**Study protocol **

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

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# Background

Respiratory disease affects one in five people and is the third biggest cause of death in England.1 National2 and international guidelines2, 3 define pulmonary rehabilitation (PR) as an individualised, multi-disciplinary, programme of twice-weekly exercise and education delivered over 6-8 weeks. It is designed for people with chronic respiratory disease (e.g. COPD) and functional limitation due to breathlessness.4 It is established in national4 and international3 guidelines as an important and cost-effective intervention. Scientific3, 4 and national5 audit data confirm that it improves breathlessness and quality of life3 and results in fewer and shorter hospital admissions,6 readmissions7 and deaths.8 Despite this, national audit data indicate that PR is only offered to 13% of eligible people with COPD,5 with individuals from ethnic minority groups,9 areas of social deprivation,10, 11 women and individuals ≥70 years11 less likely to be referred. The reasons for this are unclear. Uptake is also poor with rates ranging from to 24%12 to 31%10 but there are no data on specific disadvantaged groups, which may be anticipated to be even lower.

Interventions to address low referral and uptake rates are lacking. To date only one randomised controlled trial (RCT) has been designed with the primary aim of increasing referral and uptake in COPD using an educational video (no behavioural science component), but the intervention did not work.13 Other studies (one cluster-RCT14 but predominantly audits and uncontrolled studies with no consideration of equality, diversity and inclusion (EDI)), which were not specifically designed to increase referral and uptake, have methodological and reporting limitations, and did not improve these outcomes.15 No study has investigated the conversation between healthcare professionals (HCPs) and patients about PR, which has been cited as an enabler of referral and uptake.16

The NHS Long-Term Plan aims to significantly increase the number of people receiving PR.17 There is currently no intervention that achieves this. This is reflected in the British Thoracic Society Clinical Statement on PR where increasing referral and uptake has been identified as a research priority.18

Current Medical Research Council guidance on developing complex interventions suggests that existing interventions may be adapted and evaluated for alternative purposes.19 Very Brief Advice (VBA) is a behaviour change approach20 for HCPs who are not smoking cessation specialists to encourage smokers to accept a referral to a smoking cessation service and quit.21 It was developed by leading behavioural scientists (Professor Robert West, Professor Susan Michie) at the National Centre for Smoking Cessation and Training, who are funded by the Department of Health. VBA is a simple, conversation-based, patient-centred approach that can be delivered effectively in 30 seconds after a free 30-minute e-learning course.22 It follows the framework of ‘ASK (who smokes), ADVISE (best method of quitting smoking) and ACT (on patients’ response) and the key mechanism is the positive focus of offering hope and assistance, rather than directly telling patients to quit.22

A Cochrane review demonstrated that VBA compared to no advice (17 RCTs) resulted in a significant increase in referral rates to smoking cessation services and uptake of smoking cessation (RR (95%CI) 1.66 (1.42-1.94) at longest follow-up (6-36 months).23 Meta-analysis (13 RCTs) suggest that VBA is more effective than advice in increasing referral rates to smoking cessation services and uptake of smoking cessation (RR (95%CI): VBA: 1.69 (1.24-2.31); advice: 1.39 (1.25-1.54).24 Qualitative research has demonstrated that VBA is acceptable to HCPs who reported that it improved communication style and persistence in addressing referral for smoking cessation25 and the online training course was associated with improvements in knowledge and self-efficacy.26 Furthermore, qualitative research involving 50 smokers who received VBA from their GP indicated that it was positively received and confirmed the motivational role of advice when delivered in a supportive manner.27

Given the strong evidence-base, the systematic provision of VBA across the NHS is recommended by NICE28 and national commissioning guidance for smoking cessation services.29 Therefore, it is a familiar tool to HCPs and aligns with the principles of NHSE ‘Making Every Contact Count’30 and policy guidelines including the Easy, Attractive, Social and Timely principles from the Behavioural Insights Team.31

As VBA is based on broad behavioural approaches such as the Capability Opportunity Motivation (COM-B) model, it can be adapted to other behaviours. For example, this was done with VBA Physical Activity for nurses to support cancer patients increase activity levels32 and was shown to be acceptable but data on effectiveness were not collected.33 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.

