

Very brief advice for pulmonary rehabilitation

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| Submission date 29/05/2024 | Recruitment status Recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 30/05/2024 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 09/07/2025 | Condition category Respiratory | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Over 1.2 million people living in the UK live with a lung condition known as chronic obstructive pulmonary disease (COPD) which causes people to get short of breath. A treatment that helps with shortness of breath is an exercise and education programme called pulmonary rehabilitation (called rehab for short). However, only a small number of people are referred for and start rehab. People from ethnic minority groups, those living in poor areas, women and older people are less likely to be referred. Increasing the number of people receiving rehab is an urgent NHS priority.

In the past, there were similar problems with the referral of smokers to stop smoking services. However, a way of changing people's behaviour, called Very Brief Advice, has increased the number of people referred for support and who stop smoking. Very Brief Advice, which is widely used in the NHS, involves an online training course for healthcare workers that teaches them how to discuss a referral to stop smoking services with smokers. Changing Very Brief Advice so it can be used by healthcare workers to discuss a rehab referral with people living with COPD may be a way to increase the number of people who agree to be referred to rehab.

Working with different types of people living with COPD, their carers/family and healthcare workers, this study aims to change Very Brief Advice so it can be used by healthcare workers to discuss a rehab referral with people with COPD (called Very Brief Advice for rehab).

Who can participate?

People aged 18 years and over living with COPD, their carers and family, as well as healthcare professionals who work in or refer people living with COPD for pulmonary rehabilitation can take part in the study.

What does the study involve?

People living with COPD, their carers/family and healthcare workers will be interviewed online or by telephone or in their home, if they don't use the Internet. This is to understand the problems around rehab referral and how Very Brief Advice can be changed to discuss a rehab referral. Together, people living with COPD, healthcare workers, researchers and the National Centre for Smoking Cessation and Training, the organisation that developed Very Brief Advice, will change Very Brief Advice and develop the online training course to teach healthcare workers how to use Very Brief Advice to discuss a rehab referral. This will be done by a series of co-

design workshops and focus groups online, or by telephone if the participant doesn't use the Internet. More funding will then be sought to test whether Very Brief Advice for rehab works and is acceptable to people living with COPD.

What are the possible benefits and risks of participating?

This study does not involve any treatment and people who take part are unlikely to benefit from taking part. As a gesture of thanks, participants will be given a £25 voucher for taking part in the interview and two focus groups. Participants who take part in the two co-design workshops will be given an additional £25 voucher. Healthcare professional participants who take part in the intervention pilot and focus group will be given an additional £25 voucher.

This is a low-risk study. Care will be taken to minimise any distress during the study and the following distress protocol will be used to manage any distress that arises:

If participants become upset during any study activity e.g. consent, interview, workshop, focus group, the researcher will first offer to pause, postpone or stop the activity and advise again that participation is voluntary. In the case of severe distress, participants will be encouraged to share their feelings with a member of their healthcare team, or manager if the participant is a healthcare professional. The researcher will offer to contact the participant's healthcare team on their behalf. It is anticipated that distress caused by the research will be infrequent and is likely to reflect the presence of COPD and not the research processes.

Where is the study run from?

The study is being run from Brunel University London (UK) but people from all across England can take part as the study can be done online or by telephone.

When is the study starting and how long is it expected to run for?

June 2022 to May 2026

Who is the main contact?

Dr Emma Norris, chat_study@brunel.ac.uk

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Emma Norris

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

345336

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 345336, CPMS 63000

Study information

Scientific Title

Co-design of a very brief behavioural change approach to assist healthcare professionals discuss pulmonary rehabilitation with people with COPD

Acronym

CHAT

Study objectives

Pulmonary rehabilitation (PR), an exercise and education programme for people with chronic obstructive pulmonary disease (COPD), improves breathlessness and decreases the frequency of hospitalisations. National data report that PR referral and uptake are low, with ethnic minority groups, those living in deprived areas, women and older people less likely to be referred. Increasing the number of people receiving PR is an urgent priority of the NHS Long-Term plan.

Very Brief Advice (VBA), which is widely used in the NHS, is an evidence-based behavioural change approach that increases the referral rate to smoking cessation services and uptake of smoking cessation. It involves an online training programme for healthcare professionals that provides training in the three stages of VBA: ASK (who smokes), ADVISE (best method of quitting) and ACT (on patient's response). As referral and uptake are behavioural issues, adapting VBA, a behavioural change approach, to enable healthcare workers to discuss PR with patients may be a plausible way to increase referral and uptake.

