Shared medical appointments (SMA) in primary care for improving self-management of Chronic Obstructive Pulmonary Disease (COPD) amongst underserved groups: feasibility randomised control trial in North East and North Cumbria (NENC)

Feasibility RCT: SMAs for COPD in primary care

This protocol has regard for the HRA guidance and order of content

Version 2 27 Mar 2023

FUNDER RESEARCH REFERENCE NUMBERS: NIHR203548

Study start date: 12.09.2022

End date: 11.09.25

Duration: 36 months

PROTOCOL VERSION V2 27.03.23

RESEARCH REFERENCE NUMBERS

HOST ORGANISATION: NHS Commissioning Board - NHS North of England CSU

NECS Reference Number: 7819

SPONSOR: The University of Newcastle Upon Tyne

SPONSOR Number: NU008967

NHS REC Reference Number: 23/NS/0022

IRAS number: 315909

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the Good Clinical Practice guidelines, the Sponsor's (and any other relevant) Standard Operating Procedures, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Signature: Date:
..../...../.....

Name (please print):

Kay Howes

Position:
.....

Chief Investigator(s):

Signature: Date:
..../...../.....

Name: (please print):

Fiona Graham

Position: Research Associate

Signature: Date:
..../...../.....

Name: (please print):

Eileen Kaner.

Position: Professor of Public Health and Primary care

KEY TRIAL CONTACTS

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i. i. LIST of CONTENTS

Contents

ii. LIST OF ABBREVIATIONS

AE	Adverse Event
CI	Chief Investigator
COPD	Chronic Obstructive Pulmonary Disease
CRF	Case Report Form
CRN	Clinical Research Network
DE	Deep End
DMC	Data Monitoring Committee
ICF	Informed Consent Form
IMD	Index of Multiple Deprivation
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
NENC	North East North Cumbria
NHS R&D	National Health Service Research & Development
PCN	Primary Care Network
PCUQ	Patient Care Use Questionnaire
PI	Principal Investigator
PPI	Patient Public Involvement
PIS	Participant Information Sheet
PMG	Project Management Group
QA	Quality Assurance
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SSI	Site Specific Information
SUSAE	Suspected Unexpected Serious Adverse Event
TMF	Trial Management File
TMG	Trial Management Group
TSC	Trial Steering Committee

iii. TRIAL SUMMARY

Trial Title	Shared medical appointments (SMA) in primary care for improving self-management of Chronic Obstructive Pulmonary Disease (COPD) amongst underserved groups: feasibility randomised control trial in North East and North Cumbria (NENC)
Internal ref. no. (or short title)	SMAs for COPD in primary care
Trial Design	Feasibility randomised controlled trial with mixed-methods evaluation
Trial Participants	Interventionists: Staff involved in the organisation and delivery of COPD care in primary care practices in North East and North Cumbrian region of England. Patients: Adults aged 18 years or older with a diagnosis of COPD undergoing management in general practice.
Planned Sample Size	132 patients with COPD
Treatment duration	Attend one 90 minute SMA
Follow up duration	6 months (3 months post intervention) 12 month (9 months post intervention)
Planned Trial Period	3 years, Sept 2022 -Sept 2025
	Objectives
Primary objectives	1. To measure the feasibility of study processes i.e. • Recruitment rates • patient adherence rate • retention rates at 12 months • completion rates of questionnaires and proformas, (including those to collect economic data)
Secondary objectives	2. To rehearse data collection methods for future trial: Completion of questionnaires by post, telephone or using online form: – Patient knowledge, skills, and confidence for self-management measured by Patient Activation Measures – (PAM) (13 questions) – Anxiety and depression measured by Hospital Anxiety and Depression Scale (HADS) (14 questions) – Quality of Life, used to estimate quality adjusted life years, measured by (EQ-5D-5L) (6 questions)

	Healthcare service use captured from GP records (by screening logs, patient case report form at 12 months) and patient questionnaires measuring number of: – hospital admissions, – emergency department visits, – primary care (e.g. GP) appointments, – referrals and completion (yes/no) of pulmonary rehabilitation – referrals and completion (yes/no) of smoking cessation services) – patients that stop smoking – rescue packs prescribed (antibiotics and steroid use) Other economic outcomes measured will include: – Intervention site resource use – Patient time and travel (or IT internet) costs 3. Explore the feasibility and acceptability of study processes and SMAs for COPD with patients and general practice staff (interventionists).
Intervention, Dose, Delivery	Shared medical appointment delivered by community-based pharmacist/ practice nurse, social prescriber (facilitator) healthcare assistant / research team equivalent (note-taker and time keeper). Delivered either in practices face-to-face or by teleconference.
Number of study sites	8 primary care practices (TBC)

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
NIHR Research for Patient Benefit	£239,377.00
NIHR Clinical Research Network pump priming funds	£2667.60
NIHR Applied Research Collaboration North East North Cumbria	Financial to cover costs of translation if required.
NIHR Applied Research Collaboration North East and North Cumbria	Financial to cover the costs of EK, LV, JW, OMcG
NIHR Policy Research Unit Behavioural Science	Financial to cover the costs of FG, AOD, SE time to develop and apply for NIHR RfPB. SE funded from RfPB grant.

v. ROLE OF TRIAL SPONSOR AND FUNDER

Newcastle university (trial sponsor) and NIHR (trial funder) will not have any role in the trial design, conduct, data analysis and interpretation, manuscript writing, or dissemination of results.
The sponsor and funder will not decide whether a future definitive trial is warranted on the basis of the findings of this study. This is the responsibility of the trial steering committee (TSC).

vi. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

(See Appendix 1)

vii. Protocol contributors

Helen Riding- Research manager in host organisation, NECS. Responsible for allocating funds, collaboration agreements and issuing honorary contract for FG. Study design, recruitment of primary care networks (PCN), project management group, dissemination of reports to local stakeholders including clinical commissioners

Andrew Sturrock- Academic pharmacist and Associate Professor of Public Health and Primary Care, Northumbria University. Responsible for providing clinical expertise of COPD management in primary

care, patient safety, qualitative research, recruitment, project management group, reporting, dissemination via local, national and international pharmacy networks.

Stuart Edwards- Public and COPD patient perspective on all aspects of research process. Recruitment of and support for patient public representatives from NENC, PPI activities and data collection and evaluation. Project management group. Study design, analyses, reporting and dissemination.

Jonathan Coates- General practitioner in Deep End (DE) Practice and research fellow. Lead clinician responsible for providing expertise in COPD management in primary care and ensuring good quality clinical care and raising and handling medical safety issues. Will provide expertise on the set up and delivery of COPD SMAs in practice. Will support site recruitment via NENC DE GP network. Project management group, clinical expertise, medical safety issues, SMA implementation trainer, reporting, dissemination.

Karen Marshall- Respiratory nurse consultant at The Newcastle Upon Tyne Hospitals NHS Foundation Trust. Clinical expertise in COPD self-management. Experienced COPD researcher including earlier SMA COPD work and RCTs involving healthcare professionals. SMA implementation trainer. Project management group, analysis, reporting, dissemination.

Luke Vale- Professor of Health Economics, Newcastle University. Theme lead for ‘Enabling Methodologies’ within the NIHR ARC NENC. Co-applicant Behavioural Science PRU. Provides health economics expertise. Project management group, supervision of the health economics will co-ordinate support for the statistical analysis.

Oonagh McGee- NIHR Applied Research Collaboration NENC, Chief Operating Officer. PPI lead, design and implementation and evaluation of PPI strategy, mentor public co-applicant, project management group, dissemination to national policy makers.

Josephine Wildman- Research Fellow at Newcastle University. NIHR Applied Research Collaboration NENC. Health Inequalities and Marginalised Communities expertise. Protocol development, project management group, recruitment of Deep End practices through work with Deep End General Practice network, interpretation and reporting of results examining implications for health inequalities, dissemination via local and national DE primary care networks.

Mei Yee Tang- Lecturer in Health Psychology at Newcastle University. Health Psychology and SMA expertise. Member of project management group, contribution to qualitative data collection, analysis, reporting, dissemination via health psychology networks.

Amy O’Donnell-Senior Lecturer in Public Health at Newcastle University. NIHR PRU in Behavioural Science, NENC ICS Mental Health and Substance Use. Mixed methods research and implementation science expertise. Design and delivery of behavioural interventions in primary care, including use of digital technology and social prescribing. Project management group, study protocol, oversight of qualitative data analysis and data integration, contribution to reporting, dissemination via NENC ICS networks.