This research aims to co-design and investigate the feasibility and acceptability of conducting a full-scale cluster-RCT of a very brief behaviour change approach, with consideration of EDI, for HCPs to discuss PR referral with people with COPD, in order to increase referral and uptake rates. This research does not focus on PR completion as this behaviour is influenced by behaviours, factors (e.g. PR attendees, illness, time) and people (PR service) different to those that influence referral and uptake.

# Aims

Use co-design and behaviour change theory, with consideration of EDI, to adapt VBA to develop a very brief behavour change approach (VBA-PR) for HCPs to assist conversations on PR referral with people with COPD.

# Objectives

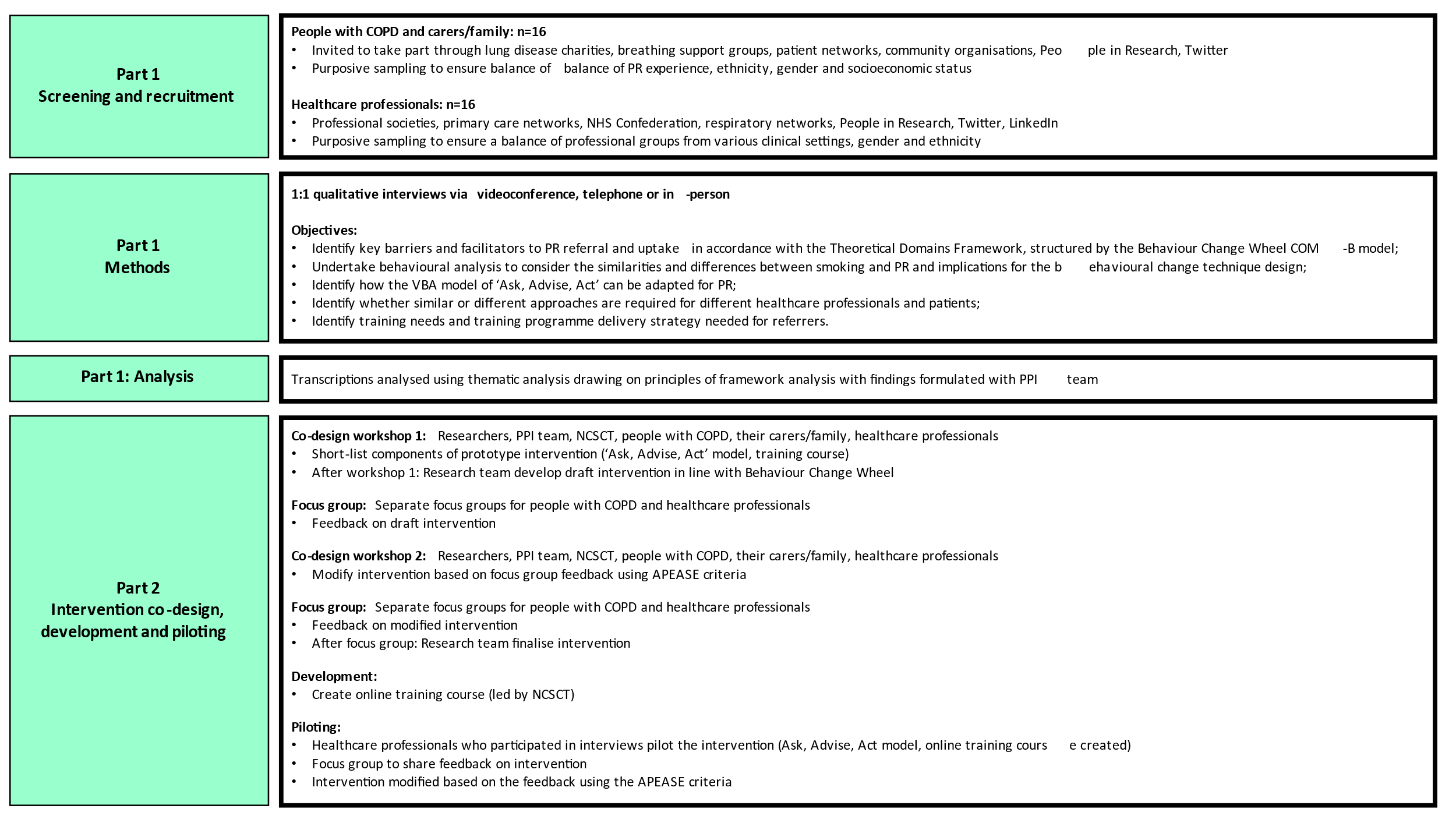
1. Identify perceived barriers and facilitators to referral and uptake (including the impact of the pandemic) amongst HCPs, patients their carers/family, including those experienced by under-represented communities, and associated behaviours in accordance with the Theoretical Domains Framework, structured by the Behaviour Change Wheel COM-B model;34
2. Undertake behavioural analysis to consider the similarities and differences between smoking and PR and implications for the behavioural change approach design;
3. Identify 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;
4. Identify whether similar or different approaches are required for different HCPs and patients;
5. Identify training needs and programme delivery strategy to support HCPs;
6. With stakeholders, co-design and develop the behaviour change approach and online training course based on behavour change theory and findings from qualitative interviews;
7. Pilot the online training course on HCPs who participated in the qualitative interviews and modify it based on feedback.