Therefore, this research aims to use co-design and behaviour change theory, with consideration of equality, diversity and inclusion, to adapt VBA to develop a very brief behaviour change approach for healthcare professionals to discuss PR referral with people with COPD.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 03/05/2024, College of Health, Medicine and Life Sciences Research Ethics Committee (Brunel University London, London, UB8 3PH, United Kingdom; +44 (0)1895 27400; louise.mansfield@brunel.ac.uk), ref: 48000-MHR-Apr/2024- 50735-1

Study design

Study 1: Qualitative study based on semi-structured interviews with people with COPD, their carers/family and healthcare professionals; Study 2: Intervention co-design, development and piloting

Primary study design

Observational

Secondary study design

Qualitative study

Study setting(s)

Home, Internet/virtual

Study type(s)

Treatment

Participant information sheet

Patient information material can be found at: https://figshare.com/projects/Co-design_of_a_very_brief_behavioural_change_approach_to_assist_healthcare_professionals_discus

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease

Interventions

Study 1: Qualitative interviews

1:1 interviews will be conducted by a researcher who does not know the participant via videoconference, telephone or in the participant's home. The topic guide, which covers salient areas of concern, is informed by the research aims and objectives, behaviour change analysis and based upon current literature and patient and public involvement (PPI) input, will allow novel perspectives raised by participants to be explored in depth. The topic guide has been piloted to check for clarity and flow with an experienced PR professional, an experienced primary care professional and two people living with chronic lung disease (none will be recruited to the study). The topic guide includes the aims of the study and interview, introductory questions (patients: their experiences of pulmonary rehabilitation, healthcare professionals: role in pulmonary rehabilitation) and a number of topic areas which will explore their opinions on Very Brief Advice. The interviewer may intervene to clarify, prompt, or move the discussion on. The interview will last 30-40 minutes, with a comfort break offered after 30 minutes. There will be flexibility within this format as needed.

To increase reflexivity and transparency of interpretation, concurrent field notes and reflection on interviewer role and potential biases will be used. The interviews will be audio-recorded and transcribed using the videoconference software/transcribed professionally, or if conducted by telephone or in-person, recorded using a recording device and transcribed professionally. The transcripts will be anonymised and checked for accuracy prior to analysis

Anonymised transcripts will be imported into NVIVO (QSR International, Australia) to facilitate analysis which will be based on thematic analysis drawing on the principles of framework analysis. Two researchers will read the first five transcripts and independently define a preliminary thematic framework which will be compared and reconciled where necessary. The initial framework will be developed based on questions from the topic guide and the

researchers' observations and adapted accordingly as analysis proceeds. Each transcript will be coded in an iterative process. Themes and subthemes which emerge will be discussed in order to agree content and key concepts. Steps will be taken to increase reflexivity and transparency of interpretation e.g. use of concurrent field notes, interviewer role, PPI data interpretation workshop.

Study 2: Intervention co-design, development and piloting

The purpose of this phase of the study is to co-design, develop and pilot the very brief behavioural intervention. It will involve co-design workshops and focus groups.

Intervention co-design

The findings from the interviews and behavioural analysis will be used to adapt the Very Brief Advice for pulmonary rehabilitation i.e. 'Ask, Advise, Act' model and develop the components of the online training course. The course format and delivery strategy will be based on Very Brief Advice (films, written material) as they are acceptable to healthcare professionals but tailored to pulmonary rehabilitation based on interview findings and the PRIME Theory of Motivation. Intervention functions and key behaviour change techniques to be included in the intervention will be identified based on recommendations of the Behaviour Change Wheel to address key COM-B barriers and facilitators: education, persuasion, training (functions) and information about health consequences, and capability (behaviour change techniques).

Two workshops will be chaired by the research team and attended by the PPI team, two people with COPD (identified during qualitative interviews), three healthcare professionals (identified during qualitative interviews: one pulmonary rehabilitation professional (i.e. pulmonary rehabilitation delivery experience) and two healthcare professionals from primary and secondary care with PR referral experience), health psychologist. If more participants express an interest in taking part in the workshops than there are spaces available, then participants will be selected to ensure a range of perspectives are represented (patient participants: ethnicity, gender; healthcare professional participants: profession, ethnicity, gender). Patient participants will be encouraged to invite their carers or family to the workshops. The workshops will be facilitated by two researchers, last 1-2 hours with a comfort break and will be audio-recorded and transcribed. An email will be sent to workshop attendees to confirm the meeting time and share the meeting link.

