Study protocol

Feasibility and acceptability testing of a very brief behavioural change approach to assist healthcare professionals discuss pulmonary rehabilitation with people with COPD (CHAT-2)

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Change summary: Changes following HRA REC review. Summary: End of study definition added (section 14); fidelity sub-study: transcription level and qualitative analysis (section 5.3.4 and 5.6); Carer and family member involvement defined (section 5.3.4 and 6.2.4).

Protocol version 4 (29/04/2026):
Change summary: 1) Addition of four NHS Trust sites for pulmonary rehabilitation service data collection; 2) Change to data collection timeframe for clinical data; 3) Change to audio recording device used ; 4) Clarifying Trust involvement for Royal Cornwall Hospitals NHS Trust and Cornwall Health Partnership NHS Foundation Trust as separate NHS Trusts; 5) Clarifying methods for patient participant identification (screening) and patient participant recruitment.

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1 Background

Respiratory disease affects one in five people and is the third biggest cause of death in England.[1] National[2] and international guidelines[2, 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 national[4] and international[3] guidelines as an important and cost-effective intervention. Scientific[3, 4] and national[5] audit data confirm that it improves breathlessness and quality of life[3] and results in fewer and shorter hospital admissions,[6] readmissions[7] 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 years[11] 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 are 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-RCT[14] 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 approach[20] 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 eLearning 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 cessation[25] 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 NICE[28] 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 levels[32] 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. Therefore, in conjunction with 22 HCPs and 17 people living with COPD and their carers/family, we co-designed very brief behaviour change approach for HCPs to discuss PR referral with people with COPD, called VBA-PR. It includes a 30-minute eLearning training programme that educates referrers about PR e.g. referral criteria, what PR involves, benefits, local PR programme information and a framework to help referrers discuss PR with their COPD patients. However, it is not known whether VBA-PR is feasible to deliver or acceptable to HCPs and people living with COPD.

2 Aims

To investigate the feasibility of conducting a large-scale cluster-randomised controlled trial (CRT) of VBA-PR and explore the acceptability of VBA-PR amongst patients, their carers/family, and HCPs.

3 Objectives

Aim 1: To investigate the feasibility of conducting a large-scale CRT of VBA-PR

Objectives:

1. Identify the duration to set-up sites;
2. Investigate the feasibility of recruiting 50 HCPs and associated timeframe;
3. Estimate the cluster size for the full-scale trial (i.e. how many individual patients are assessed for each HCP over the three-month study period);
4. Investigate the feasibility of collecting data on intervention implementation (e-learning programme completion);
5. Investigate the feasibility of collecting referral and uptake data, the quality of data and associated timeframe;
6. Identify whether the primary outcome of the full-scale trial will be referral or uptake by using the information collected in objective 5 and Patient and Public Involvement (PPI) input;
7. Use data collected in objective 5 and 6 to inform the sample size calculation for the full-scale trial;
8. Evaluate intervention fidelity and intervention receipt against pre-specified intervention components;
9. Investigate the feasibility of collecting intervention development and intervention costs.

Aim 2: Explore the acceptability of VBA-PR amongst HCPs and patients, their carers/family

Objectives:

10. Explore the experiences of HCPs of the online training course e.g. acceptability, clinical utility, relevance, ease of use, modifications required;
11. Explore HCPs experiences of using VBA-PR during consultations with patients e.g. acceptability, ease of use, change in behaviour, patient reaction, modifications required;
12. Explore the experiences of patients and/or their carers/family, of the conversation about PR with their HCP e.g. experience and acceptability of the conversation, knowledge attainment, likelihood accepting a referral, modifications required;
13. Modify VBA-PR based on the focus group findings.

4 Methods

The Pragmatic Clinical Trials Unit will advise on: document storage, quality assurance; work with the team in developing the statistical analysis plan; contribute to the decision about progression to a main trial; provide statistical oversight and advice in analysis and interpretation of results, attend Trial Steering Committee and Independent Advisory Group meetings.

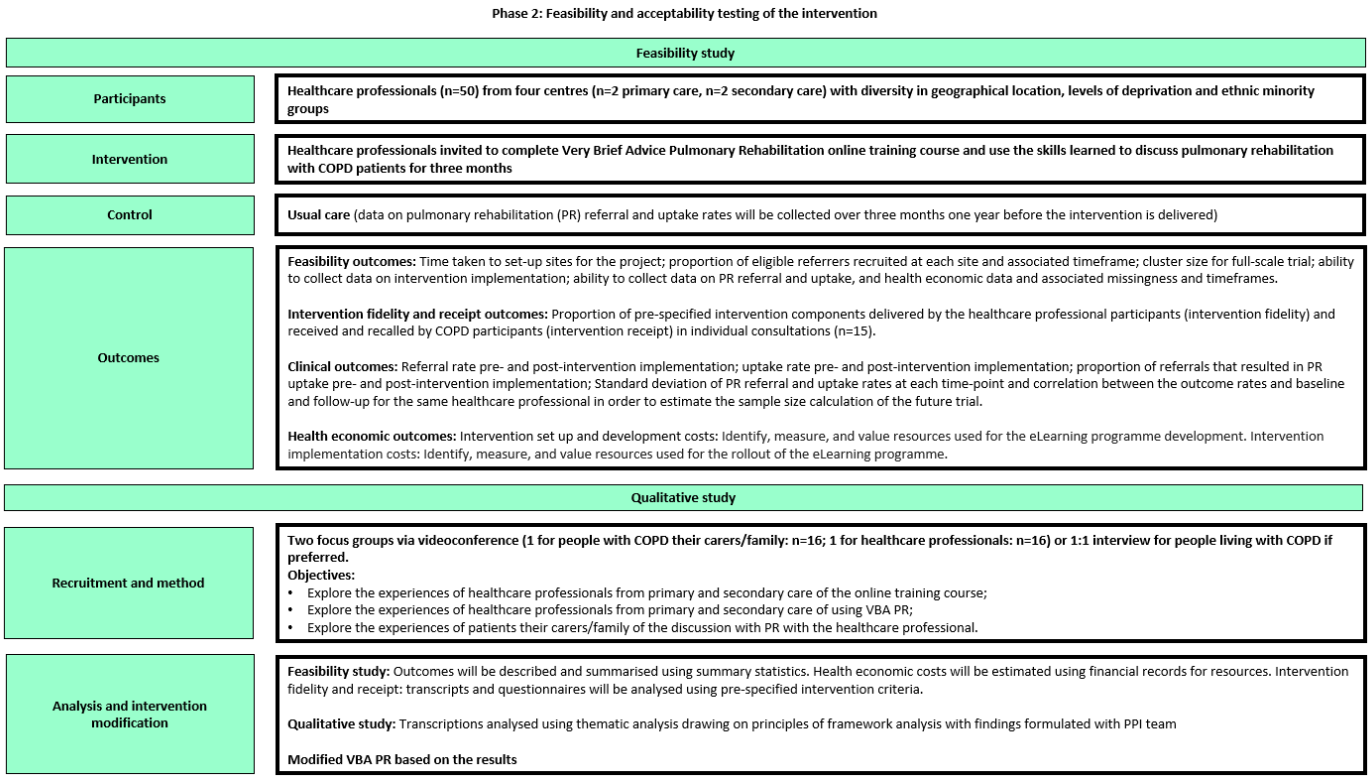
4.1 Study design:

Mixed-method, multicentre, non-randomised feasibility study.