# Methods

The study is composed of two parts outlined in figure 1.

Part 1: Qualitative study based on semi-structured interviews with people with COPD, their carers/family and HCPs (objectives 1-5).

Part 2: Intervention co-design, development and piloting (objectives 6-7).



## Figure 1. Study overview

*Abbreviations: COM-B: Capability, Opportunity and Motivation – Behaviour; COPD: Chronic Obstructive Pulmonary Disease; PPI: Patient and Public Involvement; PR: Pulmonary Rehabilitation; NCSCT: National Centre for Smoking Cessation and Training; VBA: Very Brief Advice.*

# Part 1: Qualitative interviews

Study design: 1:1 qualitative interviews and with people with COPD, their carers/family and HCPs.

## Inclusion criteria

1. Adult ≥18 years with COPD OR healthcare professional with at least one years’ experience working in PR (e.g. physiotherapist, nurse, occupational therapist) OR healthcare professional with at least one 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.

## Exclusion criteria

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

Potential participants who do not speak English will be supported to take part in the study using translators and translated study material.

## Participant recruitment

Patient participants: People with chronic lung disease (n=16) will be recruited through lung disease charities, breathing support groups, patient networks, community organisations, People in Research website and Twitter/X. Purposive sampling will ensure variation in PR experience (programme completion versus never attended versus declined / dropped out of programme), ethnicity (white versus ethnic minority group), socioeconomic status (< and ≥ 50th centile of the multiple deprivation index35) and gender. Participants will be encouraged to invite their carers or family for support and because of their key role in COPD management.

Healthcare provider participants: Participants (n=16) will be recruited through professional societies, primary care networks, NHS Confederation, respiratory networks, Twitter/X and LinkedIn. Additionally, snowball sampling will enable the researchers to identify key stakeholders, and opportunistic sampling will allow the researchers to take opportunities during data collection to select potentially important cases. Purposive sampling will ensure variation in rehab role (PR delivery versus PR referrer with more referrers recruited due to the nature of the proposed intervention), clinical setting (primary versus secondary versus tertiary versus community care), gender and ethnicity (white versus ethnic minority group).

## Specific recruitment strategies

Lung disease charity recruitment strategy:The research team will email a study introduction letter to Asthma and Lung UK (SEE ATTACHMENT: STUDY INVITATION LETTER\_ALUK) to share with their members. Interested individuals can read and complete the online participant information sheet and screening form (SEE [CHAT: Study information sheet and screening form for people living with COPD (office.com)](https://forms.office.com/Pages/DesignPageV2.aspx?origin=NeoPortalPage&subpage=design&collectionid=hzuv8h3jbnyig4jykstoyw&id=sZetTDVZA0GoZletmKFRftIWawBGoUZGlD94z5BpRDBUREZZNzdSOVhQRlhCU1VWWTBUV0VIUkRWWS4u) OR ATTACHMENT: CHAT\_ Study information sheet and screening form for people living with COPD) or contact the research team through the study email account or telephone number if they would prefer the information sheet to be sent by email or post.

Breathing support group, patient network, community organisation recruitment strategy: The research team will email a study introduction letter (SEE ATTACHMENT: STUDY INVITATION LETTER\_ GENERAL PATIENT) to the group leader or nominated individual to share with their members.

People in Research website recruitment strategy:A study synopsis (SEE ATTACHMENT: STUDY INVITATION LETTER\_PEOPLE IN RESEARCH) will be posted on the People in Research website.

