG, this will contain the first 6-8 available volunteers regardless of characteristics.
    - Formal data collection will involve 2 sets of FGs each containing 3 FGs:
        - **Set 1:** Patients with COPD *and* anxiety and depression. Split into:
            - Patients with newly diagnosed COPD.
            - Patients with established COPD.
            - A mix of newly diagnosed and established COPD.
        - **Set 2:** Patients with COPD who do not have anxiety and depression. Again split into:
            - Patients with newly diagnosed COPD.
            - Patients with established COPD.
            - A mix of newly diagnosed and established COPD.
- BHUs health professionals will invite the patients to participate in the study when attending routine appointments.
- FGs will take place in the BHUs, the visit will last approximately 3 hours. During the first hour participants will asked to complete various questionnaires (see below). The FG itself will last up to two hours with a coffee break in between.
- FGs will be audio recorded, anonymized and transcribed.

Instruments:

1. **Personal Information form** (e.g. name, gender, date of birth, address, phone number, email address).

2. **Screening questionnaire**
   All questionnaires will be administered by trained researchers, respecting the different levels of education among the participants.

    - **Patient Health Questionnaire-9 (PHQ-9):**

Patients with depression will be identified using the PHQ9. This is a brief instrument

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for assessment, diagnosis and monitoring of depressive disorder according to DSM-IV criteria. It contains nine items, ordered on a four-point scale: 0 (not once) to 3 (almost every day), with a score ranging from 0 to 27 to assess the frequency of signs and symptoms of depression in the last two weeks.[57,58] It has been validated for use in primary care.[59]Severity is interpreted according to the total score: Depression Severity: 0-4 none, 5-9 mild, 10-14 moderate, 15-19 moderately severe, 20-27 severe.[63] Depression patients will be invited to the FG at different severity levels.

- **Generalized Anxiety Disorder 7-item (GAD-7):**

Brief instrument for assessment, diagnosis and monitoring of anxiety. Composed of seven items, arranged on a scale of four points: 0 (not once) to 3 (almost every day), with a score ranging from 0 to 21 when measuring frequency of anxiety signs and symptoms over the past two weeks. It is considered a positive indicator of signs and symptoms of anxiety disorders, value equal to or greater than 10. [58] Severity is interpreted according to the total score : 5-9 mild, 10-14 moderate and greater than 15 severe.[64 P]atients with anxiety at different severity levels will be invited to the FG.

Individuals with depression and severe anxiety and clinical impairment will be referred for evaluation by the BHU health team.

- **Godin questionnaire (activity level):**

It is a short questionnaire designed to be self-administered and its purpose is to evaluate the frequency and intensity of physical activity performed in one week. The respondent reports the number of times practices for at least 15 minutes physical activity of vigorous, moderate and light intensity, considering a period of seven usual days. The frequency indicated by the subject is multiplied by an effort coefficient that corresponds to the energy expenditure in metabolic equivalents (MET) of the referred activity, generating a score of arbitrary units. Higher score indicates higher AFTL level and lowest score lower AFTL level. [64]This will be used to ensure patients with varying activity levels are included in the FGs.

- **General Health Questionnaire (GHQ-12)**

Is a psychometric instrument for self-completion widely used nationally and internationally for the detection of minor mental disorders (mild to moderate anxiety and depressive disorders) in community, hospital, and clinical and psychometric research settings. Its administration allows the evaluation of a broad spectrum of signs and symptoms related to sleep disturbance, stress, depression, anxiety and psychological problems. Considered to be one of the main tools for evaluating different dimensions of health. The 12-item version of this instrument 1 is the shortest and probably one of the most commonly used to measure psychological well-being. [65]

3. Socio-demographic and health status questionnaire

- Containing sociodemographic aspects (the topics are marital status, household members, educational level, co-morbidities, smoking status, general health questionnaire). This will be used to describe the study population and to ensure that FGs include patients with a mixture of education levels and smoking status.

4. From medical records

- FEV1 – this will be used to describe the study population.
- COPD assessment test (CAT score) this identifies severity of disease. This will be used to ensure patients with varying disease severities are included in the FGs.