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

- Part 1: Investigate the feasibility of conducting a large-scale CRT of VBA-PR.
- Part 2: Explore the acceptability of VBA-PR amongst HCPs and patients, their carers/family.

A study poster will be placed on a notice board in participating sites to inform service-users that the study is taking place (the advert is not for recruitment purposes). A QR code link and the study team email and telephone number will be on the advert where the service-users can find more information.



4.2 Figure 1: Study overview

Abbreviations: COPD: Chronic Obstructive Pulmonary Disease; PPI: Patient and Public Involvement; PR: Pulmonary Rehabilitation; VBA-PR: Very Brief Advice Pulmonary Rehabilitation.

5 Part 1: Feasibility of conducting a full-scale cluster RCT of VBA-PR

5.1 Participant eligibility criteria

Individual HCPs are the participants.

5.1.1 Inclusion criteria

1. Any HCP e.g. doctor, nurse, physiotherapist, pharmacist, paramedic who refers people living with COPD for PR;
2. Able to provide informed consent.

5.1.2 Exclusion criteria

- Cognitive impairment that would preclude taking part in an eLearning training programme.

5.2 Participant recruitment

Patient recruitment at a site will only commence once the study team has ensured that the following approval/ essential documents are in place:

- College of Health Medicine and Life Sciences Research Ethics Committee, Brunel University of London approval;
- Health Research Authority (HRA) approval;
- Local Site Delegation of Duties and Signature Log is completed (if applicable).

All participants who wish to enter the study will be fully screened and consented by the Chief Investigator, the researcher, someone else from the research team who is suitably qualified.

Participants (n=50) will be recruited from four sites (Hillingdon Hospital NHS Foundation Trust, Royal Cornwall Hospitals NHS Trust, Castle Mead Medical Centre (East Midlands Regional Research Delivery Network (RRDN)) and North West RRDN. The study team (TUFFNELL, NOLAN) will introduce the study to potential HCP participants at an online/in-person (depending on site preference) team meeting, with an opportunity for potential participants to ask questions. Subsequently, the study introduction letter will be shared by email with potential participants via gatekeepers (Hillingdon Hospital: Dr Samantha Kon, Royal Cornwall Hospitals NHS Trust: Dr Sarah Deacon, Castle Mead Medical Centre: Dr Ian Abraham, and Brownlow Group Practice: Dr Sarah Nosib). The introduction letter, which provides a brief overview of the study, will include a QR code and weblink to the online participant information sheet and screening form (screens for eligibility criteria). Interested individuals can read the participant information sheet and complete the screening form. Potential participants can contact the study team by email (chat_study@brunel.ac.uk) or telephone (07551 311641) if they have any questions about the study.

The study team will screen the online screening form for eligibility. Individuals who do not meet the eligibility criteria will be informed by email with an appropriate explanation. Information submitted in the online screening form will be deleted.

Individuals who do meet the eligibility criteria will be sent an email with a weblink to the online participant characteristics form (collects participant data e.g. profession, setting (e.g. primary care, secondary care), years' experience, sex, ethnicity) and a weblink to the online consent form.

5.2.1 Informed consent

Informed consent will be obtained using MS forms. All participants will provide consent.

Consent to enter this study will be obtained after a full account has been provided of its nature, purpose, risks, burdens and potential benefits, and the participant has had the opportunity to deliberate. The participant will be allowed to specify the time they wish to spend deliberating, usually up to 24 hours.

Periods shorter than 24 hours will be permitted if the participant feels that further deliberation will not lead to a change in their decision, and provided the person seeking consent is satisfied that the participant has fully retained, understood and deliberated on the information given.

Likewise, periods longer than 24 hours will be permitted should the participant request this. The Chief Investigator, the investigator or designee will explain that the participants are under no obligation to enter the study and that they can withdraw at any time during the study, without having to give a reason.

A copy of the signed consent form along with a copy of the participant information sheet will be given to the study participant. The original signed consent form will be retained at Brunel University in the study master file.

If new safety information results in significant changes to the risk–benefit assessment, the consent form will be reviewed and updated if necessary. All participants, including those undergoing the intervention, will be informed of the new information, given a copy of the revised consent form and asked to re-consent if they choose to continue in the study.

5.2.2 Discontinuation of the study / withdrawal from the study

Participants should be withdrawn from the study if the intervention is deemed unsafe. Should participants wish to withdraw from the study, no further interventions would be carried out on the participant under the study protocol and no new personal data would be collected. 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 voluntary withdrawal from the study will be documented. Participants who are withdrawn from the trial will not be replaced. If the Chief Investigator deems that there are obvious safety concerns the trial will be terminated prematurely.

5.2.3 Study procedure

5.2.4 Intervention: eLearning training programme and VBA-PR discussion framework

Once the participant completes the consent form, access details to the VBA-PR eLearning platform (including instructions on how to access the site and contact details to discuss any problems accessing the site) will be shared by email with the participant. The participant will be asked to complete the 30-minute eLearning programme within a one month period. The eLearning training programme includes education for referrers about PR e.g. referral criteria, what PR involves, benefits, local PR programme information and a framework to help referrers discuss PR with their COPD patients. It includes text-based information, videos, patient and HCP testimonials.

Participants will be required to complete a short knowledge and confidence based questionnaire before and after the eLearning course: this will be integrated into the eLearning platform and data will be collated by the NCSCT. The NCSCT will report on the number of people who register for the eLearning programme, the number who have started the eLearning programme and the number who have completed the eLearning programme. Data collected by the NCSCT will be stored on secure servers and securely transferred via email to the study team in a password protected Excel spreadsheet.

Participants will be encouraged to use what they learned from the programme when discussing PR with their COPD patients for the duration of the study (subsequent three months) during relevant healthcare consultations e.g. primary care consultations, secondary and tertiary care inpatient, outpatient and home-based consultations.

5.3 Intervention fidelity and receipt sub-study:

This sub-study relates to objective 8 and involves assessment of intervention fidelity and intervention receipt, that is the use of the VBA-PR referral discussion framework by the HCP when discussing PR with their patients. The consultation between 15 HCPs and 15 COPD patients will be audio-recorded to evaluate the referral discussion against pre-specified intervention components (intervention fidelity). The study team will complete a telephone questionnaire with 15 patient participants to evaluate the referral discussion recall against pre-specified intervention components (intervention receipt).