Twitter/X and LinkedIn recruitment strategy: The use of social media for recruitment is becoming increasingly common as a way of reaching a wider audience of participants. A series of seven messages with graphics and images to enhance recruitment will be used (SEE ATTACHMENT: SOCIAL MEDIA RECRUITMENT STRATEGY), but will not target specific individuals so will remain a passive strategy.36 However, the tweets will request readers to retweet and share more widely in line with snowballing strategy.

The tweets will be sent from Dr Nolan’s professional Twitter/X and LinkedIn account. There is no personal information on the account. Discoverability settings are switched off, so Dr Nolan is not discoverable by linked personal email address, registered phone number or location.

The Twitter/X handle and profile detail reads @clairemnolan and ‘Lecturer in Physiotherapy & #NIHR Advanced Fellow @bruneluni Interested in #pulmrehab, all things #respiratory, #MLTC &supporting #AHP research. Views my own’. Twitter/X privacy account settings enable tweets to be seen by people who do not follow the account. Direct messages can only be sent by people who follow the account. No direct messaging via the Twitter/X platform will be encouraged in the tweet text. Interested individuals will contact the research team through the study email account.

The LinkedIn profile reads “Claire M Nolan: Lecturer in Physiotherapy, Brunel University London and Senior Research Physiotherapist, Royal Brompton Clinical Group. No direct messaging via LinkedIn will be encouraged in the tweet text.

Professional society recruitment strategy:The research team will email a study introduction letter to the Association of Chartered Physiotherapists in Respiratory Care and Community Pharmacy England (SEE ATTACHMENT: STUDY INVITATION LETTER\_ACPRC, STUDY INVITATION LETTER\_CPE) and the Primary Care Respiratory Society.

Primary care networks, NHS Confederation, respiratory networks recruitment strategy: The research team will email a study introduction letter network or confederation lead (SEE ATTACHMENT: STUDY INVITATION LETTER\_NETWORK) to share with their members.

Known clinical experts recruitment strategy:The research team will email a study introduction letter (SEE ATTACHMENT: STUDY INVITATION LETTER\_ EXPERT) to known experts (email address available publicly). These individuals make their contact details available specifically for the purposes of research/collaboration/clinical enquiries and research participation is an expected component of their role as field experts, therefore contacting them in this way is a reasonable to use of their personal information (i.e. email address).

Interested individuals, both people with COPD and healthcare professionals, can read and complete the online participant information sheet and screening form (NOTE: the screening form screens for eligibility and purposive sampling criteria; SEE ATTACHMENT: CHAT\_ Study information sheet and screening form for healthcare professionals OR CHAT\_ Study information sheet and screening form for people living with COPD) or contact the research team using the study email account or telephone number if they would prefer the information sheet to be sent by email or post.

## Process from initial contact to booking interview

The process following initial contact from prospective participants via email or telephone (from all recruitment strategies) to obtaining consent, screening for inclusion/exclusion criteria and purposive sampling criteria, and booking the interview is as follows:

If participants request the information sheet to be sent by email, an email (SEE ATTACHMENT: CORRESPONDENCE 1) will be sent inviting them to read the Patient Information Form (PIS) and complete the online screening form (SEE ATTACHMENT: LINK TO THE FORM IS IN CORRESPONDENCE 1 OR SCREENING FORM; NOTE: the screening form screens for eligibility and purposive sampling criteria) if they are interested in taking part in the study and are satisfied with the study information. If a potential participant is unable to use the Internet, the PIS will be posted to the individual and the researcher will telephone them to complete the online screening form on their behalf (NOTE: a telephone number rather than email address will be recorded in response to question 2 'Please state your email address'). This will involve the researcher reading the screening questions and noting the individual's responses.

The research team check the screening form for eligibility and purposive sampling criteria for all participants i.e. those who completed the online screening form shared in the study advert/introductory letter, the online screening form shared by email or completed by telephone.

After reviewing the screening form, if a potential participant is ineligible the researchers will inform the individual that they are ineligible and explain the reason why (SEE ATTACHMENT: CORRESPONDENCE 2A), and delete the information submitted in the online screening from once the individual has been informed of their ineligibility. If a potential participant is eligible to take part in the study, they will be informed of this and emailed a link to complete the online consent form and select an interview date (SEE ATTACHMENT: CORRESPONDENCE 2B AND ONLINE CONSENT FORM). Once the interview date has been confirmed, an email with the MS Teams link will be sent (SEE ATTACHMENT: CORRESPONDENCE 3). A reminder email will be sent one day before the interview (SEE ATTACHMENT: CORRESPONDENCE 4).