Theophile Bigirumurame- Research Fellow at Newcastle University. NIHR Applied Research Collaboration NENC. Enabling methodologies. Protocol development, support with statistical analysis and reporting of quantitative data.

viii. PPI involvement in protocol development

Our public co-applicant has been actively involved in the development of this protocol and together with the PPI lead and CI have conducted various PPI activities detailed in Section 13.

ix. KEY WORDS:	Shared medical appointments, Chronic Obstructive Pulmonary Disease, feasibility trial, self-management, Primary care

1 BACKGROUND

What is the problem being addressed?

The prevalence of COPD in the NENC region is 51% higher than the rest of England, affecting over 88,000 people (1). Incidence and mortality are highest in low-income and educationally deprived communities in both urban and rural areas (2). These groups are often older and have co-morbidities, including anxiety and depression (3). Breathlessness is the main symptom of COPD which can be difficult for patients to understand and control (4). Fear and panic can lead to over-reliance on medications, over-monitoring of symptoms and inappropriate presentation at emergency services(4,5). COPD exacerbations are the second biggest cause of unplanned hospital admissions in the UK (6), incurring estimated costs of £1.5 billion (2011) (7). Avoiding emergency hospital admissions and improving patient quality of life are key NHS and health policy priorities (2,8). Self-management planning is core to COPD care and involves supporting patients to monitor and manage their symptoms and take appropriate action when symptoms worsen (8,9).Primary care clinicians support self-management during annual review appointments in general practice(9). However, there is variation in quality and how these appointments are operationalised (10,11) with patients citing insufficient time to cover their psychological and emotional needs (12,13). To release clinician time to care, the Primary Care Foundation-NHS Alliance has promoted Shared Medical Appointments (SMAs) (14). This new type of consultation is where a group of patients (between 6-12) with the same long-term health condition meet with their healthcare professional(s) for a longer appointment (around 60-90 minutes). However, the effectiveness, cost-effectiveness and acceptability of these appointments for COPD are not yet known.

Why is this research important?

Improved self-management can delay disease progression, prevent exacerbations, reduce avoidable hospital admissions and improve patient quality of life (15). Self-management interventions that cover physical activity and mental health, such as pulmonary rehabilitation have been successful(15). However, not all patients are offered such programmes (2) and often patients do not attend, citing reasons such as being too ill or unclear about what is involved (PPI work, COPD patient, Newcastle).

SMAs have the potential to enhance the quality of self-management in primary care and better support patients to tell the difference between an exacerbation and day-today symptom variation. The group setting may overcome feelings of isolation, enable patients to share experiences and management strategies, meet realistic role models and spend more time with their healthcare provider so they feel more supported(16). SMAs hold particular promise for those with low levels of health literacy to learn 'vicariously' and gain peer support(17).

The importance of home-based self-management has been enhanced by the COVID-19 pandemic as capacity for in-person appointments has reduced. Practitioner training has been offered to support the delivery of SMAs by video-link (VSMAs) (18) yet uptake and barriers and facilitators to implementation and acceptability are under-researched. Like remote one: one appointments, VSMAs offer potential advantages such as improved access by sparing the cost and inconvenience of travel (19) (the costs of primary care are not covered by the Healthcare Travel Costs Scheme). They also are inclusive of those who remain hesitant about mixing in publish or shielding from Covid. SMAs may provide additional immediate benefits such as connecting patients with others in their community, helping to overcome feelings of isolation that have been exacerbated by lockdown measures (PPI work, COPD patient, Newcastle). However, VSMAs may pose challenges, in terms of digital exclusion and for those with low levels of digital and health literacy. Confidentiality concerns were raised by our PPI panel in relation to finding private space at home to connect. Recent research found that most patients and staff expressed largely positive experiences with this new model of care during COVID-19 restrictions.(20) Additional work was needed to support caring relationships at a distance, enable IT and online facilitation skills, align with remote care practices in the crisis context, and take account of digital inclusion(20). Digital services to support respiratory illness in general practice are a key component of NHS plans (2), it is therefore important to establish how VSMAs compare to SMAs delivered in-person (PSMAs) and usual care in terms of effectiveness, cost-effectiveness and acceptability. This research will inform the current use and roll-out of either form of SMAs for COPD in general practice, thus has the potential to benefit patients and reduce demand on healthcare services nationally within the next 5 years.

2 RATIONALE

Review of existing evidence – How does the existing literature support this proposal?
There is promising evidence that SMAs are effective in improving health outcomes for patients with other conditions such as diabetes (21), though evidence for COPD is scarce. Our systematic review (22) found that most studies were conducted in the USA and Australia, with only one randomised control trial (RCT) of SMAs in the UK for osteoporosis(23). Prior to the pandemic, some practices in the region were delivering COPD care by SMAs, though evaluation of these is limited. Further research in the UK context for COPD is therefore warranted. Our qualitative review found patient experiences of SMAs were positive, with patient-reported benefits including peer support and reassurance, improved motivation for self-care, and enjoyment of the relaxed informal atmosphere(24). This was echoed in our PPI work; 'I enjoyed the session, particularly being able to hear answers to questions I had not thought to ask' (NE COPD patient with positive SMA experience). However, our review and fieldwork found that some patients dislike the group format sharing concerns over poor group management and reluctance to share private information in a group setting (24,25). Most evidence concerns SMAs delivered in person, we found only one study of VSMAs (26). We

polled 173 people with COPD as part of our PPI work; 45 expressed interest in PSMAs, 31 expressed interest in VSMAs and 57 needed more information to decide (27). Free text fields captured respondent views about SMAs. Respondents expressed frustration with telephone consultations and welcomed in-person appointments, including PSMAs, though would attend VSMAs if pandemic restrictions persisted to inform policies and resource provisions appropriately.

2.1 Assessment and management of risk

Overall, this intervention (care delivery model) is of minimal risk to patients' wellbeing and or care. (A future definitive trial would categorised as Type A= no higher than the risk of standard medical care).

There is a slightly greater risk of confidentiality breach for those attending SMA/VSMAs compared with usual one-to-one care. This is minimised through the requirement to agree on the study participant consent form not to share information divulged in the group setting with others beyond the group, and to only share personal information with others in the group that they feel comfortable with. To minimise confidentiality breaches in video SMAs, clinicians and facilitators will deliver the SMAs from a private room. Participants will also be strongly encouraged to join from private room and use headphones where possible. Video conferencing calls will be accessible only via a private link sent directly to patients, these links will be password protected.

With regards resources required by practices (and patients), the set-up and delivery of the appointments will require additional administrative tasks for participating practices (such as identifying patients, obtaining consent to be contacted, inviting patients to attend the SMA) and additional training for staff within the primary care networks to attend in preparation for delivering the SMAs in-person and online.

FG has conducted a project management risk assessment (see project work tracker in Team here).

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

This study aims to establish the feasibility and acceptability of conducting a RCT that compares the use of SMAs delivered in-person (PSMAs) or by video-link (VSMA) with usual care with regards to improving self-management of COPD amongst patients living in under-served communities in NENC.

3.1 Primary objective

- To assess whether a definitive RCT is justified and feasible by measuring recruitment and retention rates, including differential questionnaire completion rates and attrition rates per study arm.

3.2 Secondary objectives

- To explore acceptability of intervention and study processes via qualitative interview work with patients who participate in the study (including those that were invited to but did not attend an SMA).
- To assess participant burden via measuring engagement with SMAs and completeness of outcome measures in patients (and via qualitative exploration).

- To explore feasibility of study procedures via qualitative interview work with patients and interventionists (practice staff) to identify barriers and facilitators to implementation
- To rehearse data collection methods for an economic evaluation of SMAs to develop and refine methods for a subsequent definitive trial exploring whether an additional approach to measuring economic outcomes adds value.
- To apply 'stop-go' criteria to key parameters derived from this study to inform the decision regarding a future definitive RCT. (Identify key characteristics of a definitive trial, and if appropriate, produce a protocol for a definitive RCT including criteria for clinical and cost-effectiveness)

3.3 Outcome measures/endpoints

3.4 Primary outcome

The primary outcomes of this feasibility trial will be:

- Recruitment rates (proportion of patients that are invited to participate that participate in the study during the recruitment window)
- patient response and retention rates at 12 months (9 months post intervention) i.e. the proportion of patients that remain in the study and return and complete questionnaires at 12 months)
- completion rates of questionnaires and proformas, (including those to collect economic data) acceptability and feasibility of SMAs and study processes: willingness to enter the trial, the acceptability of the study design, attendance at the SMAs and acceptability of PAM questionnaire as the proposed outcome measure).