Workshop 1: The findings from the interviews and behavioural analysis will be presented, and feedback invited. The facilitators will ask the group to highlight key themes that would be important to include in the design of the intervention. Participants will then form co-design groups (with an even mix of patient and healthcare professionals) for unstructured discussion to review themes and shortlist key components of a prototype intervention.

After workshop 1: The research team will use the key components identified at the workshop to draft the intervention, in line with the Behaviour Change Wheel approach to developing interventions.

The research team will facilitate four online focus groups ($n = 8/\text{participants}$) for participants who took part in the interviews (each participant will attend only one focus group).

The online focus groups will be held on Microsoft Teams or if a participant is unable to use the Internet, the intervention will be discussed by telephone and feedback invited. For participants who don't use the Internet, a time and date will be arranged by telephone. Potential patient participants will be advised that their informal carers or family can be involved in the focus group if the person wishes.

During the focus groups, the intervention will be shared, and feedback invited. A topic guide will not be used as we want to understand participants' opinions using unstructured discussion and the dynamics of group interaction to reveal participants' similarities and differences of opinion.

The focus group should last 1 hour, with a comfort break offered after 30 minutes. There will be flexibility within this format as needed. As described in the interview methods section, to increase reflexivity and transparency of interpretation, concurrent field notes and reflection on interviewer role and potential biases will be used. The focus groups will be recorded and transcribed using the videoconference software, or if conducted by telephone, recorded using a recording device and transcribed professionally. The transcripts will be anonymised and analysed using thematic analysis.

Workshop 2: The members of the research team and key stakeholders will modify the intervention based on the themes identified in the online focus groups using the APEASE criteria.

After workshop 2: The research team will facilitate four online focus groups (n=8/participants) for participants who took part in the interviews (each participant will attend only one focus group). For participants unable to use the Internet, attendance options described in 'After workshop 1' will be offered. The duration, recording and analysis will be as described in 'After workshop 1'.

During the focus group, the draft intervention will be presented and feedback invited. After workshop 2, the research team will use the feedback to finalise the intervention.

Intervention development

In collaboration with the research team, the National Centre for Smoking Cessation and Training will lead the creation of the online training course which will involve creating the online platform, writing training material and filming videos of the intervention using actors.

Intervention piloting

Healthcare professionals who participated in the interviews will be invited to complete the online training course and attend a subsequent focus group to share their feedback. The focus group will be facilitated by two researchers, will last 1-2 hours with a comfort break and will be audio-recorded and transcribed. The National Centre for Smoking Cessation and Training and the research and PPI teams will modify the intervention based on their feedback using the APEASE criteria. The intervention will then be ready for testing as part of a future feasibility study.

Intervention Type

Behavioural

Primary outcome measure

1. Perceived barriers and facilitators to referral and uptake (including the impact of the pandemic) amongst HCPs, patients their carers/family, including those experienced by under-represented communities, and associated behaviours in accordance with the Theoretical Domains Framework, structured by the Behaviour Change Wheel COM-B model at the end of the study
2. Similarities and differences between smoking and PR and implications for the behavioural change approach design, assessed using behavioural analysis at the end of the study
3. How the VBA model of 'Ask, Advise, Act' can be adapted for PR, e.g. how and what referrers can say that is likely to be well-received and lead to a referral, how to support patients make a

decision and manage responses, assessed using qualitative interviews, co-design workshops and focus groups at the end of the study

4. Approaches required for different HCPs and patients, assessed using qualitative interviews, co-design workshops and focus groups at the end of the study

5. Training needs and programme delivery strategy to support HCPs, assessed using qualitative interviews, co-design workshops and focus groups at the end of the study

6. Behaviour change approach and online training course co-designed and developed based on behaviour change theory and findings from qualitative interviews with stakeholders at the end of the study

7. Feedback on the online training course from HCPs who participated in the qualitative interviews at the end of the study

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/06/2022

Completion date

31/05/2026

Eligibility

Key inclusion criteria

1. Adult ≥ 18 years with COPD OR healthcare professional with at least 1 years' experience working in PR (e.g. physiotherapist, nurse, occupational therapist) OR healthcare professional with at least 1 years' experience of making referrals to PR OR known clinical expert in PR e.g. member of national or international committee

2. Able to provide informed consent

Participant type(s)

