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Pulmonary rehabilitation service set up in Georgia

Submission date 10/10/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/10/2018	**Overall study status** Completed	
Last Edited 05/10/2022	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Evidence suggests that pulmonary rehabilitation (PR) has benefits when delivered after admission for a chronic obstructive pulmonary disease (COPD) exacerbation. PR helps with fatigue and breathlessness, and improves quality of life and exercise capacity, with evidence that at least 4 weeks of exercise training are needed for benefits to be observed, whilst the ATS /ERS Statement on PR recommends a minimum of 6 weeks of exercise training and more recent guidance recommends a minimum of 8 weeks of exercise. Exercise is recommended to be 2-3 times per week and is often delivered in two supervised or monitored sessions, with a third unsupervised session. Recent recommendations from the ATS/ERS state that “to qualify as PR, programs must include, at a minimum: a structured and supervised exercise program for patients with a variety of respiratory conditions, a patient education/behavioural program intended to foster health enhancing behaviour, patient assessment and outcomes measures, and provision of recommendations for home-based exercise and physical activity”. There are currently no PR services offered to the patients in Georgia. In this context, where resources are limited, yet COPD is a major burden, research is needed to evaluate whether offering PR is feasible and to assess whether the intervention would have similar effects to those observed in other settings. Using a short supervised course and unsupervised home-based exercise is likely to more economically viable. With limited availability of pharmacotherapy (drug treatment), there is also an opportunity to test the effectiveness of different components of PR or to evaluate a tiered approach tailored to patient need. The aim of this study is to assess the feasibility of delivering a culturally tailored PR intervention in Georgia.

Who can participate?
Patients with COPD, able to walk 10 meters independently, and able to exercise with some degree of independence within a group setting

What does the study involve?
Participants are randomly allocated to one of the two programmes: a culturally-adapted PR programme and a short education programme (control group). Participants are followed up at the end of the PR programme (8 weeks) and at 6 months. Interviews are carried out with patients and rehabilitation specialists to assess intervention feasibility and acceptability.

What are the possible benefits and risks of participating?
This research will help to understand whether an adapted PR programme is a feasible treatment for people with COPD in Georgia. If the results from the study show that the programme is beneficial, it could influence policy, PR could be delivered more widely in Georgia, and help improve future outcomes for people with COPD in Georgia. The PR programme, short education programme and questionnaires pose limited risk to participants. Furthermore, participants will not be recruited if they are considered a high risk patient. In the event that participants are identified as having any clinical issues or needs through the research, they will be referred to the appropriate health professional and managed based on the standard clinical practice in Georgia.

Where is the study run from?
Chapidze Emergency Cardiology Center (Georgia)

When is the study starting and how long is it expected to run for?
June 2017 to September 2020

Who is funding the study?
National Institute for Health Research (NIHR), using Official Development Assistance (ODA) funding

Who is the main contact?
Dr Maka Maglakelidze

Contact information

Type(s)
Scientific

Contact name
Dr Maka Maglakelidze

Contact details
Chapidze Emergency Cardiology Center
N. Javakiahvili #1
Tbilisi
Georgia
0159

Type(s)
Scientific

Contact name
Dr Rachel Jordan

ORCID ID
http://orcid.org/0000-0002-0747-6883

Contact details
Reader in Epidemiology & Primary Care
Institute of Applied Health Research
University of Birmingham

Edgbaston
Birmingham
United Kingdom
B15 2TT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol V1.0

Study information

Scientific Title
Feasibility trial of an adapted pulmonary rehabilitation programme in Georgia

Acronym
Pulmonary rehabilitation in Georgia (Breathe Well)

Study objectives
Objectives:
Conduct a randomised controlled trial to assess the feasibility of delivering a culturally tailored PR intervention in Georgia

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Acad. G. Chapidze Emergency Cardiology Center medical ethical committee, Tbilisi, Georgia, 23/03/2018
2. University of Birmingham STEM International Trials Sub-committee, 11/07/2018, ref: ERN_18-0856

Study design
Single-centre non-blinded two-armed randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease

Interventions
Participants are individually randomly allocated to one of two study arms: culturally-adapted pulmonary rehabilitation programme and a shorter programme (control group).