3.5 Exploratory outcomes (qualitative work)

- Patient and interventionist views and experiences of SMAs and study processes

3.6 Table of endpoints/outcomes

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
1. To assess whether a definitive RCT is justified and feasible by measuring recruitment and retention rates, including differential attrition rates and response rate questionnaire per study arm.	Recruitment rates Retention/attrition rates at 12 months Questionnaire response rates	End of recruitment period 12 months (9 months post intervention)
2. To explore acceptability of intervention and study processes via qualitative	Patient experiences/views	Post intervention

interview work with patients who participate in the study.		
3. To assess participant burden via measuring engagement with SMAs and completeness of outcome measures in patients (and via qualitative exploration).	SMA attendance PAM, HADS, EQ-5D-5L questionnaires response and completion rates	During intervention Baseline, 6 months (3 months post intervention), 12 months (9 months post intervention)
4. To explore feasibility of study procedures via qualitative interview work with interventionists (general practice staff) and identify barriers and facilitators to implementation	Explore fidelity and potential cross contamination between groups attending SMAs in person and VSMAs.	Post SMA interviews
5. To rehearse data collection methods for an economic evaluation of SMAs to develop and refine methods for a subsequent definitive trial exploring whether an additional approach to measuring economic outcomes adds value.	Primary care costs (staff time and consumables) Detailed screening logs and case report form at 12 months collecting details of healthcare service use Patient Care Use questionnaire (healthcare service use over previous 6 months- including primary care appointments and reasons for attending) Time and travel costs response and completion rates	Immediately after the intervention Baseline, 12 months (9 months post intervention) Baseline, 6 months, 12 months 1 month post intervention
6. To apply progression criteria to key parameters derived from this study to inform the decision regarding a future definitive RCT. (Identify key characteristics of a definitive trial, and if appropriate, produce a protocol for a definitive RCT including		Once all data has been collected.

criteria for clinical and cost-effectiveness)		

4 TRIAL DESIGN

Exploratory feasibility randomised controlled trial that has a parallel group design. Mixed-methods evaluation.

5 TRIAL SETTING

This is a multisite trial. GP practices within PCNs in NENC England with high COPD prevalence will be identified using the NIHR targeting tool(1). Practices will be purposively selected to ensure the sample includes practices from a range of urban, semi-urban and rural areas which will increase the transferability of findings to other parts of England. Practices in very deprived areas called 'Deep-end' (DE) practices will be included as this population group are underserved by current research (28). Deep End GP practices are those with high proportions of patients (between 98 and 54%) living in the 10% most deprived postcodes as defined by the IMD. The research team will meet with the practice manager/partners to discuss the research study and explain what is involved. The local Clinical Research Network (CRN) and DE practice network will support recruitment. As proposed by our PPI representatives, we aim for at least 50% of study practices be Deep-End practices. We anticipate a total of 8 participating practices, of which 4 will be DE practices.

6 PARTICIPANT ELIGIBILITY CRITERIA

6.1 Inclusion criteria

Patients

Participant eligibility criteria have been developed with practitioners and PPI representatives following the INCLUDE framework (29) to ensure inclusivity and diversity.

- Aged 18 years or older with a diagnosis of COPD
- Under ongoing management in general practice
- Able to give informed consent

Interventionists

Staff involved in the organisation and delivery of COPD care in participating practices will form multidisciplinary teams to deliver the SMAs to patients across PCNs. COPD primary care is often delivered by nurse practitioners though, more recently, pharmacists based in general practice play an increasing role in supporting the management of respiratory illnesses(2). Nurse practitioners or pharmacists will be trained to have the role of the consulting clinician during the SMA. A social

prescribing link worker will facilitate the overall SMA session. Where available a healthcare assistant (or equivalent research team member) will have the role of note-taker and provide general support during the SMA. A member of the administrative team will also be invited to the training to learn more about this new way of delivering care so will be able to answer any questions that patients may have about the SMAs. We plan to involve least 8 members of staff from participating practices (2 nurse practitioners/ pharmacists, 2 social prescribers, 2 healthcare assistants and 2 practice administrators) to create two teams of interventionists – one that will deliver all the in person SMAs and one that will deliver the VSMAs at the level of the PCN. Where certain staff (such as social prescribers) aren't available, other members of the primary care staff will take on this role). We will invite all interventionists to participate in a post intervention interview.

To be eligible to participate in a post SMA interview as interventionists participants will be:

- involved in the organisation and delivery of care to patients with COPD (practice administrator, social prescribing link worker, nurse practitioner, pharmacist)
- from participating practices/PCN
- able to provide informed consent
- willing to participate in study evaluation- including an audio recorded telephone/zoom interview

6.2 Exclusion criteria

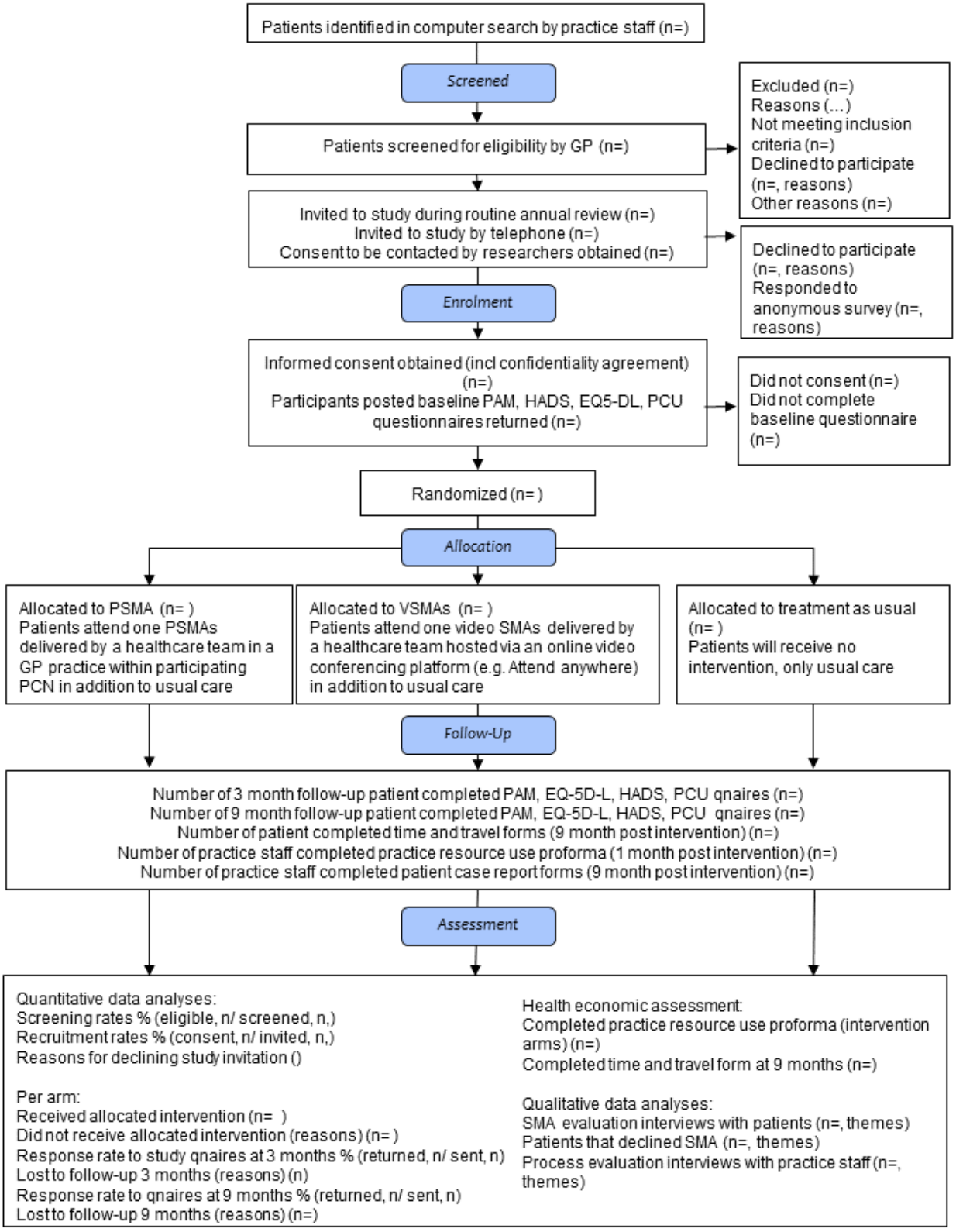
Patients

- Without capacity to consent i.e., with dementia or significant learning difficulties
- With severe mental ill-health
- Requiring Palliative care, or
- Diagnosed with a condition likely to limit life expectancy to <1 year

Interventionists

- failure to meet inclusion criteria

7 TRIAL PROCEDURES



PCN= primary care network, GP = general practice, VSMA= shared medical appointment delivered by video link, PSMA= shared medical appointment delivered in-person. PAM= patient activation measure, EQ-5D-L= Quality of life measure, HADS= Hospital Anxiety Depression Score, PCU= Patient Care Use, Time and Travel Questionnaire

Schedule of events: See SoECAT document.