If an individual doesn't use the Internet the consent form and stamped addressed envelope will be posted to them, and/or consent will be obtained over the telephone (depending on the individual's preference) and the interview date booked (SEE ATTACHMENT: CONSENT FORM AND TELEPHONE CONSENT FORM). Telephone consent involves the researcher completing the consent form on the potential participant's behalf. It involves the researcher reading each point on the consent form to the individual who indicates whether or not they agree with each point. The researcher records the response and sends a copy of the completed form. The telephone call is witnessed by a second researcher who also signs the consent form. Potential patient participants will be encouraged to invite their carers or family to the interview. An opportunity will be provided for them to contact the researcher with any queries beforehand via email or telephone. A confirmatory letter with the interview details will be posted to the individual (SEE ATTACHMENT: CORRESPONDENCE 3). An opportunity to discuss any questions/issues arising with the researcher will be provided within each contact.

## 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 to achieve objectives 1-4. The topic guide (SEE ATTACHMENT: INTERVIEW TOPIC GUIDE HCP / PATIENT), which covers salient areas of concern, will be 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 VBA. The interviewer may intervene to clarify, prompt, or move on the discussion. 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

## Sample size

This is based on the predicted number of participants required to achieve sufficient information power to meet the study aim. Information power indicates that the more information the sample holds, relevant for the actual study, the lower the number of participants is needed.37  Based on previous experience of qualitative studies in respiratory research and the specifics of this study, 16 patients, their carers/family and 16 HCPs will be interviewed (total n=32).

## 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.38Two 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.

# Part 2: Intervention co-design, development and piloting

The purpose of this phase of the study is 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 VBA for PR 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 VBA (films, written material) as they are acceptable to HCPs25 but tailored to PR based on interview findings and PRIME Theory of Motivation.39 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, capability (behaviour change techniques).

Two workshops will be chaired by NOLAN and Chief Executive of the National Centre for Smoking Cessation and Training and attended by PPI team, two people with COPD (identified during qualitative interviews), three HCPs (identified during qualitative interviews: one PR professional (i.e. PR delivery experience) and two HCPs from primary and secondary care with PR referral experience), health psychologist (STEED). 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; HCP 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 (SEE ATTACHMENT: CORRESPONDENCE 5).

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.40

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)

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. An email will be sent to confirm the focus group date and time to provide the MS Teams link (SEE ATTACHMENT – CORRESPONDENCE 6). For participants who don't use the Internet, a time and date will be arranged by telephone and a confirmatory letter with these details will be posted to the individual (SEE ATTACHMENT – CORRESPONDENCE 6). 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. We will not use a topic guide 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 one 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. 41

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

HCPs who participated in the interviews will be invited to complete the online training course (SEE ATTACHMENT: CORRESPONDENCE 7) attend a subsequent focus group (SEE ATTACHMENT: CORRESPONDENCE 8) to share their feedback. The focus group will be facilitated by two researchers, 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.41The intervention will then be ready for testing as part of a feasibility study.

# Management of study risks

Distress of participants during interviews, workshops and focus group: 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 and/or 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, the participant will be encouraged to share their feelings with a member of their healthcare team (for patient participants, their carer/family) or GP (for HCP participants). The researcher will offer to contact their health care team (for patient participants, their carer/family) or GP lead (for HCP participants) on their behalf. We anticipate that distress caused by the research will be infrequent and is likely to reflect the presence of lung disease (for patient participants, their carer/family) and not the research processes.

If participants disclose ideation of self-harm or other risk to themselves or others, then this will be dealt with as an urgent matter and help will be sought guided by Sponsor protocol, if possible in agreement with the participant. However, if the research team believes the participant to be at imminent risk and refuses to allow voluntary disclosure to the clinical team, the research team will breach confidentiality. Based on our experience with other studies, we anticipate that this will be an extremely rare occurrence. Provision will be made to ensure researchers have Chief Investigator back up available by phone whenever they are undertaking research activities.