Patient, Health professional

Age group

Adult

Lower age limit

18 Years

Upper age limit

130 Years

Sex

Both

Target number of participants

Healthcare participants: 22; People with COPD participants: 17

Key exclusion criteria

Cognitive impairment that would preclude taking part in an interview and/or workshop

Date of first enrolment

01/06/2024

Date of final enrolment

30/10/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Association of Chartered Physiotherapists in Respiratory Care

United Kingdom

EC4A 1AB

Study participating centre

Asthma and Lung UK

18 Mansell Street

London

United Kingdom

E1 8AA

Study participating centre

Breathe Easy Andover

United Kingdom

SP116TY

Study participating centre

Breathe Easy Basingstoke

United Kingdom

RG224NN

Study participating centre

Breathe Easy Darlington

United Kingdom

DL14DH

Study participating centre
Breathe Easy South Sea
United Kingdom
PO29QA

Study participating centre
Bristol University Primary Care Network
United Kingdom
BS81TH

Study participating centre
Caribbean and African Health Network
United Kingdom
M130LN

Study participating centre
Community Pharmacy England
United Kingdom
DA12JH

Study participating centre
The Confederation Hillingdon Cic OOH
Link-1a
Civic Centre
High Street
Uxbridge
United Kingdom
UB8 1UW

Study participating centre
Council of Somali Organisations
United Kingdom
EC2A 4NE

Study participating centre
Cumbria and North East Primary Care Network
United Kingdom
No postcode

Study participating centre
Hillingdon Primary Care Network
United Kingdom
No postcode

Study participating centre
Homerton Patient Network
United Kingdom
No postcode

Study participating centre
Keele University Primary Care Network
United Kingdom
ST5 5AU

Study participating centre
Liskeard and Saltash Breathers
United Kingdom
PL126DJ

Study participating centre
Live Well with COPD Fareham and Gosport
United Kingdom
No postcode

Study participating centre
London Pulmonary Rehabilitation Network
United Kingdom
No postcode

Study participating centre
Market Harborough and Bosworth Primary Care Network
United Kingdom
No postcode

Study participating centre
National Respiratory/Pulmonary Rehabilitation Network
United Kingdom
No postcode

Study participating centre
NIHR School for Primary Care Research at University of Oxford
University of Oxford
University Offices
Wellington Square
Oxford
United Kingdom
OX1 2JD

Study participating centre
Nottingham University Primary Care Network
United Kingdom
NG7 2RD

Study participating centre
Patient Support groups in North East England
United Kingdom
No postcode

Study participating centre
Primary Care Respiratory Society
United Kingdom
B93 0LL

Study participating centre
Royal Brompton Hospital Lay Advisory Group
United Kingdom
SW3 6NP

Study participating centre
Social Action for Health
United Kingdom
E83DQ

Study participating centre
Southwest Respiratory Network
United Kingdom
No postcode

Study participating centre
University Hospitals Leicester Multimorbidity Patient and Public Involvement Group
United Kingdom
LE17RH

Study participating centre
Social media - Twitter/X
United Kingdom
W1B 5AN

Study participating centre
Social media - LinkedIn
United Kingdom
EC1R 3DA

Study participating centre
Social media - Facebook
-
-
United Kingdom
No postcode

Sponsor information

Organisation
Brunel University London

Sponsor details
Kingston Lane
London
England

United Kingdom
UB8 3PH
+44 (0)1895 274000
vic.gill@brunel.ac.uk

Sponsor type

University/education

Website

<https://www.brunel.ac.uk/>

ROR

<https://ror.org/00dn4t376>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care 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

With the PPI and Brunel Public Policy teams, a broad strategy will be used to maximise dissemination:

1. Study updates and results shared on the study website (Plain English summaries, podcast, participant newsletter), Twitter/X
2. Videoconference to share results with participants, patient and healthcare professional networks, professional societies, charities
3. Press release for relevant media e.g. professional societies, charities written in collaboration

with the Brunel University media team

4. Open-access publications: pre-print of study protocol on Figshare before starting recruitment and main manuscript in an open-access, peer-reviewed journal.

Intention to publish date

31/12/2026

Individual participant data (IPD) sharing plan

Anonymised interview, workshop and focus group transcripts will be published on Figshare following the publication of the main manuscript.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---------|--------------|------------|----------------|-----------------|
| Participant information sheet | | | 30/05/2024 | No | Yes |
| Protocol (other) | | | 30/05/2024 | No | No |