Summary of processes:

- Practice administrators/managers search electronic GP systems to identify patients with COPD
- GP screens lists of COPD patients to identify those that meet study eligibility criteria
- Patients are contacted by their GP administrator, introduced to the study and asked if they are interested in being sent further information about the study. Patients will be asked to provide verbal consent for their name and contact details to be passed to the research team. The practice administrator will complete the electronic consent to be contacted form with the participants name, contact detail and NHS numbers that will be shared securely with the research team.
- The practice administrator will complete the electronic screening logs in which they will capture pseudonymised demographic information about the potential participant. They will also record (using a drop down list) the main reason why patients decline to further information about the study where applicable.
- The practice administrator will share with the research team the pseudonymised screening logs.
- The research team will post potential participants information sheets and consent forms including a free post return envelope.
- Research team will follow up with potential participants by telephone after 7 days to check they've received the information and answer any questions.
- Potential participants that have not read/received the information sheet when phoned, will be informed about the study verbally. They will be asked if they would like to take part or for more time to think about taking part. Those that request more time will be given at least 24 hours before being phoned by the researcher again and invited to participate. Those that agree to participate will be asked to complete the consent form (by returning signed form by post, email or audio recorded verbally by phone).
- Participants will be asked if they would prefer to complete study questionnaires by post, via an online form or by telephone.
- Baseline questionnaires complete by participants.
- Patients will be randomised by the research team to attend one of the three study arms. The GP practice will be informed which patients have been allocated which arm and practice administrators will be asked to organise the room/teams call and sent out invitation letters to participants accordingly. Patients in each arm will then be offered a choice of days and times from which select the most convenient as per usual practice when arranging appointments. Those allocated to receive usual call will receive a letter from their GP with this information.
- Patients allocated one of the intervention arms will attend a single SMA/ VSMA lasting 60-90 minutes. These SMAs might be held in a local GP practice or held on Microsoft Teams. (Patients in the control group will receive care as usual).
- Interventionists will keep a record of the patients that attended the SMA or dropped out and will complete a fidelity checklist and return them to the research team.
- Practice managers will complete a resource use form after the SMA.

- Participants will be asked to complete a 'time and travel' questionnaire approximately 1 month after the intervention (approximately 7 months post allocation). This will record their expenses in attending care as usual/SMAs/VSMAs.
- Interventionists will participate in an interview with the research team about their experiences of the study and intervention.
- After the intervention, some patients (in treatment and control arm) will be invited to participate in an interview with the research team about their experiences.
- All patients will complete study questionnaires at 3 months and 9 months post intervention (approx. 6 and 12 months post allocation).
- At 12 months (9 months post intervention), practice administrators/ managers will run searches on GP records to complete a healthcare service use form for each participant recording their healthcare service use in the past 12 months.

7.1 Recruitment

7.1.1 Participant identification

Patient participants

Practice managers will identify patients with COPD from their patient lists. Only a member of the patients existing clinical care team will have access to patient records without explicit context to see if they meet the inclusion criteria.

Interventionists (GP staff)

Potential interventionists will be identified by practice managers/GPs in participating practices. Practice mangers will provide the research team with contact details of the potential interventionists (colleagues). Contact details of those that agree to deliver the intervention will kept on file and upon delivering the intervention they will be invited to participate in an interview with the research team. They will be emailed/handed an information sheet about the interview which will include the risks and benefits involved. They will also be sent a copy of the consent form that they will be asked to complete before participating in the interview.

7.1.2 Screening

GPs will screen the list of COPD patients to identify eligible patient participants. All eligible participants will be invited to take part in the study. The practice administrator will contact patients by telephone and seek consent for them to be approached by the research team. There will be up to 5 attempts to contact each patient if there is no initial reply. The research team will provide each practice administrator with a script to support this initial recruitment work and to record reasons why patients decline to be contacted (or participate in the study) using a detailed screening log.

7.1.3 Payment

To support participation from under-represented groups, study participants will receive a £10 high street voucher for their time.
Participants randomised to the VSMA group will be provided with internet data and/or loaned equipment where needed for the duration of the study.

Travel costs (up to £20) will be reimbursed for those attending in-person SMAs not held in their usual practice. Family and carers that attend will also be provided with £10 high street voucher as reimbursement for their time.

Patient participants that attend an interview after the SMA to discuss their views and experiences will also be provided with an additional £10 high street voucher as reimbursement for their time.

See SoECAT for primary care service support and treatment costs.

7.2 Consent

Informed consent will be obtained from research participants by FG or RA who have received training in the principles of Good Clinical Practice.

Potential patient participants that have given consent to be contacted will be sent a study information pack by the research in the post. This will include a participant information sheet detailing why they have been invited, what participation entails, and what the potential risks and benefits might be if they are to receive care via SMA (video or in-person) the use and handling of data for assuring ethical use of the data, contact details and how to file a complaint. Study documents (including information sheets, consent forms) will be primarily infographics with minimal text to ensure the information is accessible to those with low (health) literacy. At the site initiation visit with target practices, managers will be asked to indicate the three most common non-English languages exclusively spoken by their patients. Study documents will be translated into non-English language where needed (we have budgeted for up to 3 other languages). It will be explained to potential participants that other patients in the shared appointment may be at different stages of disease- some may be at more advanced and some at a less advanced stages. The potential positive or negative implications of this will be outlined in the information sheets which will also include how we will support any patients who become distressed as a result. The information sheet will also contain the contact details of the researcher who they can contact to find out more information about the study and a PPI representative if they wish to discuss the public participation elements.

The pack will also include a copy of a consent form with an explanation about how the research team will obtain informed consent. Shortly after sending out the information packs (1-2 weeks), the research team will follow up with a telephone call to check that they have received the information and answer any questions. Participants will be given at least 24 hours to reflect and ask questions/discuss any concerns relating to the study before the consent is obtained. Participants will have opportunity and be

encouraged to discuss with their friends and family if they wish. It will be explained in the PIS, and again verbally on the telephone that they can withdraw from the study at any time, without giving a reason. After 24 hours potential participants will be followed up with a second phone call to answer and questions and to ask if they are willing to participate in the study. Patients will be asked if they are willing to provide a reason (from a list- which includes concerns about sharing with others in more/less advanced stages of the condition) why they do not want to participate and recorded accordingly. However the researcher will stress the voluntary nature of this, explain the purpose of asking this question, and reassure the patient that they are not required to provide a reason should they choose not to.

Patients that agree to participate will be asked to initial, sign and date the consent form. They will be given the option to return it in the freepost envelope provided, or by email. Alternatively, if they prefer, patients can provide audio-recorded verbal consent to participate over the phone.

Patients will be informed in the information sheet and verbally over the phone that they are free to withdraw from the study at any time without giving reason. It will be explained that withdrawing from the study will not affect their legal rights or care in anyway. Participants will be told to contact the research team using the contact details in the participant information sheet should they wish to withdraw. It will be explained that since this is a feasibility study it would be helpful to know the reasons why they have chosen to withdraw and will therefore be asked to indicate the reasons why (from a list that includes concerns about sharing with others in more/less advanced stages of the condition). It will be explained that their data will be removed from the study unless it is has been combined in the analysis or after the report of the findings have been written so it will not be possible to remove their contribution from the findings. It will be explained that their data will be anonymised and therefore it will not be possible to identify them in any written reports or summaries.

7.3 Randomisation process

Once patients have consented to participating in the study, they will be randomised to one of three study arm.

The lead researcher will use number generator to randomise the patients in a ratio of 1:1:1 to either the in-person SMA arm, video SMA arm or usual care arm of the trial using variable length random permuted blocks within strata.

FG will contact administrators in participating practices to inform them which treatment arm their patients have been allocated. There will be no concealment of allocation. Practice staff will record the randomisation number and treatment arm in the patient's notes and arrange for patients to be invited to attend an in person/ video SMA according to the allocation. Patients in the control group (usual care) will be informed of their allocated treatment by telephone call from the research team.

Patients allocated to treatment arms (PSMAs/VSMAs) will be asked to choose an SMA appointment at a time and day most convenient for them. The SMA will comprise 6-8 patients, which will likely be mixed in terms of patient sex, ethnicity, length of diagnosis. Group size/characteristics have been informed by PPI work, clinician input and existing literature.

The randomisation number will be kept in the participant case report form in the site file.

