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Is it possible for people living with chronic obstructive lung disease in India to use a digital smartphone app to help them manage their illness?

Submission date
07/01/2020

Recruitment status
No longer recruiting

Registration date
20/02/2020

Overall study status
Completed

Last Edited
04/03/2024

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The prevalence of chronic obstructive pulmonary disease (COPD) in India is high. Efforts are needed to further develop methods to help adults living with COPD manage their health condition. The overall aim of this project is to assess the feasibility of a digital smart-phone based lifestyle app by adults living with COPD in India.

Who can participate?
Adults living with COPD and caregivers to adults living with COPD.

What does the study involve?
The study involves the collection of participant's views regards the use of technology in managing COPD. The study also tests a digital smart-phone lifestyle application in adults living with COPD.

What are the possible benefits and risks of participating?
The benefits of participation are to contribute to informing the development of a smart-phone lifestyle application for adults living with COPD in India. There are no risks to participation.

Where is the study run from?
Symbiosis International (Deemed University) (India)

When is the study starting and how long is it expected to run for?
April 2018 to March 2023

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Mark Orme, mwo4@leicester.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Mark Orme

ORCID ID
http://orcid.org/0000-0003-4678-6574

Contact details
Centre for Exercise and Rehabilitation Science
NIHR Leicester Biomedical Research Centre- Respiratory
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP
+44 01162583113
mwo4@leicester.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
Version 1

Study information

Scientific Title
A digital smartphone self-management app for people living with COPD in India: a feasibility study (Global RECHARGE India)

Acronym
Global RECHARGE India (digital app)

Study objectives

To assess the feasibility of a digital self-management app intervention for people living with COPD in India using information collected through the app and Focus Group Discussions (FGDs) both pre- and post-intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/11/2019, University Ethics Sub-Committee for Medicine and Biological Sciences (University of Leicester, University Road, Leicester, LE1 7RH; ethics@le.ac.uk), ref: 22522-avj1-s: respiratorysciences,deptof

Study design
Single-arm feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Internet/virtual

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
Adults with chronic obstructive pulmonary disease (COPD) or their caregivers.

Interventions
This trial will consist of a mixed-methods approach and recruitment for each stage will be separate. Suitable participants will be identified. Once a participant has provided informed voluntary written consent, they will be enrolled into the trial. The trial consists of two stages:
1. Focus Group Discussions (FGDs) will be conducted (with approximately 3-10 participants). The purpose of these FGDs is to gain an understanding of patients' views on the use of smartphone technology in the management of chronic health conditions and more specifically COPD. These FGDs will also seek to examine patients' views on the need for such an app for COPD patients living in India, along with their views on the preferred level of support and their preliminary feedback on the basic interface of the digital app.
2. A feasibility trial assessing a self-management app for patients living with COPD. The content of the digital app will be based on the principles of the SPACE for COPD manual (an evidence-based self-management manual for adults with COPD) with the addition of yoga exercises. Patients will be allowed to work through the App 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 program. The app will allow users to set goals, monitor their progress towards those goals, and provides feedback to users. The study team will explain

the utility of the app initially, after which the app can be used independently by the individual with COPD for 8 weeks from the day they were provided with the app. Patient adherence will also be discussed in post-intervention FGDs with patients and their caregivers upon the completion of the app trial. Each FGD will be comprised of 3-10 patients and will be conducted face-to-face using a single moderator and a secondary note-taker (observer) using a checklist. The purpose of the post-intervention FGDs is to obtain constructive feedback about patients' experiences of using the app. This will include discussion of how patients utilized the app, the app's usefulness as an intervention, the level of acceptance of the app as a self-management tool for COPD, and patients' opinions on the scalability of the intervention. Qualitative data will also be collected to understand the views of caregivers for adults living with COPD, specifically regarding technology-based health solutions in COPD.

Intervention Type
Behavioural

Primary outcome measure
Feasibility of a digital self-management app intervention for people living with COPD in India. Measured by collecting data captured through the app and pre- and post-intervention FGDs between baseline and 8 weeks. The measurements to determine feasibility will be:
1. Number of participants identified, approached, consented, randomised and completed
2. Performance of participants – completion rate, perceived usefulness, burden etc.
3. Record of patient login, accessibility and adherence
4. App analytics including app usage -frequency, no. of views to read knowledge information, exercise information, video seen, incomplete use and drop-outs etc.
5. Insights on need, demand, usefulness of digital technology/app in COPD healthcare
6. Insights on their user-friendliness with smart phones, perceptions about using app for chronic health
7. COPD Assessment Test (CAT) will be important to identify severity of symptoms
8. Borg scale
9. MRC dyspnoea scale to indicate the extent to which breathlessness affects their mobility
10. Monitoring of physical exercises through app
11. COPD grading and clinical history and medical examinations, conditions, practicality of delivering the intervention in the proposed setting
12. Serious adverse events

Secondary outcome measures
1. To assess the demand for a digital self-management App for people in India living with COPD
This will be achieved by conducting pre- and post-intervention FGDs to assess patient insights on the need, demand, and usefulness of a digital self-management app for COPD patients. Further insights will also be sought from patients about the use of digital smartphone apps in the management of chronic health conditions, along with the practicality of delivering the intervention in the proposed setting. Measured at baseline and 8 weeks.
2. Determine the adaptability of the 'SPACE for COPD' content and Yoga to ensure it is culturally appropriate for a global audience and specifically for India through literature review and pre-intervention FGDs with patients at baseline.
This will be achieved through Communications and correspondences with the research team and the app developers in order to develop well-defined and verified content for the app.
3. Acceptability of the app for people living with COPD in India assessed through post-intervention FGDs with patients and/or their caregivers at 8 weeks
4. Patient compliance/adherence to the exercise sessions will be analyzed via data collected from the app at 8 weeks.

Overall study start date
01/04/2018

Completion date
01/03/2023

Eligibility

Key inclusion criteria
1.Patients:
a. ≥18 years
b. Stable COPD, confirmed on spirometry, as having a forced expiratory volume in 1 s (FEV1) post-bronchodilation of <80% and a predicted ratio of FEV1 to forced vital capacity of 0.70
c. Patients with MRC dyspnoea score ≥2
d. Able to read Marathi or Hindi
e. Signed informed consent
2. Caregivers providing care and support to adults living with COPD.

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Co-morbidities or significant cardiovascular, hepatic, renal, neurological, orthopedic, neoplastic diseases that may hamper the participation of the patient and outcome of the program
2. Recent major surgery ≤1 month before enrolment
3. Pregnancy
4. Active pulmonary tuberculosis
5. Severe cognitive impairment such as dementia

Date of first enrolment
01/04/2021

Date of final enrolment
30/10/2022

Locations

Countries of recruitment
India

Study participating centre
Symbiosis International (Deemed University)
Symbiosis Knowledge Village
Gram: Lavale, Tal: Mulshi
Pune
India
412115

Sponsor information

Organisation
University of Leicester

Sponsor details
University road
Leicester
England
United Kingdom
LE1 7RH
+44 1162522522
smd8@leicester.ac.uk

Sponsor type
University/education

Website
https://le.ac.uk

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 10/02/2021:
It is anticipated that the results from this study will be published in international journals and presented locally, nationally and internationally at appropriate meetings and conferences. All data that will be collected is anticipated to be published.

Previous publication and dissemination plan:
It is anticipated that the results from this study will be published in international journals and presented locally, nationally and internationally at appropriate meetings and conferences. All data that will be collected is anticipated to be published.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request.

IPD sharing plan summary
Available on request