5. Focus group (FG)

Qualitative research technique used to facilitate the design of something new, such as health interventions. Volunteers meet as a group to discuss the topic of interest and debate encouraged.[67]FGs aim to uncover greater depth of perceptions, not just a comparison of different groups. [67]

C. Focus groups

Focus groups will be run by a moderator (researcher responsible for the research) and two observers with interchangeable roles. The moderator will lead the discussion,[67,68] facilitating the dynamics and detecting situations in which it is necessary to intervene in order to enhance the objectivity of the task guaranteed from the perspective of group production.[67,68]

Observers are critical to the success of the technique. They will act as participants in the FG, becoming part of the group's functioning by watching and listening. They will follow up and record participants' expressions (verbal and nonverbal), helping to conduct the meetings, as well as controlling the time and recording equipment.[67,68]

D. Topic Guide

The topic guide will consist of a series of open questions, such as knowledge of COPD; participants' perception of the importance of PA, their motivation to participate in PA the benefits of PA in your health, we are considering designing a new programme that will involve a programme of activity to reduce breathlessness and improve patient wellbeing. Patients would be referred to this service. Their views on how PA might be introduced : goal setting, community based activities or as part of their daily routine; the obstacles faced in carrying out PA and the facilitating factors (Table1).

Table 1 – Topic Guide

Focus Group Session	
Opening	Reception, thanks for the participation, presentation of the researchers and research objective.

Team building icebreaker **15 minutes**	Participants introduce themselves to each other
Organizing the work **10 minutes**	Session development information and topic guide. Clarifications on the dynamics of the participatory discussion (Focus Group)

Sub topics for Debate **90 minutes**	
COPD	1. What do you know about this disease? 2. Do you feel any symptoms of this disease? 3. How does the disease affect your life?
Anxiety	4. What emotions and experiences do you think are related to anxiety? 5. How do you think anxiety can affect your life?
Depression	6. What emotions and experiences do you think are related to depression? 7. How do you think depression can affect your life?
Physical	8. Do you like to do physical activity? Yes or no and why? What kinds do you prefer? For example: walking, swimming, cycling, dancing, etc.

activity	9. Do you think anxiety and / or depression interfere with physical activity?
Exploring opinion about a physical activity program in in the community	ysical activity can help you a lot in controlling your disease, what you get from having a physical activity program at UBS aimed at it?
Closing and thanks Book Delivery DP What?	

2. DATA ANALYSIS

- Sample characteristics
- Descriptive statistics will be used to describe the sample population.

Qualitative data analysis - FGs

- The FGs will be transcribed clean verbatim. Data will be analysed by thematic induction [14,72] using the framework method for the analysis of qualitative data. Data will be managed in Microsoft Excel. The approach is inductive and grounded but can also have some deductive elements when it is also used to respond to set goals and objectives. The transcripts will be read by the interviewer several times to facilitate familiarisation with the data by searching for sought meanings and patterns in concepts, and emerging themes with intention of develop a coding scheme. The

emerging coding scheme will be discussed among the researchers to verify a consistent pattern and any contradictory information.

- Data from all transcripts will be mapped under emerging themes and concepts, providing a detailed account of participants' views and experience. Emerging themes and questions raised by participants will also be grouped. To ensure data reliability there will be maximization by reviewing and discussion coding between the researchers and the University of Birmingham study steering group.

3. DATA STORAGE

Only the Brazilian research team will have access to participants' personal data, this will not be passed onto any outside bodies. Information stored on a computer will be password protected. Paper records (e.g. typed transcripts of the interviews) will be stored in a locked cabinet in a locked room at the Collective Health Study Center (CESCO). Identifiable data will be stored in a separate filing cabinet (e.g. consent forms & contact details). All participants will be given an identification number and this number will be used to link all data provided by each individual. Identifying details will be removed from all transcripts. All personal data collected will be treated in strict accordance with the UK's General Data Protection Regulation and Data Protection Act 2018.