7.4 Blinding

Blinding the participants or healthcare teams to the treatment will not be possible due to the nature of the intervention. As this is a feasibility trial outcome assessors (LV, TB) will not be blinded to the treatment allocation of the patients.

7.5 Baseline Assessments and Data

7.5.1 Quantitative data

Recruitment, patient adherence, retention rates
Detailed screening logs documenting each patient approached to participate will be kept by each site recording patient demographics (e.g., age range, gender, ethnicity, first 3 digits of postcode to derive level of IMD) and characteristics (e.g., length of time since COPD diagnosis, smoking status, number of inhalers and number of rescue packs prescribed in last 12 months, comorbidities, number of exacerbations in last 12 months). The number of patients requiring support/access to digital technologies will be recorded as part of the recruitment process to provide an indication of feasibility and costs required for full scale trial. Reasons for declining to participate will also be recorded by screeners where possible using a drop-down list.

Patient attendance at the SMA will be recorded by interventionists on an attendance register. The interventionists will also record whether the patient remained for the duration of the SMA. This information will be emailed to the research team for assessment. This is to help inform how acceptable the care delivery model is to patients and provide an indication of the number of patients that may drop-out of the sessions.

Questionnaire completion rates and data quality
Several tools will assess response variability in key measures proposed to be used in a future definitive trial where the primary outcome measures would likely be:

- Patient knowledge, skills, and confidence for self-management measured by Patient Activation Measures (PAM) (30), (13 questions)
- Anxiety and depression measured by Hospital Anxiety and Depression Scale (HADS) (31), (14 questions)
- Quality of Life, used to estimate quality adjusted life years, measured by (EQ-5D-5L) (32), (5 questions)

Participant questionnaires, including the were selected and developed with PPI input. Participant questionnaires (PAM, HADS, EQ-5D-5L) will be completed at baseline, 6 (3 months post intervention) and 12-months (9 months intervention). Participants will have the option to complete these questionnaires by post, over the telephone with the research team or by online form. The research team will use a case report form for each patient to record questionnaire responses and completion rates and mode of completion at each time point to determine which approach is most feasible and whether data is of sufficient quality for use in a future trial.

Economic data (healthcare service and resource use)
Other future trial outcome measures include healthcare service use, measured by number of:

- hospital admissions,

- emergency department visits,
- primary care (e.g. GP) appointments,
- referrals and completion (yes/no) of pulmonary rehabilitation
- referrals and completion (yes/no) of smoking cessation services)
- patients that stop smoking
- rescue packs prescribed (antibiotics and steroid use)

Other economic outcomes measured will include:

- Intervention site resource use
- Patient time and travel (or IT internet) costs

Healthcare service use, together with smoking status, no. exacerbations and rescue pack prescriptions together with will be collected for all patients retrospectively (previous 12 months) by practice managers at baseline (using screening logs) and 9 months post intervention (case report form) using data recorded on patient medical records.

To compare data collection methods, the same data will be collected for all patients using the patient care use questionnaire (PCUQ). This will capture their healthcare use in previous 6 months. Patient costs (out of pocket expenses) will also be collected on the CUQ. The CUQ will be completed by patients at baseline, 3 and 9 months post intervention and returned by free post/by telephone or via online form.

A case report form will be completed by practice managers in the intervention sites to record resource implications (e.g., staff time, consumables) at a practice level. This will be completed within 6 weeks of the SMA.

Costs of accessing care will be elicited using a time and travel questionnaire completed 1 month after the intervention. (To avoid questionnaire burden at 3 and 9 months). This data will be used to calculate the cost for each patient accessing each type of care.

As the EQ-5D-5L may not capture all the benefits of the interventions, the interview transcripts (see below) will be reviewed to understand whether a broader measure of benefit (e.g. a discrete choice experiment or a contingent valuation) would be useful to capture patient preferences for the process of care, health and non-health impacts of each intervention.

Table 1 Summary of quantitative data collection

		Time point			
Data	**Source**	**T1** **Baseline**	**T2** **1 month after intervention**	**T3** **3 months post intervention**	**T4** **9 months post intervention**
Demographic data					
Gender	Screening log-GP record	√			
Age range (based on year of birth)	Screening log-GP record	√			
Date of COPD diagnosis (no. months)	Screening log-GP record	√			
Ethnic Group	Screening log-GP record /Patient demo form	√			
Marital Status	Patient demo form	√			
Highest Educational Attainment	Patient demo form	√			
Co-morbidities	Patient demo form	√			
Outcome measures					
Patient Activation Measures (PAM)	Participant questionnaire	√		√	√
Hospital Anxiety and Depression Scale (HADS)	Participant questionnaire	√		√	√
Quality of Life (EQ-5D-5L)	Participant questionnaire	√		√	√
Health care utilisation: • No. hospital admissions in past 6 months • No. primary care visits in past 6 months • Emergency department visits in past 6 months • Referrals and completion	Screening and follow-up case report form PCUQ	√ √		√	√ √

(yes/no) of smoking • Referrals and completion (yes/no) of pulmonary rehabilitation cessation services					
No. rescue packs prescribed (steroid and antibiotic use) in past 6 months	Screening log- GP medical records	√			√
Smoking Status (Yes/no) pack years (no.)	Screening log- GP medical records	√			√
Other feasibility data					
Patient time and travel/internet	TTQ		√		
GP resource use	Resource use form		√		
Adherence and fidelity	Attendance register and implementation checklist		√		

PCUQ- patient care use questionnaire, TTQ- patient time and travel questionnaire, T1- Time point 1, T2- Time point 2, T3- Time point 3, T4- Timepoint 4

7.5.2 Qualitative data

Semi-structured patient interviews will explore acceptability of SMAs including appointment access issues, group size, confidentiality concerns, preferences of group composition (e.g., mixed gender). Interviews will be conducted via telephone or online (i.e., using Zoom/Microsoft Teams). However, subject to COVID-19 related restrictions, face-to-face interviews will also be offered.

A purposive sample will be invited based on sex, age, severity of condition, locality (urban/rural) to ensure a diverse range of views are captured. Data collection will end when data saturation is reached; we anticipate approximately 24 interviews. We aim to conduct interviews within 8 weeks of the SMAs taking place.

All GP staff involved in delivering the SMAs (interventionists) will be invited to take part in a semi-structured interview to explore the acceptability of SMAs and feasibility of the implementation process. A topic guide will be developed drawing on findings of earlier qualitative work. Normalisation Process Theory (NPT) (33) constructs will be used to examine the feasibility of delivering SMAs. NPT provides a robust conceptual framework to help understand and evaluate how new healthcare practices are embedded and sustained in routine practice. We aim to conduct interviews within 8 weeks of the SMAs taking place. The researcher will keep fieldwork diaries to stimulate a reflective approach.

7.7 Fidelity Analyses

- Paper/electronic implementation checklists will be completed by healthcare assistants or equivalent research team members during the SMA, will be collected and assessed by the research team after the intervention. This is to ensure that the SMAs is delivered as intended.
- Aspects of the intervention not delivered as planned will identified and explored further during qualitative interviews with the interventionists in the post-SMA.

7.8 Long term follow-up assessments

- Participants will be encouraged to set themselves reminders to complete the questionnaire and return them by specific dates. Patients will have up to 4 weeks after the 3 month and 9-month time points to return their questionnaires after which they will be considered lost to follow up.
- As this is a feasibility study the numbers of completed forms (75% of questionnaire/form items completed) received at baseline, 3 months post intervention and 9 months post intervention will be recorded and used in the feasibility assessment of the study.

7.9 Withdrawal criteria

- Participants can choose to withdraw from the study at any point. They can choose whether to withdraw all their information or agree to what has already been collected to remain in the dataset. (It will be made clear in the PIS and verbally to the participant that once data has anonymised and combined in the analysis it will not be possible to withdraw their data.)
- Participants that choose to withdraw from the study will continue to receive care as usual, any withdraw will not affect their future treatment. (Those that are invited but do not attend an SMA will still be eligible to participate in an interview with the research team to discuss the reasons why they did not attend.)
- Should a participant decide to withdraw from the study, all efforts will be made to report the reason for withdrawal as thoroughly as possible. Reasons for withdrawing will be recorded by the research team on a trial site file where possible.

7.10 End of Trial

The end of the trial will be defined as the date of last data collection for the last participant.

8 TRIAL INTERVENTION

Study participants will be randomised to one of three study arms:

A- in-person SMAs

B- Video SMAs

C -usual care.

All participants in the treatment arms and control arm will receive standard care. Participants in the two intervention arms (arms A and B) will receive standard care plus intervention. Participants in the two invention groups will attend a SMA/VSMA in groups of 8 patients.