5.3.1 Recruitment

5.3.2 Healthcare professionals:

A sub-group of HCP participants (n=15) will be recruited from the 50 HCPs who consented to take part in the feasibility study and indicated their consent to take part in the intervention fidelity study (consent obtained in the consent form described in section "Informed consent" (pages 9-10)) will be invited to take part in this sub-study.

5.3.2.1 Inclusion/exclusion criteria

The eligibility criteria are outlined on page 8. If more than 15 individuals express an interest in taking part in the study, purposive sampling will ensure variation in setting (primary vs secondary care), profession (doctor vs nurse vs physiotherapist vs pharmacist vs paramedic). Individuals who do not meet the purposive sampling criteria will be informed by email with an appropriate explanation.

5.3.3 People living with COPD:

5.3.3.1 Inclusion criteria:

- Adult ≥18 years with a HCP-confirmed diagnosis of COPD as per GOLD criteria[43]
- Eligible for referral to PR in line with national quality standards[4],
- Able to provide informed consent.

5.3.3.2 Exclusion criteria:

- Cognitive impairment that precludes participation in a discussion about PR referral.

If a patient's first language is not English, interpreter support will be sought in line with individual NHS Trust policy.

Hillingdon Hospital and Royal Cornwall Hospital: Potential patient participants who meet the eligibility criteria will be identified by the HCP participant or research staff, by screening upcoming appointments manually, on electronic scheduling systems or via electronic database search(es). At least 24 hours before the consultation the research staff will share the participant invitation and information sheet (in-person, online, by post, text message or telephone according to patient participant preference), and will discuss the study with the patient (in-person, by telephone) and answer any questions the patient may have. If potential participants do not respond to initial attempted contact, they may be contacted again (up to two times). Carers and family members have been invited to attend the clinical consultation to support patient participants taking part in the study. Screening for eligibility criteria and informed consent will be obtained by the research staff (in-person,

online, by post or telephone, according to patient participant preference) as recorded in the Sponsor's Delegation of Responsibilities Log.

The patient participant can ask for the audio-recording to be deleted up to one month after the recording is made, by contacting the research staff or study team.

Primary care services: Castle Mead Medical Centre (East Midlands RRDN) and North West RRDN GP practice:

Potential patient participants who meet the eligibility criteria will be identified by the HCP participant or research staff, by screening upcoming appointments manually, on electronic scheduling systems or via electronic database search(es).The research staff or GCP-trained HCP will share the participant invitation and information sheet (in-person, online, by post, text messaging or telephone according to patient participant preference), discuss the study with the patient (in-person, by telephone according to patient participant preference), and answer any questions the patient may have. If potential participants do not respond to initial attempted contact, they may be contacted again (up to two times). Carers and family members have been invited to attend the clinical consultation to support patient participants taking part in the study. Screening for eligibility criteria and informed consent will be obtained by the research staff or GCP-trained HCP (in-person, online, by post or telephone according to patient participant preference) as recorded in the Sponsor's Delegation of Responsibilities Log.

The patient participant can ask for the audio-recording to be deleted up to one month after the recording is made, by contacting the research staff, GCP-trained HCP or study team.

5.3.4 Study procedure

5.3.4.1 Intervention fidelity

The study team will provide the HCP participant with a password protected digital audio-recording device and instructions on how to use it. The HCP participant will audio-record the consultation with this device. The HCP will give the research staff the recording device and the research staff will transfer the recording to the study team in line with the organisation's data protection and sharing rules (e.g. secure nhs.net to nhs.net email, secure data sharing platform, in-person collection by the study team – Hillingdon Hospital only (the research team can walk to Hillingdon Hospital to collect the audio-recorder). The research staff will then delete the recording from the audio-recorder. When not in use, the audio-recorder will be stored in a locked drawer in a locked office. The recording will be saved on the Brunel University of London server in the study team's user-restricted folder and will be transcribed using a professional transcription company's discourse transcription service. Carers and family members have been invited to attend the clinical consultation to support patient participants taking part in the study. If their voice has been recorded during the study process this will be

redacted prior to anonymisation. Once the transcript has been anonymised, the recording will be deleted. The anonymised transcript will be saved on the Brunel University of London server in the study team's user-restricted folder.

5.3.4.2 Intervention receipt

Following the consultation, the research staff will securely share the patient participant's contact details with the study team (e.g. secure nhs.net to nhs.net email address). This process will be explained in the participant information sheet and informed consent will be sought in the consent form. The study team will contact the patient participant, either via telephone or email based, on their preference, to arrange a convenient time to complete the telephone intervention receipt questionnaire (with flexibility dependent on patient participant availability, but no more than one month (time period suggested by PPI team) after the clinical consultation). Attempted contact will be made up to once fortnightly for one month (maximum of three attempts- frequency agreed by PPI team). Completed questionnaires will be anonymised and stored on the Brunel University of London server in the study team's user-restricted folder.

HCPs and patient participants will be offered a £25 shopping voucher as remuneration for their time.

5.4 Study assessments

5.4.1 Feasibility study:

Feasibility assessments:

- Time taken to set-up sites *(OBJECTIVE 1)* – data collected by the study team from the study set-up file;
- Proportion of eligible HCPs recruited per site and associated recruitment timeframes *(OBJECTIVE 2)* – data collected by the study team from the participant recruitment log;
- Proportion of recruited HCPs who complete the eLearning programme *(OBJECTIVE 4)* – data collected by the study team from the eLearning programme platform;
- PR referral data during the three-month data collection period, associated missingness and timeframes (*OBJECTIVE 5);*
    - Post-intervention implementation: Anonymised referral data during the three-month data collection period will be assessed as follows:
        - Hillingdon Hospital: Anonymised service audit data will be requested from Hillingdon Respiratory Team (link clinician Dr Samantha Kon, Consultant Chest Physician, Research and Development Director) by the study team.