# Discontinuation/withdrawal of participants and stopping rules

Participants will be withdrawn from the study if their behaviour is not conducive to working in an interview or group environment e.g. disruptive, aggressive behaviour. Notification of withdrawal will be made in person or by telephone by the Chief Investigator, and witnessed by a member of the research team. Should participants be withdrawn or wish to withdraw from the study, they will not be included in any future interviews, workshop or focus group as described in the protocol and no new personal data will be collected. Participants can withdraw from the study by contacting the research team by telephone or email. Data already collected in relation to the participant may be retained and used for the purposes for which consent has already been given, provided they are effectively anonymised. All reasons for withdrawal from the study will be documented. Participants who withdraw from the trial will not be replaced. If the Chief Investigator deems that there are obvious safety concerns the study will be terminated prematurely.

# Data protection

All data will be stored securely on Brunel University OneDrive in line with Brunel Data management policies. A shared folder will enable access for the PI and research assistant.

For potential participants identified as ineligible to take part in the study after completing the screening form, the data collected in the screening form will deleted once the participant has been informed of their ineligibility.

Names, geographic and organisational identifiers in interview and focus group transcripts will be pseudonymised and used with the code breaker stored separately in a password protected file. The recordings of interviews and focus groups will be deleted once the transcripts have been pseudonymised.

Interviews conducted by telephone will be transcribed by an external company. This is explained in the PIS and permission to do this will be sought in the consent form.

Consent will be obtained to use pseudonymised quotes from the interviews and focus groups in dissemination material e.g. conference abstracts, manuscripts.

# Patient and public involvement (PPI)

The PPI team (SIVASUBRAMANIAM, BROWN) will be involved in every stage of the research process and the National Standards for Public Involvement will underpin involvement. They will be reimbursed for their time in line with NIHR guidelines, and training and printing costs will be covered. The team includes two members in order to ensure peer support is available and sharing of workload. NOLAN and the PhD student will be PPI leads with responsibility for leading, managing, supporting and evaluating the PPI elements of the project. Halle Johnston, Patient and Public Involvement and Engagement Manager, NIHR School for Primary Care Research, University of Bristol will provide mentorship to NOLAN/PhD student. As both members are new to PPI, they will undergo formal training (‘Public involvement training’, Imperial College London).

The PPI team will attend formal PPI meetings bi-annually (chaired by PhD student/NOLAN) and trial steering committee meetings. Prior to ethical approval being sought, the study protocols will be further reviewed in collaboration with the PPI team. During the ethics submissions, they will review all patient-facing information. The DISCERN tool will be used to assess the quality and readability of the information produced. In conjunction with the research team, the PPI team will formulate the topic guides and emerging themes from the interviews and focus groups will be developed collaboratively. The researchers and PPI team will attend workshops to co-design and finalise the intervention, and implement the dissemination strategy.

To evaluate PPI involvement in the project, NOLAN will keep a formal log to assess ongoing impact and a qualitative researcher from Brunel University will conduct a focus group with the PPI team at the end of the study to learn from their experiences of being involved in the project.

# Committees involved in the study

Patient and Public Involvement Team: This group will consist of two patient representatives (SIVASUBRAMANIAM, NEWMAN-HUNT), NOLAN and PhD student. The PPI team will attend formal PPI meetings bi-annually (chaired by PhD student/NOLAN), trial steering committee meetings and workshops to co-design the intervention.

Study Management Group: This group will consist of NOLAN and PhD student, and will meet weekly. NOLAN will send a monthly email to mentors to share study progress. Advice from mentors will be sought on an ad hoc basis.

Independent Advisory Group: This group will consist of an independent chair, independent academic, mentors, representative the National Centre for Smoking Cessation, PPI representatives, PhD student and NOLAN. It will meet bi-annually and ad hoc as required to discuss progress and resolve issues.

Mentorship meetings: This group will consist of NOLAN and VICTOR. They will meet bi-annually and on an ad hoc basis, as needed.

# Open access plan

* Register study on ISRCTN as per NIHR guidelines following ethical approval and before starting the project;
* Publish pre-print of study protocol on Figshare ([figshare - credit for all your research](https://figshare.com/)) before starting the project;
* Publish main manuscript in an open-access journal;
* Publish anonymised interview, workshop and focus group transcripts on Figshare ([figshare - credit for all your research](https://figshare.com/)) following publication of the main manuscript.

# Dissemination

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 Brunel University media team;
4. Open-access publications: 1) pre-print of study protocol on Figshare before starting recruitment and 2) main manuscript in an open-access, peer-reviewed journal.

# References

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