8.1 Study arm A, In-person SMAs

A standardised protocol for in-person SMAs will be used to ensure that the SMA model can be replicated. The protocol was informed by COPD self-management work (10,12,13,34), recent literature reviews (22,24), qualitative interviews with clinicians and patients regarding SMA experiences and PPI work. It outlines delivery agents and main components of the intervention, these are outlined in Box 1. We drew on Michie et al.,'s (2013)(35) behaviour change techniques (BCT) taxonomy v1 to clearly describe key ingredients of the intervention to supporting fidelity monitoring and enable us to contextualise our work within a wider behavioural science literature.

The SMA will be delivered by a team of healthcare professionals recruited from participating primary care practices. These teams may comprise staff from different practices within a PCN. Each member of the delivery team has a specific role within the SMA as follows:

- Healthcare assistant or research team equivalent - note-taker and timekeeper (also verifies patient ID on VSMAs, monitors fidelity)
- Social prescribing link worker- group facilitator (facilitates group discussion)
- Practice nurse/pharmacist- group consultation clinician (conducts individual patient assessments)
- Practice administrator- SMA organisation (not involved in delivery but arranges and co-ordinates set-up)

Each session will have 4 main stages:

- Stage 1- Introduction to the healthcare team and setting expectations for the session (led by the group facilitator with support of the note-taker)
- Stage 2- Facilitated group discussion about living with COPD led by the facilitator. Whilst the discussion will be primarily patient-led, the facilitator will ensure that key topics are discussed: 'living well with COPD' (covering issues such as managing breathlessness, physical activity and diet; b) 'how COPD makes you feel' (covering the emotional aspects of the condition); and c) 'support from people you know' (exploring participants' social support needs). These issues were identified in the literature, and reported by patients, to be essential elements of COPD advice often not addressed in 1:1 appointments due to time constraints. Common issues raised by participants (identified by the note-taker) will be addressed by the clinician when they join.
- Stage 3- Individual consultation- the clinician joins the session and speaks to each participants in-turn with other participants listening-in. Each participants will be allocated 5-10 minutes and invited by the facilitator to ask the clinician a question or share a concern that is common to the group as identified in the prior group discussion. The clinician will provide advice/ review medical records as appropriate. The social prescriber will sign-post the patient (and wider group) to community and statutory services for practical and emotional support as appropriate. The healthcare assistant, or research team equivalent, will keep time and prompt the clinician

to move onto the next patient. The clinician will update patient medical records at the end of the session with any changes to medication or referrals as needed.

- Stage 4-The facilitator will summarise the key topics discussed and the support resources available and draw the session to a close.

Stage (time)	Activity	Behaviour change techniques	Undertaken by
1 (10min)	Welcomes attendees Checks ID Introduces the healthcare team Sets attendee expectations		Led by healthcare/research assistant
2 (15 min)	Facilitator sparks discussion, encourages patients to share experiences and collates any key questions for clinician (living with COPD, emotional aspects, support from people you know) (BCT: 3.1 social support (unspecified).	Provide information on consequences of self-management behaviours in general Prompting focus on past success- involves instructing the person to think about or list previous successes in performing the self-management behaviours (or parts of it) Provide information about others' approval (family/carer)- involves information about what other people think about the target person's self-management behaviour (Peer) modelling- providing opportunities for participants to persuade others of the importance of adopting self-management behaviours	Facilitated by social prescriber- facilitates
3 (60 min)	Each member of the group has the opportunity/is invited to speak to the clinician 1:1 for 5-10 mins with all group members listening-in. The facilitator (HCA) keeps control of the conversation sufficiently to ensure that key areas identified in the group discussion are covered. (Clinician and social prescriber sign-post/ make referrals to support as needed during these 1:1 conversations) (BCT: 2.1 Problem solving)	Action planning- planning of what the person will do including, as a minimum, when, in which situation and/or where to act. Planning social support- Involves prompting the person to plan how to elicit social support from other people to help him/her achieve their target self-management behaviours	Facilitated by social prescriber Clinician answers questions The healthcare assistant, or research team equivalent, will keep time and prompt the clinician to move onto the next patient.
4 (5 min)	Summary of session and support available		Led by social prescriber

Earlier feasibility work has found that patients struggle to attend more than one SMA (12). Furthermore, conditions for non-inferiority were met in a trial of a single 90 minute SMA for osteoporosis patients (23). Therefore, we have opted for a single intervention session operationalised for in-person or remote delivery. The process of patients reviewing goals and developing action plans for self-management can either inform, or be a consequent development from, annual review appointments. The intervention will be held during the summer months when the prevalence of influenza and other respiratory illnesses are usually lower than in winter. (PPI representatives said that travel during the summer months was easier and they would be more inclined to attend in-person SMAs during these months.)

8.2 Study arm B, SMAs delivered by video-link

Participants randomised to this study arm will receive a letter and instructions for their appointment which will be delivered online. A separate protocol for delivering the SMA by video link will be used. The format of the SMA intervention will be the same as the in-person sessions but the session will be hosted online.

8.3 Study arm C, Comparator

Participants allocated to receive usual care (controls) will receive no additional intervention. Usual care typically includes an annual review delivered 1:1 in person, pulmonary rehabilitation (if appropriate) and primary and secondary care treatment for exacerbations. Primary care visits tend to be 1:1 appointments with the nurse practitioner/ pharmacist that last 10-15 minutes. It is also possible that they may be referred, or self-refer, to attend a 1:1 appointment with a social prescribing link-worker.

8.4 Quality control of the SMA intervention

Quality control will be maintained through adherence to the study protocol, the principles of GCP, research governance.

8.4.1 Training of interventionists

Interventionists (pharmacists and social prescribers) will attend training delivered by a Deep-End practice GP with COPD SMA experience (JC), and COPD specialist nurse consultant with healthcare professional training experience (KHM). Training materials have been co-produced by the research team (including behavioural and implementation scientists), DE clinicians, specialists (KHM) and PPI members. Two training session (one for PSMAs and one for VSMAs) lasting approximately 90 minutes will be delivered online to interventionists. They will be delivered by the same trainers to ensure consistency in the delivery of training.

Manualised training materials will be provided to the trainees. An SMA manual and intervention checklist will be provided as a prompt to ensure that the “dose” of the intervention (measured by number, frequency, and length of contact) is the same for each SMA participant in the intervention arms. There will be a follow-up online training session after the initial SMAs have been implemented to discuss and overcome any issues arising. Trainers and the research team will be available to support interventionists throughout the implementation phase of the intervention.

8.5 Schedule & Modifications

- See Appendix 3 for schedule of procedures

8.6 Known Risks

- There are no known health risks associated with attending an SMA/VSMA.

8.6.1 Potential risks of SMA participation

Patients attending SMAs will be able to witness to personal health and mental health problems of others. There is therefore a risk that other patients in the group may not keep personal information shared within the group confidential. This risk will be outlined in the participants information sheet and verbally at the start of the SMA. To mitigate this risk, the study participant consent from will include item by which patients will agree that, should they be randomised to attend an SMA, they understand that confidential medical/health information may be discussed with others during the session and agree not to share personal information of other patients with others outside the group. It will be made explicit in the information sheet and verbally at the start of the SMA that any carers or family members joining the group also agree not to share personal information of other patients with others outside the group. The social element and peer support provided by the group discussion is reported by patients to be particularly beneficial in terms of motivation and confidentiality issues have been minimally reported in the literature to date.

Patients could be sharing sensitive or embarrassing information during the group session at times which they may find uncomfortable. However, it will be made clear that they do not have to share any information during the session that the do not want to and the opportunity to ask the clinician a question is optional. If any specific concerns are raised during the SMA they can contact their own GP practice after the session to arrange a private appointment with an appropriate healthcare professional.

Patients may recognise/know other members of the group which may make them uncomfortable. This may also alter the group dynamics and make others feel excluded. The facilitator will have received training in managing group dynamics and being inclusive. Patients that do not want to participate can withdraw from the SMA or study at any point.

8.6.2 Risks specific to video SMAS

Some patients may be unable to attend due to lack of access/skills to virtual technologies. To mitigate this, and ensure equity of access, we will offer these patients a device on loan with a prepaid sim card that is able to support VSMAs. We will also show patients and/or their family/friends how to access the VSMAs on the device.

There is provision available for translation/supporting special communication needs if a family member or carer is unable to attend.

There is a risk that someone who is not a patient attempts to join the call. Standard security measures will be put in place to avoid this (including the requirement of a password/link to join the session.) All group participants will be asked to confirm their identify (asked a security question) and confirm their phone number (in case the get cut-off) and any other family member or carer present before being permitted to join the session by the research team. The online platform for hosting the VSMA will meet

NHS ethical guidelines. Other NHS guidance regarding safety checks and measures will be adhered to (36).

