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A feasibility study for web-based pulmonary rehabilitation programme

Submission date
17/05/2013

Recruitment status
No longer recruiting

Registration date
17/05/2013

Overall study status
Completed

Last Edited
11/03/2022

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
It is estimated that up to one in four people may develop chronic obstructive pulmonary disease (COPD) in their lifetime. Sufferers often face disabling breathlessness which leads to a vicious cycle of reduced activity, social isolation and depression. There is strong evidence that Pulmonary rehabilitation (PR) is effective in improving quality of life, psychological functioning and physical activity and National Institute for Clinical Excellence (NICE) recommends that PR should be available to all those who may benefit. However a survey by the British Lung foundation has found that fewer than 10% of people with COPD have access to such a service. Basically, demand far outstrips the current supply of PR programmes around the country and with an ever increasing older population, there will only be more and more pressure to provide cost effective services. We believe that the internet may provide the opportunity to increase the provision of PR while also offering an alternative and novel approach to delivering this service. Over the last few years our department has been developing a variety of new approaches to delivering PR including the development of a self management COPD workbook (SPACE for COPD™) which was developed as a collaboration between experts in the field, pulmonary patients and their carers. We have now gone on to develop an internet version of the educational content of SPACE which has similarly been developed as a collaborative effort by respiratory experts, patient and public involvement (PPI) and our web design team. The aim of this feasibility study is to explore a range of factors that will provide information on the many aspects of delivering such a novel approach. We will be examining how many people are prepared to potentially try the web-based approach, the acceptability and satisfaction with the programme, the level of drop out from the programme, as well examining a range of clinical outcomes such as exercise capacity, quality of life and anxiety and depression.

Who can participate?
The study is open to all people over the age of 18 who have a diagnosis of COPD and have been referred for PR at University Hospitals of Leicester NHS Trust (UHL). Participants with COPD can also come directly from primary care and Rehabilitation services within Leicester Partnership Trust (LPT) One of the key criteria to be eligible for the study is to have access to the internet at home and have the ability to navigate around a variety of websites (e.g. the use of online

shopping or banking websites) or regular use of email. Participants also need to be able to read and write in English. Participants must be willing to be randomly allocated to receive either hospital-based PR (standard care) or the web-based programme.

What does the study involve?
All potentially suitable participants, regardless of method of recruitment, will complete a routine standard PR assessment at either Glenfield Hospital, Leicester General Hospital or the community site that they were referred to (in the case of patients referred to LPT).This is made up of an assessment of lung function, muscle strength and exercise capacity (walking tests) as well as completing some questionnaires about quality of life and knowledge of their lung condition. For people agreeing to take part in the research we will arrange a convenient date and time for them to come back to discuss the project in more detail. If people agree to take part in the research, after signing the consent form, they will be randomly allocated to a) the web based or b) the hospital based rehabilitation group. At this point participants will be asked to wear a small monitor on their arm for a week which monitors physical activity levels as well as filling in a physical activity questionnaire and a questionnaire used to determine the overall cost to patients of having to attend for COPD treatment (the Patient Cost Questionnaire). Overall involvement in the study will last approximately 3 months. Participants will attend for an assessment visit at the end of whichever course they have been assigned to which lasts about one hour. At this assessment all the outcomes such as exercise capacity and quality of life measures which were performed at the initial assessment are repeated. These assessments are normal procedure for rehabilitation. After the final appointment, participants of the web based programme may be invited to take part in a semi structured interview. This will involve a discussion about using the web based programme and is an opportunity to feedback what was useful about the website and any suggestions for improvement. This should not last longer than an hour and can take place in the person's own home or at the hospital. Participants do not have to do this interview to still be part of the study.

What are the possible benefits and risks of participating?
We hope that the research will aid patients to understand the benefits of rehabilitation and exercise and that the study will help to inform the future of pulmonary rehabilitation services around the country.
People randomised to the web based group will not participate in the hospital based programme. However, any person who is randomised to the web based programme and on completion of the programme does not feel it was beneficial (or who withdraws from the study), will be offered the opportunity to attend the hospital based programme.