- Royal Cornwall Hospitals NHS Trust: Anonymised data available through electronic patient records (link clinician Dr Sarah Deacon, Consultant Respiratory Physician) by the study team.
- Castle Mead Medical Centre (East Midlands RRDN): Anonymised clinical notes system search data will be requested from the research lead clinician (Dr Ian Abraham) by the research team.
- Brownlow Group Practice (North West RRDN): Anonymised service audit data to be requested from the research lead/ link clinician.
- Where necessary, data collection will be supported by research staff. Anonymised data will be transferred in a password protected file in line with the organisation's data protection and sharing rules e.g. secure nhs.net email to nhs.net email or secure data transfer platform to the Brunel University of London server (study team's user-restricted folder).

o Pre-intervention implementation: Anonymised referral data for the same three-month period in the previous year will be collected as follows:

- Hillingdon Hospital: Anonymised service audit data will be requested from Hillingdon Respiratory Team (link clinician Dr Samantha Kon, Consultant Chest Physician, Research and Development Director) by the study team.
- Royal Cornwall Hospitals NHS Trust: Anonymised service data will be requested from the Cornwall Integrated Respiratory Team (link clinician Dr Sarah Deacon, Consultant Respiratory Physician) by the study team.
- Castle Mead Medical Centre (East Midlands RRDN): Anonymised clinical notes system search data will be requested from the research lead clinician (Dr Ian Abraham) by the research team.
- Brownlow Groups Practice (North West RRDN): Anonymised service data available through electronic patient records (link clinician Dr Sarah Nosib, GP Research Lead).
- Where necessary, data collection will be supported by research staff. Anonymised data will be transferred in a password protected file in line with the organisation's data protection and sharing rules e.g. secure nhs.net email to nhs.net email or secure data transfer platform to the Brunel University of London server (study team's user-restricted folder).

- PR uptake rate pre- and post-intervention implementation (OBJECTVE 5 and 6).
    - Post-intervention implementation: Anonymised uptake data will be requested from the PR services that the recruitment sites refer to. There will be a delay between referral of a patient to a PR service and uptake of PR by the patient because of PR service waiting lists, which vary between services. It is anticipated that uptake data will be collected 3 to 6 months post-referral, depending on the service.
    - Pre-intervention implementation: Anonymised uptake data for the same data collection period in the previous year will be collected from the PR services that the recruitment sites refer to.
    - The recruitment site and associated PR sites are as follows:
        - Hillingdon Hospital NHS Foundation Trust: Harefield Pulmonary Rehabilitation Unit, Harefield Hospital, Guy's and St Thomas' NHS Foundation Trust. Service audit data will be requested from Harefield Pulmonary Rehabilitation Unit (link clinician Karen Ingram, Therapy Lead, Harefield Pulmonary Rehabilitation Department) by the study team.
        - Royal Cornwall Hospitals NHS Trust: Cornwall Health Partnership NHS Foundation Trust PR service. Service audit data will be requested from Cornwall Health Partnership NHS Foundation Trust PR service (link clinician Rachel Williams, Respiratory Consultant Physiotherapist) by the study team.
        - Castle Mead Medical Centre (East Midlands RRDN): Leicestershire Health Partners PR service. Service audit data will be requested from Leicestershire Health Partners Breathlessness Rehabilitation Service (link clinician Anna Kaye, Rehab Clinical Specialist Physiotherapist) by the study team.
        - Brownlow Group Practice. Service audit data will be requested from Liverpool Heart and Chest Hospital (link clinician Hannah Platt, Pulmonary Rehabilitation Team Lead).
        - Where necessary, data collection will be supported by research staff. Anonymised data will be transferred in a password protected file in line with the organisation's data protection and sharing rules e.g. secure nhs.net email to nhs.net email or secure data transfer platform to the Brunel University of London server (study team's user-restricted folder).

Intervention fidelity and intervention receipt assessment:

- Intervention fidelity: Proportion of pre-specified intervention components delivered per consultation (*OBJECTIVE 8*) will be audited by the study team by comparing the predetermined intervention components with the transcript of the audio-recorded consultation.

- Intervention receipt: Proportion of pre-specified intervention components recalled by patient participant following their consultation with the HCP (*OBJECTIVE 8*) will be audited by the study team by comparing the predetermined intervention components with what the patient remembers using a telephone-based intervention receipt questionnaire.

5.4.2 Clinical assessment:

- Number of patients with whom the HCPs discusses PR for one-month during the three-month data collection period and proportion of these discussions that resulted in a referral (OBJECTIVE 3). The one-month data collection period will be reflective of the healthcare professionals' normal clinical caseload.

- These anonymised data will be recorded by the HCP using an electronic data log provided by the study team. This log will be password protected and saved on the study site's server. None of this information will contain identifiable data about the HCP or their patients. The HCP will send the electronic data log to the study team in line with the data protection and sharing rules of your organisation e.g. secure nhs.net email to nhs.net email transfer, data sharing platform.

    - Number of COPD patients with whom the HCP has a consultation;

    - Number of COPD patients eligible for PR;

    - Number of eligible COPD patients with whom the HCP discusses PR;

    - Number of eligible COPD patients who agree to be referred for PR;

    - Number of eligible COPD patients who are referred for PR.

- PR referral rate pre- and post-intervention implementation (OBJECTIVE 5 and 6):

    - Post-intervention implementation: Anonymised referral data during the three-month data collection period will be assessed as follows:

        - Hillingdon Hospital: Service audit data will be requested from Hillingdon Respiratory Team (link clinician Dr Samantha Kon, Consultant Chest Physician, Research and Development Director) by the study team.

- Royal Cornwall Hospitals NHS Trust: Anonymised service data will be requested from the Cornwall Integrated Respiratory Team (link clinician Dr Sarah Deacon, Consultant Respiratory Physician) by the study team.
- Castle Mead Medical Centre (East Midlands RRDN): Anonymised clinical notes system (System One) search data will be requested from the research lead clinician (Dr Ian Abraham, GP Research Lead) by the study team.
- Brownlow Group Practice (North West RRDN): Anonymised service audit data available through research leads/ link clinician (Dr Sarah Nosib, GP Research Lead).
- Where necessary, data collection will be supported by research staff. Anonymised data will be transferred in a password protected file in line with the organisation's data protection and sharing rules e.g. secure nhs.net email to nhs.net email or secure data transfer platform to the Brunel University of London server (study team's user-restricted folder).

o Pre-intervention implementation: Anonymised referral data for the same three-month period in the previous year will be collected as follows:

- Hillingdon Hospital: Service audit data will be requested from Hillingdon Respiratory Team (link clinician Dr Samantha Kon, Consultant Chest Physician, Research and Development Director) by the study team.
- Royal Cornwall Hospitals NHS Trust: Anonymised service data will be requested from the Cornwall Integrated Respiratory Team (link clinician Dr Sarah Deacon, Consultant Respiratory Physician) by the study team.
- Castle Mead Medical Centre (East Midlands RRDN): Anonymised clinical notes system (System One) search data will be requested from the research lead clinician (Dr Ian Abraham, GP Research Lead) by the study team.
- Brownlow Group Practice (North West RRDN): Anonymised service audit data available through research leads/ link clinician (Dr Sarah Nosib, GP Research Lead) by the study team.
- Where necessary, data collection will be supported by research staff. Anonymised data will be transferred in a password protected file in line with the organisation's data protection and sharing rules e.g. secure nhs.net email to nhs.net email or secure data

transfer platform to the Brunel University of London server (study team's user-restricted folder).