Patients attending an VSMA may be at risk of being overhead by someone else in the location. The PIS and joining instructions sent out with the link to join call will raise participant awareness of this risk. Participants will be encouraged to join the call from a quiet private location and the use of headphones will be recommended.

8.6.3 Risks specific to physical SMAs (including Covid-19)

In-person SMAs will only be held if they comply with NHS policies regarding the Covid-19 pandemic. If in-person care is restricted for safety reasons, we will focus on SMAs delivered by video link and adjust study parameters accordingly (including planning for a future 2-armed trial, assuming usual care refocuses on remote delivery). In-person SMAs will be restricted to groups of 6 patients (plus one family member/carer/interpreter per patient present if required) so that social distancing can be maintained. All group participants will be required to conform to pandemic safety measures regarding face masks (unless exempt/ not tolerated) and use the hand sanitisers available in the GP setting. We have planned for SMAs to be held in the summer months when the incidence of influenza and other respiratory illnesses is relatively low, therefore patients will be at lower risk of contracting such illnesses. Healthcare professionals will be present during in-person SMAs to offer any necessary medical assistance. In-person SMAs will be held in general practices where inhalers and rescue packs are available if required. Staff can refer participants for mental health support or emergency care, if deemed appropriate during in-person or remote care.

It will be made clear to participants that if they do not wish to attend a physical SMA they can choose not to.

8.6.4 Risks of interview participation (patients)

Post intervention interviews will be conducted by an impartial researcher not involved in delivering their healthcare. Some patients may feel uncomfortable discussing their condition and healthcare they receive. At the outset of the interviews, patients will be informed that they can stop the interview at any point. They will also be reassured about the non-judgmental nature of the research. The researcher will be prepared to spot signs of distress and pause or stop if necessary.

Interviews will be conducted in person, online or by telephone as per participant preference. They will be arranged at a time that is suitable for the patient. The researcher will ensure that the interviews are conducted in a private space where the researcher won't be overheard. If the interviewees choose to join the call from their own home, the researcher will make them aware that they may be overheard by others in their home. The use of headphones will be recommended.

Interview responses will be kept confidential and only anonymous quotes used in reports (e.g quote will be captioned with age range, gender, length of COPD diagnosis).

8.6.5 Risks of interview participation (NHS staff)

Interviews with NHS staff will be conducted remotely using an online platform (e.g. Microsoft Teams/ Zoom) or by telephone. Some interviews may be conducted face-to-face in their place of work as per participant preference. They will be conducted during office hours therefore it is likely participants will

be joining from their place of work. They will be asked to join the call from a private room and to use headphones where possible. Responses of healthcare professionals will be kept confidential and anonymised in any reports that are written.

NHS staff may not want to participate in an interview with the research team about SMAs. They may feel embarrassed about sharing their views, particularly if their views of SMAs are negative. It will be made clear that all their opinions are valuable, and they will not be judged.

8.7 Concomitant Medications & Therapies

- There are no restrictions on concomitant medications or therapies.
- Participants will be asked about whether they participate in any other group therapy or patient support groups at baseline as part of the demographic form.
- They will also be asked whether they are participating in any other research and the nature of that research study.

8.8 Assessment of Compliance

- The facilitator will record attendance and whether any participant left the SMA before the SMA had come to an end.

9 SAFETY AND MONITORING

9.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant, including occurrences which are not necessarily caused by or related to the intervention under study.
Adverse Reaction (AR)	An untoward or unintended response in a participant to which is related to the intervention under study i.e. that a causal relationship between the trial intervention and an AE is at least a reasonable possibility and the relationship cannot be ruled out. All cases judged by either the reporting medically qualified professional or the Sponsor as having a reasonable suspected causal relationship to the trial intervention qualify as adverse reactions.

Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • Results in death • Is life-threatening* • Requires inpatient hospitalisation or prolongation of existing hospitalisation • Results in persistent or significant disability/incapacity • Consists of a congenital anomaly or birth defect • Other important medical events that jeopardise the participant or require intervention to prevent one of the above consequences * - life-threatening refers to an event in which the participant was at immediate risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Serious Adverse Reaction (SAR)	An adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to the trial intervention, based upon the information provided.
Unexpected Serious Adverse Reaction (USAR)	A serious adverse reaction, the nature and severity of which is not consistent with the known information about the intervention under study.

9.2 Recording and Reporting AE and SAEs

This is a low-risk feasibility trial and major safety data (adverse events/deaths) are not anticipated.

- The risk of adverse events following an SMA is low. No concerns or difficulties have been reported by previous studies.
- A Safety Recording and Reporting plan will be written by CI and shared with local collaborators in GP practices that will be responsible for reporting them to FG.
- Should any adverse event occur the local collaborators at the GP practices will be responsible for reporting them to FG who will then categorise according to relatedness and severity. This will be logged in the trial master file.
- The CI will complete a SAE report form for non- CTIMPs, available from the HRA website, and send it to the REC which issued the favourable ethical opinion and the Sponsor.

For each SAE the following information will be collected:

- Full details in medical terms and case description
- Event duration (start and end dates, if applicable)
- Action taken
- Outcome

- Seriousness criteria
- Causality in the opinion of the investigator
- Whether the event is considered expected or unexpected.

Any change of condition or other follow-up information should be emailed to FG as soon as it is available or at least within 24 hours of the information becoming available. Events will be followed up until the event has resolved or a final outcome has been reached.

9.3. Recording and Reporting USARs

All USARs occurring from the intervention until 10 days post termination of trial treatment must be reported to the NHS REC. The CI will perform this reporting.

The assessment of expectedness will be performed by the CI against the known information for the trial.

USARs must be reported no later than 15 calendar days after the CI has first knowledge of the event. Any relevant follow-up information should be sought and reported as soon as possible after the initial report.

As soon as a site suspects that a SAR may be a USAR they must contact the CI, sponsor representative immediately. The reporting timeframe starts at day 0 when the Sponsor is in receipt of a minimum set of information:

- Sponsor trial reference and trial name (sponsor reference)
- Patient trial number and date of birth
- Name of intervention
- Date of notification of the event
- Medical description of the event
- Date and time of the onset of the event (including event end date if applicable)
- Causality assessment
- Seriousness of the event, particularly if life threatening or fatal
- An identifiable reporter (e.g., Local collaborator)

This information must be provided on [name of form or media of notification]. The site is expected to fully cooperate with the Sponsor in order that a full and detailed report can be submitted to the NHS REC within the required timelines.

All local collaborators will be informed of all USARs by the CI.

9.4 Responsibilities

Local GP collaborator

- Checking for AEs and ARs when participants attend for treatment or follow-up after the intervention.

- Using medical judgement in assigning seriousness and causality and providing an opinion on expectedness of events.
- Ensuring that all SAEs and SARs, including USARs, are recorded and reported to the CI within 24 hours of becoming aware of the event and provide further follow-up information as soon as available.
- Ensuring that AEs and ARs are recorded and reported to the CI in line with the requirements of the protocol.

Chief Investigator
- Immediate review of all USARs.
- Review of specific SAEs and SARs in accordance with the trial risk assessment and protocol.

Sponsor
- Assessment of expectedness of any USARs
- Expedited reporting of USARs to the REC within required timelines
- Notification of all investigator sites of any USAR that occurs

TSC
- Review of safety data collected to date to identify any trends

9.5 Notification of Deaths

- Local collaborator will inform FG about death of participant.

9.6 Reporting Urgent Safety Measures

- An Urgent Safety Measure (USM) is an action that the Sponsor or an Investigator may take in order to protect the subjects of a trial against any immediate hazard to their health or safety. Upon implementation of an USM by an Investigator, the CI must be notified immediately and details of the USM given. The Sponsor must inform the NHS REC within 3 days of the USM taking place in accordance with the Sponsor's standard operating procedures.

10 STATISTICAL CONSIDERATIONS

10.1 Participant population

Any participant randomised into the trial, regardless of whether they received intervention or not will be included in the descriptive analyses. Definitive trial would follow an intention to treat analysis.

10.2 Statistical analysis plan

The trial analyses will follow a pre-defined Statistical Analysis Plan (SAP), a version-controlled document written by the statistician, signed by the Chief Investigator, and retained in the Statistics Trial Master File.

9.2.1 Summary of baseline data and flow of patients

As this is a feasibility trial, the main quantitative analyses (including those for the economic data) will be descriptive. Recruitment and retention data (counts and percentages at each time point) for each study arm will be tabulated. Descriptive analysis will include characteristics of participating practices (e.g., number of registered patients, % patients registered with COPD), interventionists (e.g., job role, years in service) and patients (e.g. age, gender, smoking status, ethnicity).