Where is the study run from?
The study is based at the Centre for Exercise and Rehabilitation Science at Glenfield Hospital, University of Leicester NHS Trust.

When is the study starting and how long is it expected to run for?
The study is starting patient recruitment at the beginning of May 2013 and will run for a 30-month period.

Who is funding the study?
This study is being funded by the Research for Patient Benefit (RFPB) which is part of the funding body National Institute for Health Research (NIHR). The study is also supported by the NIHR Leicester Respiratory Biomedical Research Unit.

Who is the main contact?
Sally Singh
sally.singh@uhl-tr.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Ms Sally Singh

Contact details
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP
-
sally.singh@uhl-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13097

Study information

Scientific Title
A feasibility study to inform the design of a randomised controlled trial (RCT) of an interactive internet based Pulmonary Rehabilitation programme

Study objectives
It is estimated that up to one in four people may develop chronic obstructive pulmonary disease (COPD) in their lifetime. Sufferers often face disabling breathlessness which leads to a vicious cycle of reduced activity, social isolation and depression. Pulmonary rehabilitation (PR) has been proven to be effective in improving quality of life, psychological functioning and physical activity and national guidelines recommend that PR should be available to all those who may benefit. However a survey by the British Lung foundation has found that fewer than 10% of people with COPD have access to such a service.

We believe that the internet may provide the opportunity to increase the provision of PR while also offering an alternative and novel approach to delivering this service. We have previously

developed an internet based cardiac rehabilitation programme as well as a comprehensive self management workbook for patients with COPD.

We have now developed a prototype website that is based on the educational content of our self management COPD workbook and is a collaboration between experts in the field, cardiac and pulmonary patients and the web design team. We seek to evaluate the web based PR programme in a well run, randomised trial. However there are certain aspects of the trial that need further clarification such as how many people will consent to being randomised to web based or conventional rehabilitation? How can we measure the cost of providing both types of rehabilitation programme? What can we learn from patient's experiences of participating in the web based or hospital based programme? Are there any technical difficulties that need to be overcome in order to conduct a full trial? This feasibility study aims to answer these questions so that the subsequent randomised controlled trial (RCT) has the best chance of gaining funding and being successful.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Health Research Authority (NRES) Committee East Midlands - Northampton, First MREC approval date 19/11/2012, ref: 12/EM/0351

Study design
Randomised interventional treatment 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Respiratory, COPD, Pulmonary Rehabilitation

Interventions
1. Hospital-based PR programme
2. A web-based PR programme

Intervention group - web-based pulmonary rehabilitation programme (PRP)
Patients will be given an appointment to attend an initial session that will introduce the web-based PRP by a pulmonary rehabilitation specialist who is trained in the techniques of

motivational interviewing. Participants will be given a password protected secure log-in to the website as well as written instructions on website navigation.
The rehabilitation specialist will signpost the patient to all the relevant sections on the website for getting started with the programme as well as going through the home exercise programme and goal setting. There is also an individualised webpage featuring a personalised action plan designed to assist in the management of exacerbations which will be completed by the rehabilitation specialist in conjunction with the patient.
As in conventional pulmonary rehabilitation, patients will be encouraged to exercise on a daily basis at home and record their progress in the online exercise diary section. Throughout the duration of the web based programme the rehabilitation specialist will be able to review the patient's progress online and communicate with the patient via email or telephone depending on patient preference. There will be weekly contact between the patient and the rehabilitation specialist to ensure that patients are helped to progress their exercise programme appropriately and to answer any queries that arise.
The educational content of the web based programme is based on the 'SPACE for COPD' manual. Patients on the intervention arm of the study will be allowed to work through the website content at their own pace, however certain milestones need to be completed or achieved before further content can be accessed in order to ensure appropriate progress through the programme. We anticipate that it will take approximately 6 to 7 weeks to work through the online programme. Patients will then be given an appointment to come into the hospital to attend a discharge appointment once they have completed the programme.