- PR uptake rate pre- and post-intervention implementation (OBJECTVE 5 and 6).
    - Post-intervention implementation: Anonymised uptake data will be requested from the PR services that the recruitment sites refer to. There will be a delay between referral of a patient to a PR service and uptake of PR by the patient because of PR service waiting lists, which vary between services. It is anticipated that uptake data will be collected 3 to 6 months post-referral, depending on the service.
    - Pre-intervention implementation: Anonymised uptake data for the same data collection period in the previous year will be collected from the PR services that the recruitment sites refer to
    - The recruitment site and associated PR service are as follows:
        - Hillingdon Hospital NHS Foundation Trust: Harefield Pulmonary Rehabilitation Unit, Harefield Hospital, Guy's and St Thomas' NHS Foundation Trust. Service audit data will be requested from Harefield Pulmonary Rehabilitation Unit (Principle Investigator: Prof. Will Man, Consultant Respiratory Physician, Harefield Pulmonary Rehabilitation Department) by the study team.
        - Royal Cornwall Hospitals NHS Trust: Cornwall Health Partnership NHS Foundation Trust PR service. Service audit data will be requested from Cornwall Health Partnership NHS Foundation Trust PR service (Principle Investigator: Rachel Williams, Consultant Physiotherapist) by the study team.
        - Castle Mead Medical Centre (East Midlands RRDN): Leicestershire Partnership Trust PR service. Service audit data will be requested from Leicestershire Health Partners PR service (Principle Investigator: Anna Kaye, Rehab Clinical Specialist Physiotherapist, Breathlessness Rehabilitation Service).
        - Brownlow Group Practice (North West RRDN). Service audit data will be requested from Liverpool Heart and Chest Hospital (Principle Investigator: Hannah Platt, Pulmonary Rehabilitation Team Lead)
        - Where necessary, data collection will be supported by research staff. Anonymised data will be transferred in a password protected file in line with the organisation's data protection and sharing rules e.g. secure nhs.net email to nhs.net email or secure data

transfer platform to the Brunel University of London server (study team's user-restricted folder).

- Proportion of referrals that resulted in uptake pre- and post-intervention implementation (OBJECTIVE 5 and 6). Anonymised referral data will be collected from each study site and the uptake data will be collected from the associated PR service as described in the previous bullet points relating to OBJECITVES 5 and 6).

5.4.3 Health economic assessment:

- Intervention development costs *(OBJECTIVE 9)*: Identify, measure, and value resources used for the eLearning training programme development, including time spent by research staff, software, hardware, and other costs;

- Intervention implementation costs (*OBJECTIVE 9*): Identify, measure, and value resources used for the rollout of the eLearning training programme. This will cover HCPs' time spent completing the programme, time spent discussing PR with COPD patients, hosting costs, and costs associated with providing technical support.

For study objectives, outcome, data source and progression criteria see appendix 1.

5.5 Sample size

Feasibility study: For estimating parameters to inform a sample size calculation for a full-scale trial, methodologists recommend 24-70 participants[44] and feasibility studies typically arrive at a sample size of 30-50 after taking a number of practical considerations into account[45-46]. Therefore, 50 HCPs will be recruited.

Intervention fidelity and receipt sub-study: There is no specific guidance for sample size calculation for intervention fidelity studies. Therefore, based on published literature and the research team's experience of these studies, 15 HCP participants and 15 patient participants will be recruited.

5.6 Data analysis

Feasibility study: Outcomes will be described and summarized using summary statistics. Health economic costs will be estimated using financial records for resources such as software, hardware and hosting, and the

Unit Costs of Health and Social Care for time spent by HCPs and research staff. Additional data sources, such as surveys or platform analytics, may be used to supplement these estimates.

For intervention fidelity: The anonymised transcripts will undergo two rounds of analysis: 1) they be coded and compared to pre-specified intervention criteria using the treatment fidelity framework provided by the NIH's Behavioural Change Consortium[47]; 2) they will be coded in line with Braun and Clarke's Reflexive Thematic Analysis[48] to capture the themes and nuance of behaviour change present in the clinical conversations.

For intervention receipt: The anonymised questionnaires will be compared to pre-specified intervention criteria using the treatment fidelity framework provided by the NIH's Behavioural Change Consortium[47].

6 Part 2: Acceptability of VBA-PR

This study involves online focus groups or online/telephone interviews for HCPs and people living with COPD. There will be separate focus groups or interviews for both groups.

6.1 Healthcare professionals

6.1.1 Inclusion criteria

- HCP e.g. doctor, nurse, physiotherapist, pharmacist, paramedic who consented to participate in feasibility study;
- Able to provide informed consent.

6.1.2 Exclusion criteria

- Cognitive impairment that precludes participation in a focus group or interview.

6.1.3 Recruitment

Participants (n=16) will be recruited from the group of 50 HCPs who consented to take part in the feasibility study and indicated their consent to take part in an online focus group (consent obtained in the consent form described in section "Informed Consent" (pages 9-10). If more than 16 individuals express an interest in taking part in the study, purposive sampling will ensure variation in setting (primary vs secondary care), profession (doctor vs nurse vs physiotherapist vs pharmacist vs paramedic).

6.1.4 Study procedure

Online focus groups of 4-8 participants will be held on Microsoft Teams. If a participant is unable to attend a focus group, an interview will be held on Microsoft Teams. The focus group/interview will take place at the end

of the three-month data collection period to aid participant recall. An email will be sent to confirm the focus group/interview date and time, and to provide the Microsoft Teams link. A topic guide (the content of which is subject to change depending on information gleaned during the study and focus group/interview discussions) will be used to explore the experiences of HCPs of the online training course e.g. acceptability, clinical utility, relevance, ease of use, modifications required, and using VBA-PR during consultations with patients e.g. acceptability, ease of use, change in behaviour, patient reaction, modifications required.
The focus group should last 1-1.5 hours, with a comfort break offered half-way through the meeting. 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 focus groups will be audio-recorded and transcribed using the videoconference software. The transcripts will be anonymised and the recording deleted after this stage.

6.2 People living with COPD

6.2.1 Inclusion criteria:

- Adult ≥18 years with a health professional-confirmed diagnosis of COPD as per GOLD criteria[43] whose HCP discussed PR with them as part of the feasibility study;
- Able to provide informed consent.

6.2.2 Exclusion criteria:

- Cognitive impairment that precludes participation in a focus group/interview.

6.2.3 Recruitment

Patient participants (n=16) will be recruited as follows. During the feasibility phase of the study HCPs will offer their COPD patients with whom they discussed PR a study invitation letter. The letter will introduce the study to the individual and include a QR code and weblink which links to the online participant information sheet and screening form (screens for eligibility and purposive sampling criteria). The leaflet will also list the phone number and email address of the research team who can share the participant information sheet by post or email and answer any questions the potential participant may have. Interested individuals will read the participant information sheet and complete the screening form. This can be returned via the online form, email or post (a stamped-addressed envelope will be provided) to the study team.