4. RESULTS

The data collected will enable us to:

- Describe the sociodemographic characteristics, health perceptions and frequency of current PA within the sample;
- Describe the barriers and enablers to physical activity and exercise programme;
- Describe patients' opinions on development of an exercise programme relevant for Brazil and any adaptations to the programme that might be needed for those with anxiety or depression;
- Describe barriers and facilitators to physical activity in the study sample;
- Describe opinions about PA in the sample;

5. ETHICS & RESEARCH GOVERNANCE

The Project will be submitted to the Ethics Committee of the ABC School of Medicine. The committee meets twice a month. The deadline for project evaluation and approval is usually 30 days, if there is no backlog in the requested documentation. Once ethical approval has been obtained the project will also be submitted to the University of Birmingham's ethical review committee.

5.1. Risks and discomfort: The procedures used in this research comply with the Ethics Criteria in Research with Human Beings according to resolution no. 466/12 of the National Health Council - Brasília - DF. The procedures used offer minimal risk: possible embarrassment and information gathering.

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6. STAKEHOLDER, INCLUDING PATIENT & PUBLIC INVOLVEMENT (PPI)

Patients, clinicians and policy makers participated in a research prioritization process (November 2017) to discuss research studies and potential. The study in question along with the BW1, among others, were prioritized.

7. INVOLVING POLICY-MAKERS

Municipal policy makers were involved in the prioritization process held in November 2017. They are regularly informed by the research team through meetings or reports on project development.

Patients, clinicians and policy makers involved will receive study updates twice a year during the study, and all stakeholders will be consulted at the end of the study for advice on appropriate means of disseminating study results. The research team will disseminate the study results through municipal, state and international events and through national and international publications.

8. NECESSARY ACTION

- Not applicable at this time.

9. IMPACT

PR is one of the most effective treatments for COPD patients, but there is little/no evidence of its use in Brazil. The proposed research will identify factors affecting the acceptability of such an intervention, which could inform the development of a culturally appropriate programme aimed at increasing physical activity and selfcare in COPD patients. The research therefore has the potential to make a significant impact to the field of public health in Brazil.

10. POTENTIAL PROBLEMS

- Delays in ethical approval.
- Recruitment difficulties due to being unable to recruit patients.

11. TRAINING NEEDS

Team training (researcher and observers) on focus group methodology and data analysis.

12. TIMETABLE

Activities	2019									2020										2021								
	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep

Meeting / Training in Bucharest																													
Literature review and project design																													
FMABC Ethics Committee Submission																													
Committee Approval																													
Start PhD																													
UoB UK ethics submission																													
Committee Approval																													
Focus group data collection and analysis training.																													
P2 methodological alignment with other participating researchers																													
Selection of patients with COPD (Polyclinic BW1 and BHU) from São Bernardo)																													
Pilot P2																													
Start –P2																													
P2 data analysis																													
Preparation of papers																													
Submission papers																													

13. BUDGET / ESTIMATED RESOURCES

A= STAFF

Staff Costs	Descriptions	Claim Total
Academic Leader	General coordination - 3 month	£3.500,00
Project Management	General coordination - 3 month	£3.500,00
Administrative Management	Executive coordination - 3 month	£1.500,00
Assistant	Support coordination - 3 month	£1.500,00
Field Coordination	Invite people to the focus groups - 2 month	£1.500,00
Field Researchers	Application of screening questionnaires	£1.500,00
	6 – 7 focus groups	£2.799,10
		£1.500,00
Researchers Qualitative	Qualitative research analysis	£1.500,00
		£1.500,00
Transcription / Translation	Focus group transcription and translation	£10.000,00
	Sub-total Staff	**£30.299,10**

B= Non staff EXPENSES

Date	Descriptions	Claim Total
Supplies	Office supplies, rental, equipaments and others	£500,00
Events / Meetings	Reunions and coffees	£500,00
Copies / Prints	Copies and handouts / books / gifts	£700,00
CESCO	Overhead of project execution - 12%	£29.537,88
	Sub-total Non-Staff : £31.237,88	
TOTAL : A + B = £61.537,0		

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ANNEX

1. Invitation letter
2. Informed Consent Form
3. Sociodemographic Questionnaire
4. Mental Health Questionnaire : PHQ-9 and GAD-7
5. Physical Activity Questionnaire – Godin