Trial arm 1: Culturally-adapted pulmonary rehabilitation programme
A pre-rehabilitation session, which will include a 1:1 session for a tailored exercise prescription. This will be followed by an 8-week (2 supervised sessions per week) adapted pulmonary rehabilitation (PR) programme, consisting of two main components: exercise and education on the management of COPD.

Trial arm 2: Short education programme
Participants randomised to the control group will be offered to attend a 2–3 hour educational session. This will be carried out by the rehabilitations specialists 6 months after study enrolment, once follow-up is complete.

Intervention Type
Behavioural

Primary outcome measure
As the primary outcome measures are feasibility outcome measures, most will be assessed at the end of the delivery of the PR intervention, i.e. 8-12 weeks depending on time to attend the 16 PR session (referred to as programme end). Feasibility study outcomes will include:
1. Delivery with fidelity (assessment of exercise prescription at programme end)
2. Acceptability to participants (qualitative interviews at programme end)
3. Recruitment rate
4. Follow-up rate at 6 months
5. Adherence to intervention (attendance rates and completion of exercise prescription at programme end)
6. Ability to carry out trial procedures (6 months)
7. Feasibility of methods to measure costs of PR (assessments of 8-week follow up questionnaire)
8. Other COPD-related health care utilisation (8-week and 6-month follow up questionnaires)
9. Patient-incurred costs (8-week follow-up questionnaire)

Secondary outcome measures
Outcome measures to inform a future trial to evaluate clinical and cost effectiveness (end of PR programme and at 6 months):
1. Health-related quality of life (HRQoL), measured with SGRQ and EQ-5D-5L
2. Exercise capacity measured by the incremental shuttle walk test (ISWT)
3. Smoking status validated by cotinine (saliva test)
4. The impact of COPD on their life, measured with the COPD Assessment Test (CAT)

5. Self-reported physical activity, measured using IPAQ
6. Self-efficacy, measured using the Stanford self-efficacy for managing chronic disease 6-item questionnaire
7. Anxiety and depression, measured using PHQ-9 and GAD-7
8. Self-reported exacerbations
9. Self-reported health care utilisation including hospital admissions
10. Self-reported costs/resource use incurred by patients

Overall study start date
01/06/2017

Completion date
30/09/2020

Eligibility

Key inclusion criteria
1. MRC score 2+
2. Confirmed COPD diagnosis based on spirometry (predicted ratio of FEV1/FVC of 0.7)
3. Patient must be able to walk 10 meters independently
4. Patient able to exercise with some degree of independence, and within a group setting

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 participants

Total final enrolment
60

Key exclusion criteria
1. Musculoskeletal or neurological conditions that prevent exercise
2. Unstable CVD (e.g. unstable angina, aortic valve disease, unstable pulmonary hypertension)
3. Severe cognitive impairment
4. Severe psychotic disturbance
5. Contagious infectious disease
6. Very poor balance

Date of first enrolment
29/10/2018

Date of final enrolment
31/05/2019

Locations

Countries of recruitment
Georgia

Study participating centre
Chapidze Emergency Cardiology Center
N. Javakiahvili #1
Tbilisi
Georgia
0159

Sponsor information

Organisation
Chapidze Emergency Cardiology Center

Sponsor details
N. Javakiahvili #1
Tbilisi
Georgia
0159

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research, Official Development Assistance (ODA) funding

Results and Publications

Publication and dissemination plan

The plan is to publish the study protocol in a peer-reviewed journal. The study results will also be published in a peer-reviewed scientific journal and presented at an international conference. Web-links to publications will be provided on the Breathe Well website (https://www.birmingham.ac.uk/breathewell).

Intention to publish date

30/06/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Kate Jolly (c.b.jolly@bham.ac.uk).
Type of data: individual participant data, quantitative (anonymised)
When the data will become available and for how long: December 2020
Access criteria for sharing data:
o With whom: academics
o For what types of analyses: observational/meta-analyses
o By what mechanism: Data acquisition forms will be available from the Investigator. Submitted forms will be reviewed by the Programme Directors, before contacting the applicant directly
Participant consent: Participant consent will be obtained to release anonymous data to other researchers
Data anonymization: all identifiable data will be removed prior to sharing data with other researchers

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/09/2022	29/09/2022	Yes	No
Protocol file	version 2.0	13/05/2019	05/10/2022	No	No