The study team will screen for eligibility. If more than 16 individuals express an interest in taking part in the study, purposive sampling will ensure variation in setting (primary vs secondary care), ethnicity (white vs minoritized ethnicity), sex, socioeconomic deprivation (< vs ≥ 50th centile). Individuals who do not meet the

eligibility or purposive sampling criteria will be informed by email with a considerate explanation. Information collected in the screening form will be deleted.

Written informed consent (online form, by telephone) will be obtained as per the informed consent procedure outlined in section “Informed Consent” (pages 10-11).

The patient will be notified that they can withdraw from the study as outlined in section “Discontinuation of the study / withdrawal from the study” (page 10). Due to the nature of focus groups, it may not be possible to withdraw the data however all data will be fully anonymised and the recordings deleted at the earliest ability (after one month)

6.2.4 Study procedure

Online focus groups of 4-8 participants will be held on Microsoft Teams. If the participants preference is to attend an interview this may take place via Microsoft Teams or telephone, as requested by the participant. The focus group/interview will take place as close as is feasible to the participant’s consultation with their HCP to aid participant recall.

An email will be sent to confirm the focus group/interview date and time to provide the Microsoft Teams link or confirm the participant’s preferred telephone contact details. Potential patient participants will be advised that their informal carers or family can be involved in the focus group or interview, if the person wishes. Carers and family members will be invited to attend the focus groups/ interviews to support patient participants taking part in the study. If their voice has been recorded during the study process this will be redacted prior to anonymisation.

A topic guide (developed with the study PPI team but the content of which is subject to change depending on information gleaned during the study and focus group/interview discussions) will be used to explore the experiences of patients and/or their carers/family, of the conversation about PR with their HCP e.g. experience and acceptability of the conversation, knowledge attainment, likelihood accepting a referral, modifications required.

The focus group/interview should last 1-1.5 hours, with a comfort break offered half-way through the meeting. 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 focus groups/interviews 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 the recording deleted after this stage. The recordings (until deletion) and transcripts will be saved on Brunel University of London’s server in the study team’s user-restricted folder.

HCPs and patient participants will be offered a £25 shopping voucher as remuneration for their time.

6.3 Sample size

The estimated sample size is based on the predicted number of participants required to achieve sufficient information power to meet the study aim[37]. Based on previous experience of qualitative studies in respiratory research and the specifics of the proposed study we expect that 16 purposively sampled HCPs and 16 patients, their carers/family will be recruited.

6.4 Analysis

Anonymised transcripts will be imported into NVIVo (QSR International, Australia) to facilitate analysis which will be based on thematic analysis according to Braun and Clarke[48]. Two researchers will read the first four transcripts and code each one using an iterative process. They will independently define a preliminary coding framework which will be compared and reconciled where necessary. The remaining transcripts will be coded using an iterative process. The researchers will generate and review themes in order to agree content and key concepts before defining and naming themes. Steps will be taken to increase reflexivity and transparency of interpretation e.g. use of concurrent field notes, interviewer role, PPI data interpretation workshop.

7 Amendments and Progression to effectiveness trial

In line with published recommendations[49], we will use our a-priori Progression Criteria (see appendix) as guidelines to support decision-making regarding progression to a full trial.

Decision-making regarding progression to a full-scale trial will draw on mixed-method data, and discussions with key stakeholders including IAG, TSC and PPI teams. To ensure transparency, we will report against each progression outcome, and provide a statement of overall trial feasibility based on our findings.

Where required, a mixed-method matrix of qualitative and key quantitative data will be used to inform adaptation and/or optimisation of the intervention and the future trial design. Modifications to the intervention will be implemented using the APEASE decision criteria, to ensure the intervention is likely to be implemented and effective in clinical practice[50].

8 Management of study risks

This study is a non-clinical trial of an interventional medicinal product (non-CTIMP). The intervention (eLearning programme, framework to discuss PR with people living with COPD) does not involve any interventions or measurements that are likely to pose significant risk to the participants and/or service-users.

Feasibility study – intervention receipt sub-study: Breach of privacy

Patient participants will be provided with a one month period to withdraw consent for the recording of their consultation with their HCP to be used in the study. During this time they can contact the research staff / GCP-trained HCP or study team to withdraw from the study, following which the recording will be deleted. This is explained in the participant information sheet.

Feasibility study – intervention fidelity and receipt sub-study: Distress of participants

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 or telephone questionnaire, the researcher will first offer to pause, postpone or stop the activity and advise again that your participation is voluntary. In the case of severe distress, participants will be encouraged to share your feelings with their healthcare team. The researcher will offer to contact the healthcare team on the participant's behalf. We anticipate that distress caused by the research will be infrequent and not the research processes.

If patient participants become upset during the consultation with their HCP, the HCP will also offer to pause, postpone or stop the recording. The HCP will reiterate that taking part in the study activity is voluntary and offer to delete the recording. If the patient participant decides to take part they are still free to withdraw at any time without detriment or without having to give a reason. They can also ask for the audio-recording to be deleted up to one month after the recording is made, by contacting the research staff or study team. However, it will not be possible to extract the data if the transcript has been anonymised (one month after the original recording has taken place).

Acceptability study: Distress of participants

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, focus group/interview, 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.

Feasibility and acceptability study: Data protection during data transfer and storage

Please refer to 'Data protection' section.

9 Monitoring and Audits

The PCTU will conduct a risk assessment. An audit of the Trial Management File will be undertaken. This may be a self-assessment audit based on the results of the risk assessment.

10 Data protection

General

All data will be stored securely on Brunel University of London's SharePoint in line with Brunel Data management policies. A shared folder will enable access for the CI and the researcher – this will be user-restricted and password protected.

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.

All participants will be will be allocated a study ID (pseudonymised) with the code breaker stored separately in a password protected file.

Study data will be anonymised as soon as is reasonable e.g. interview transcripts will be anonymised one month after the interview recording. After study completion, the study data will be fully anonymised and securely archived for 10 years in line with Brunel guidance, after which the study data will be destroyed.

Feasibility study

The NCSCT will collect participant data (name, email address, study site) and store these in a password protected file on a secure server. Data will be collated on an excel spreadsheet and transferred to the study

team via email in a password protected file at regular intervals (weekly/ bi-weekly) during the study period. The NCSCT will retain this data for the study period, after which time the data will be destroyed.

The password protected anonymised electronic data log completed by the HCP participant as part of the feasibility study will be stored on the study site's server for the data collection period. The HCP will then send the data log to the study team in line with the study site's data protection and sharing rules e.g. secure nhs.net to nhs.net email, secure data protection platform.

Anonymised referral and uptake data will be sent to the to the study team from the study site or PR service in line with the study site's data protection and sharing rules e.g. secure nhs.net to nhs.net email, secure data protection platform. This file will be password-protected.