Standard care group - hospital-based pulmonary rehabilitation programme (PRP)
Standard care for patients referred for pulmonary rehabilitation at UHL is hospital based rehabilitation and community-based for those referred to LPT. The PR programme at UHL has been running for nearly 20 years and is a well established programme with a strong evidence base . Patients randomised to standard care will commence conventional rehabilitation according to the standard care at their referred site on the next available date.
Conventional pulmonary rehabilitation programmes consist of twice weekly sessions each lasting 2 hours which are divided into an hour for exercise training and an hour for an education session covering a variety of relevant self management topics. The exercise training consists of endurance based walking, static cycling and strength training with weights. The programme is run by pulmonary rehabilitation specialists who progress people through the exercise programme as able and appropriate. Patients are encouraged to also complete a home exercise programme on the days when they do not attend at the hospital and to fill in an exercise diary. The educational sessions are conducted as group sessions and delivered by experts in their field. There is opportunity for discussion as well as questions and answers and the topics include medication, relaxation skills, chest clearance and breathlessness management and energy conservation. After completing the hospital based programme, patients will be given an appointment to attend a discharge assessment.
At the end of the discharge assessment all patients will be given advice on continuing their home exercise programme, regardless of group allocation.

Follow Up Length: 3 months

Study Entry : Registration and One or More Randomisations

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
1. Incremental shuttle walking test measured at baseline and discharge from programme

Secondary outcome measures
Anxiety and depression; Timepoint(s): Baseline
Discharge; Endurance shuttle walking test; Timepoint(s): Baseline
discharge; Health status measures; Timepoint(s): Baseline
Discharge; Physical activity; Timepoint(s): Baseline
1. Anxiety and depression
2. Endurance shuttle walking test
3. Health status measures
4. Physical activity

Measured at baseline and discharge

Overall study start date
07/05/2013

Completion date
30/10/2015

Eligibility

Key inclusion criteria
1. Male & Female ; Lower Age Limit 18 years
2. Willing to undertake pulmonary rehabilitation
3. Willing to take part in the web-based pulmonary rehabilitation programme if randomised to that arm of the study
4. Access to the internet and ability to navigate around a variety of websites (for example, uses online shopping or banking websites) or regular use of email
5. An established diagnosis of Chronic Obstructive Pulmonary Disease (COPD)
6. Medical Research Council (MRC) dyspnoea score of between 2 and 5
7. Able to read and write in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

UK Sample Size: 120; Description: This is a feasibility study so recruitment of potential and eventual participants to the study is one of the key areas of interest of the study.

Total final enrolment
103

Key exclusion criteria
1. Inability to participate in the exercise component of the rehabilitation programme e.g. neurological, locomotive or psychiatric disability
2. Unwilling/unable to take part in the web-based programme
3. Has taken part in Pulmonary Rehabilitation in previous 12 months
4. Unable to read or write in English.

Date of first enrolment
07/05/2013

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Glenfield Hospital
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
R&D department
Leicester General Hospital
Gwendolen Road
Leicester
England
United Kingdom
LE5 4PW

Sponsor type
Hospital/treatment centre

Website
http://www.leicestershospitals.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0711-25127

Results and Publications

Publication and dissemination plan
The protocol for the study is to be published September 2015. Initial qualitative findings are being presented at the European Respiratory Society Congress, September 2015. The main results will hopefully be published towards the end of the year/beginning of 2016.
The findings of the trial will be disseminated to participants, local primary and secondary care interface groups, such as commissioning teams and service managers and fellow researchers. The strategy for this will be coordinated by the PPI and steering group. The results of this feasibility study will be presented at appropriate national, international and regional respiratory and physiotherapy conferences, local study days in primary and secondary care as well as through peer reviewed journals.

Intention to publish date
01/01/2016

Individual participant data (IPD) sharing plan
Not provided at the time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/08/2015		Yes	No
Results article	results	31/03/2017		Yes	No
	physical activity results				

Results article	10/03/2022	11/03/2022	Yes	No