Feasibility study – intervention fidelity sub-study

The intervention fidelity consultation will be audio-recorded by the HCP participant using a password protected digital audio-recording device. The HCP will give the research staff the recording device who will transfer the recording to the study team in line with the organisation's data protection and sharing rules (e.g. secure nhs.net to nhs.net email, secure data sharing platform, in-person collection by the study team – Hillingdon Hospital only (the research team can walk to Hillingdon Hospital to collect the audio-recorder). The research staff will then delete the recording from the audio-recorder. When not in use, the audio-recorder will be stored in a locked drawer in a locked office. If appropriate, Microsoft Teams (audio only) can be used instead of the audio recording device, in line with individual Trust policy (data transfer of recording will the same procedure as the audio-recording device recording). The recording will be saved on the Brunel University of London server in the study team's user-restricted folder and will be transcribed using a professional transcription company. Once the transcript has been anonymised, the recording will be deleted. The anonymised transcript will be saved on the Brunel University of London server in the study team's user-restricted folder.

Feasibility study – intervention receipt sub-study

Following the consultation between the HCP and patient participant, the research staff will securely share the patient participant's contact details with the study team (e.g. secure nhs.net to nhs.net email address). This process will be explained in the participant information sheet and informed consent will be sought in the consent form. Following completion of the assessment by telephone, completed questionnaires will be anonymised and stored on the Brunel University of London server in the study team's user-restricted folder.

Feasibility study – intervention fidelity and receipt sub-studies and acceptability study:

Names, geographic and organisational identifiers in intervention fidelity assessment consultations, intervention receipt questionnaires and focus groups/interviews transcripts (acceptability study) will be anonymised and used with the code breaker stored separately in a password protected file. The recordings of the intervention fidelity assessment consultations and focus groups/interviews transcripts (acceptability study) will be deleted once the transcripts have been anonymised.

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

Participants who take part in a focus group will be required to provide written informed consent to commit to keeping the identifies of other participants and the focus group discussions confidential.

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

11 Data Management

11.1 Personal data

All data will be stored securely on Brunel University of London's SharePoint in line with Brunel Data management policies. A shared folder will enable access for the CI and Researcher – this will be user-restricted, and password protected. Study files will be maintained by Brunel University of London for 10 years. Personal identifiable information will be kept for the study period (1 year). If participants consent to receiving updates on the study results, contact details will be stored for two years.

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 be deleted once the participant has been informed of their ineligibility.

All participants will be allocated a study ID (pseudonymised) with the code breaker stored separately in a password protected file.

The password protected anonymised electronic data log completed by the healthcare professional participant as part of the feasibility study will be stored on the study site's server for the collection period. The healthcare professional will then send the data log to the study team in line with the study site's data protection and sharing rules e.g. secure nhs.net to nhs.net email, secure data protection platform.

Anonymised referral and uptake data will be sent to the to the study team from the study site or pulmonary rehab service in line with the study site's data protection and sharing rules e.g. secure nhs.net to nhs.net email, secure data protection platform. This file will be password-protected.

11.2 Audio recordings and transcripts

The intervention fidelity consultation will be audio-recorded by the healthcare professional participant using a password protected digital audio recording device. If appropriate, Microsoft Teams (audio only) can be used instead of the audio recording device, in line with individual Trust policy. The healthcare professional will give the research staff/ research clinician (as per delegation log) the recording device who will transfer the recording to the study team in line with the organisation's data protection and sharing rules (e.g. secure nhs.net to nhs.net email, secure data sharing platform, in-person collection by the study team – Hillingdon Hospital only (the research team can walk to Hillingdon Hospital to collect the audio-recorder). The research staff/ healthcare professional will then delete the recording from the audio-recorder. When not in use, the audio-recorder will be stored in a locked drawer in a locked office. The recording will be saved on the Brunel University of London server in the study team's user-restricted folder and will be transcribed using a professional transcription company (TypeOut). Once the transcript has been anonymised, the recording will be deleted. The anonymised transcript will be saved on the Brunel University of London server in the study team's user-restricted folder.

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

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

11.3 Access to Data

Names, geographic and organisational identifiers in intervention fidelity assessment consultations, intervention receipt questionnaires and focus groups/interviews transcripts (acceptability study) will be anonymised and used with the code breaker stored separately in a password protected file. The recordings of the intervention fidelity assessment consultations and focus groups/interviews transcripts (acceptability study) will be deleted once the transcripts have been anonymised.

Intervention fidelity sub-study: Following the consultation between the healthcare professional and the consented patient participant, the research staff/ healthcare professional will securely share the patient participant's contact details with the study team (e.g. secure nhs.net to nhs.net email address). This process will be explained in the participant information sheet and informed consent will be sought in the consent form. Following completion of the assessment by telephone, completed questionnaires will be anonymised and stored on the Brunel University of London server in the study team's user-restricted folder.

11.4 Archiving

Paper consent forms (patient participants) will be stored in a locked cabinet, in a locked room at the study site during the study period. When study sites close at the end of the study period, paper consent forms will be archived electronically.

Electronic study files will be archived and maintained by Brunel University of London for 10 years after the study completion. They will then be deleted, as per Brunel's policy.

12 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. TUFFNELL will be PPI lead with responsibility for leading, managing, supporting and evaluating the PPI elements of the project, with support from NOLAN/ KILBRIDE. Halle Johnston, Patient and Public Involvement and Engagement Manager, NIHR School for Primary Care Research, University of Bristol will provide mentorship to NOLAN.

The PPI team will attend formal PPI meetings bi-annually (chaired by TUFNELL), trial steering committee meetings and data interpretation workshops. In preparation for ethical approval being sought, the study protocol has been further reviewed in collaboration with the PPI team and they have reviewed all patient-facing information. In conjunction with the research team, the PPI team have been involved in the topic guide development will be involved in developing emerging themes from the focus groups/interviews (acceptability study). The researchers and PPI team will also plan and implement the dissemination strategy.

To evaluate PPI involvement in the project, TUFFNELL will keep a formal log to assess ongoing impact and a qualitative researcher from Brunel University of London 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.

13 Committees involved in the study

Patient and Public Involvement Team: This group will consist of two patient representatives (SIVASUBRAMANIAM, NEWMAN-HUNT), NOLAN/ KILBRIDE and TUFFNELL. The PPI team will attend formal PPI meetings bi-annually (chaired by TUFFNELL), trial steering committee meetings and data interpretation workshops.

Study Management Group: This group will consist of NOLAN/ KILBRIDE and TUFFNELL, and will meet bi-weekly.

Trial Steering Committee: This group will consist of a chair, STEED, MAN, TAYLOR, representatives from PCTU, NOLAN, KILBRIDE, NORRIS, TUFFNELL, and will meet quarterly and ad hoc as required to discuss progress and resolve issues.

Independent Advisory Group: This group will consist of an independent chair (Prof Michael Steiner, Consultant Respiratory Physician), independent academic (Dr Elaine Bevan-Smith, primary care nurse), STEED, MAN, TAYLOR, representatives from PCTU and National Centre for Smoking Cessation, NHS collaborators, PPI team, TUFFNELL, KILBRIDE, NORRIS and NOLAN. It will meet bi-annually and ad hoc as required to discuss progress and resolve issues.

14 End of study definition

The end of the study will be the date the last data collection and follow up monitoring has taken place. After the study end point data analysis may continue however no new data will be collected.

When the study ends the research team will notify the North West – Greater Manchester Research Ethics Committee (REC) within 90 days of the study ending using the appropriate form. A final report to the REC will be submitted within 12 months of the end of the study.

Where indicated, the participants will be contacted at the end of study and thanked for their contributions and told what it helped the researchers find out.

15 Publication and dissemination

15.1 Open science 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 (open access website) before starting the project;
- Publish main manuscript in an open-access journal;
- Publish anonymised data, anonymised intervention fidelity assessment and focus group/interview transcripts on Figshare (open access website) with consent of participants (described in the participant information sheet with consent sought in the consent form), following publication of the main manuscript.

15.2 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 HCP 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.

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17 Appendices

CHAT 2 objectives, outcome, data source and progression criteria

Objective	Feasibility outcome	Contributing data and data source	Progression criteria		
			Green	Amber	Red
Part 1: Investigate the feasibility of conducting a full-scale cluster-RCT of VBA-PR					
1. Identify the duration to set-up sites	Time taken to set-up each study site	Study set-up file (data collected by the study team)	<3 months	3-6 months	>6 months
2. Investigate the feasibility of recruiting 50 healthcare professionals (HCP) and associated timeframe	Proportion of eligible HCP recruited per site and associated timeframe and reasons for non-participation	Screening data recorded in screening log Recruitment data recorded in the participant recruitment log (data collected by the study team)	⩾20% screened eligible ⩾60% eligible recruited	19–10% 59–40%	<10% <40%
3. Estimate the cluster size for the full-scale trial (i.e. how many individual patients are assessed for each HCP)	Number of individual patients assessed by each HCP	Electronic data log (data collected by each HCP participant)	NA	NA	NA

4. Investigate the feasibility of collecting data on intervention implementation (eLearning programme completion)	Proportion of recruited HCPs who complete the eLearning programme	eLearning programme platform	⩾60% recruited complete the programme eligible	40 to 59% recruited complete the programme eligible	<40% recruited complete the programme eligible
5. Investigate the feasibility of collecting referral and uptake data, the quality of data and associated timeframe	Post-intervention implementation: Number of referrals sent by each site during the three-month data collection period	Service audit data from each site (routine clinical data collected by HCPs)	NA	NA	NA
	Pre-intervention implementation: Number of referrals sent by each site during the same three-month period in the previous year	Service audit data from each site (routine clinical data collected by HCPs)	NA	NA	NA
	Post-intervention: Number patients who attend PR assessment following referral from each site (3-6 months depending on PR service waiting list)	Service audit data from each site (routine clinical data collected by HCPs)	NA	NA	NA
			NA	NA	NA

	Pre-intervention: Number patients who attend PR assessment following referral (same data collection period as post-intervention but in the previous 12 months) Timeframe to collect data Proportion of missing data	Service audit data from each site (routine clinical data collected by HCPs) Study database (data collected by study team) Service audit data from each site (routine clinical data collected by HCPs)	<3 months (following the data collection period) Missing data of ⩽10% for each measure	3-6 months (following the data collection period) 11–25%	>6 months (following the data collection period) >25%
6. Identify whether the primary outcome of the full-scale trial will be referral or uptake by using the information collected in objective 5 and Patient and Public Involvement (PPI) input	Acceptability of outcome measures to PPI group and study team Proportion of missing referral and uptake data	PPI workshop and IAG Service audit data from each site (routine clinical data collected by HCPs)	Participant-reported acceptability Missing data of ⩽10% for each measure	Some 11–25%	None >25%
7. Use data collected in objective 5 and 6 to inform the sample size calculation for the full-scale trial	Refer to objectives 5 and 6	Refer to objectives 5 and 6	NA	NA	NA

8. Evaluate intervention fidelity and intervention receipt against pre-specified intervention components	Fidelity: Proportion of pre-specified intervention components delivered per consultation Receipt: Proportion of pre-specified intervention components recalled by patient participant following their consultation with the HCP	Fidelity assessment (audio-recording collected by HCP participant and data analysed by study team using checklist) Receipt assessment (data obtained by study team using checklist during phone call with patient participant)	⩾80% of pre-specified components implemented ⩾80% of pre-specified components recalled	79-50% 79-50%	<50% 79-50%
9. Investigate the feasibility of collecting intervention development and intervention costs	Intervention development costs: Identify, measure, and value resources used for the eLearning programme development Intervention implementation costs: Identify, measure, and value resources used for the rollout of the eLearning programme Proportion of missing data	Intervention development log (data collected by CN) Intervention implementation log (data collected by CN and NCSCT) Intervention development and implementation logs	NA NA Missing data of ⩽10% for each measure	NA NA 11–25%	NA NA >25%

Part 2: Explore the acceptability of VBA-PR amongst HCPs and patients, their carers/family					
10. Explore the experiences of HCPs of the eLearning course e.g. acceptability, clinical utility, relevance, ease of use, modifications required	Acceptability of the intervention to HCP participants	Recordings of HCP participant focus groups/interviews (data collected by study team)	Reported as acceptable (or can be with minimal modification)	Reported as acceptable with modification	Intervention not acceptable
11. Explore HCPs experiences of using VBA-PR during consultations with patients e.g. acceptability, ease of use, change in behaviour, patient reaction, modifications required	Acceptability of VBA-PR to HCP participants	Recordings of HCP participant focus groups/interviews (data collected by study team)	Reported as acceptable (or can be with minimal modification)	Reported as acceptable with modification	VBA-PR not acceptable
12. Explore the experiences of patients and/or their carers/family, of the conversation about PR with their HCP e.g. experience and acceptability of the conversation,	Acceptability of PR referral discussion to patient participants	Recordings of patient participant focus groups/interviews (data collected by study team)	Reported as acceptable (or can be with minimal modification)	Reported as acceptable with modification	PR referral discussion not acceptable

knowledge attainment, likelihood accepting a referral, modifications required					
13. Modify VBA-PR based on the focus group findings	Refer to objectives 10-12	Refer to objectives 10-12	NA	NA	NA

Traffic-light progression criteria (Avery et al BMJ Open 2017) as follows. Green: likely no concerning issues; amber: potentially remediable issues; red: potentially intractable issues.