9.2.2 Primary outcome analysis

Number of patients attending SMAs and numbers of completed screening logs/case report forms, participant questionnaires at 6 and 12 months will be compared across study arms. (Completed forms/questionnaires will be those in which 75% of questions/items are complete). Outcome measures will be presented in simple descriptive tables presenting percentages, means and standard deviations for each arm of the study.

9.2.3 Secondary outcome analysis

Comparison of the data collection methods for the healthcare service use (i.e. data collected using patient medical records- screening logs and healthcare use proforma at 12 months), and via patient CUQ) will be examined. This information will be used to inform the design, choice of primary outcome, sample size, method of data collection, and analysis approach of the future definitive trial.

10.3 Sample size calculation

Our trial sample size estimation was informed by Teare et al. 2014 (37). Using PAM scores as the candidate primary (continuous) outcome measure for a future trial design, we aim to analyse 35 subjects per arm. Allowing for 20% loss to follow-up, as reported in the SMA literature (22), this gives a sample size of 44 per arm (total of 132 across 3 arms).

10.4 Interim analysis and criteria for the premature termination of the trial

- There will be no interim analysis for this feasibility RCT.
- As this is a feasibility trial it is very unlikely that this this study will be prematurely terminated. Instances such as a very low recruitment rate (<1 patient a month) or a major outbreak of Covid-19 may make it impossible to continue. The study sponsor (Newcastle University) has the ultimate authority to stop or modify the trial.

10.5 Procedure(s) to account for missing or spurious data

- To maximise follow-up to prevent missing data, the research team will contact participants at 6 and 12 months to remind them to complete and return the questionnaires.
- Reasons for missing data will be recorded on patient case report forms

10.6 Qualitative data analyses

Anonymised interview transcripts will be analysed using a two-stage approach. First, Framework Analysis will be used to sift, chart, and sort the interview data in a five-step process 1) familiarisation; 2) identifying a thematic framework; 3) indexing; 4) charting and 5) mapping and interpretation. In the second stage, theory-driven data analysis will be conducted thought an iterative processes, whereby the initial inductive themes are mapped against four Normalisation Process Theory (NPT) constructs: coherence (or sense-making); cognitive participation (or engagement); collective action (work done to enable the intervention to happen); and reflexive monitoring (formal and informal appraisal of the benefits and costs of the intervention (38). NPT provides a robust theoretical framework to help explain the 'work' involved in implementing a set of healthcare practices. This two-stage approach mitigates against "forcing" data into predetermined conceptual categories, ensuring interpretation remains data-driven. At both stages, two researchers will read the transcripts repeatedly to familiarise themselves with the data and code the transcripts independently using the framework. Any divergence between coders will be resolved through discussion. Analysis will be discussed at research team meetings to identify and refine themes. NVivo Software will be employed to support data management and analysis.

10.7 Pathway to RCT assessment

Progression criteria for a pilot study have been developed using the guidance from Charlesworth et al. (39) and Avery et al. (40) informed by previous SMA RCT literature (22). See Table 1. Using the approach outlined by Bugge et al. (41) and in discussion with the NIHR RfPB team, we will convene an independently chaired trial steering committee (TSC) to review and interpret the data against progression criteria to determine whether the study design is feasible and if a future trial is merited. If deemed feasible we will apply to NIHR Health Technology Assessment (HTA) panel for funding to conduct a definitive RCT with internal pilot.

Table 1 Progression criteria for a definitive trial

Feasibility outcomes	Data Source	Green (feasible)	Amber (remediable factors)	Red (do not proceed)
Eligibility, recruitment	Screening logs	>20% of those invited per month participate	10-19% of those invited per month participate	<10% of those invited per month participate
Uptake rates (enrol in study)	Enrolment logs	>70% enrolled attend	50-69% enrolled attend	<49% enrolled attend
Retention rates	Case report forms	75% completed at 12 months	60-74% completed at 12 months	<59% completed at 12 months

Feasibility of data collection methods (incl. economic data)	Completeness and quality of patient completed questionnaire at all follow-up points with the denominator all those eligible to complete them - i.e., missing data within key outcomes and percentage of participants with missing data	>80% of PAM, HAD and EQ-5D- 5L questionnaires completed >80% of health service questionnaire completed >50-59% time and travel questionnaire completed	60-79% of PAM, HAD and EQ-5D-5L questionnaires completed 60-79% health service questionnaires completed 30-49% time and travel questionnaire completed	<59% of PAM, HAD and EQ-5D-5L questionnaires completed <59% of patient care use questionnaires completed <30% time and travel questionnaires completed
	Completeness and quality of patient case report form, NHS resource use proforma at all follow-up points with the denominator all those eligible to complete them	>90% completion of the case report forms and NHS resource use proforma	70-89% completion of the case report forms and NHS resource use proforma	<69% completion of the case report forms and NHS resource use proforma
Feasibility and acceptability of study processes and procedures	In-depth interviews with healthcare staff and patients	Themes indicate positive experience with minor changes to study processes required	Themes indicate positive experience with major changes to study processes required	Themes indicates negative experience and unintended consequences arising
	Completeness of implementation checklists by healthcare assistants (fidelity assessment and monitoring)	>80%of checklists completed post intervention (>80% of intervention components implemented)	60-79% of checklists completed post intervention (60-79% of intervention components implemented)	<59% of checklists completed post intervention (<50% of intervention components implemented)
Acceptability of intervention	In-depth interviews with healthcare staff and patients	Themes indicate positive experience with minor changes to study processes and intervention required	Themes indicate positive experience with major changes to study processes and intervention required	Themes indicates negative experience and unintended consequences arising

11 DATA HANDLING

Please see data management plan for full details. Below is a summary.

11.1 Data collection tools and source document identification

Data collection tools:

- Electronic screening logs will be used to record details about people that agree and decline to be contacted by the research team- these will be pseudonymised and shared securely with the research team.
- Electronic consent to contact forms to be used to share contact details of eligible patient that have provided consent to be contacted by the research team
- Electronic recruitment logs will be used to record details of consent procedures.
- Participant consent forms-physical, electronic/audio files
- Electronic case report forms (eCRFs) will be created for each individual patient participant. Only the data required by the protocol are captured in the CRF.
- Electronic demographic forms (completed by researcher over the phone with participants)
- Participant questionnaires HADs, PAM, ED-5D-5L
- Patient care use questionnaire (completed by patients)
- Healthcare service use proformas (completed by practice staff)

11.2 Data handling and record keeping

Participants will be given a unique participant identification code that allows identification of all the data reported for each participant. The document with which links the unique code with the participant identifiable information will be kept in a separate password protected folder to the pseudonymised data.

Identifiable information will be kept in password protected folders on the University file store service.

- Participant log: NHS number, name and contact details
- Electronic demographic forms
- Electronically signed informed consent forms (and digitised consent forms/ audio recordings of consent)

All electronic documents will be stored in a password protected folder on Newcastle University Teams accessible by only the research team. Source documents will include:

- Pseudonymised screening logs
- Pseudonymised recruitment logs
- Electronic case report forms (eCRFs) will be created for each individual patient participant. Only the data required by the protocol are captured in the CRF.
- Standard operating procedures
- Training materials

Physical documents will be kept in locked filing cabinets on university premises. Physical documents will include

- Written participant informed consent forms
- Physical copies of completed participant questionnaires (standardised tools and patient time and travel questionnaire). These data will be transferred to the eCRFs. Hard copies will be stored in locked filing cabinets and shredded at the end of the study.

11.3 Access to Data

- Only the RA and FG will have access to the data files and be able to input the data.
- Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections- in line with participant consent.

11.4 Archiving

- The CI and RA will be responsible for archiving and sharing data upon completion of the study.
- Personal data (name and contact details of participants) will be deleted upon completion of the study. (Audio files of participant interviews will be deleted once the data has been analysed.)
- Pseudonymised datasets will be archived in a separate folder to the key for the unique identifier. These will be stored for up to 10 years.
- Digitised consent forms and audio consent files will be retained confidentially in a password protected excel file on the shared drive for up to 10 years after completion of the trial. (Any hard copies will be shredded).
- As outlined in the data management plan, anonymised datasets and corresponding meta-data will be archived in the Newcastle University repository (data.ncl) for at least 10 years after the end of the study.

12 MONITORING, AUDIT & INSPECTION

12.1 Trial Monitoring

- The day-to-day study conduct, and monitoring will be provided by FG who will visit/call all participating practices periodically during the recruitment and allocation phases to provide support and record any issues that may arise.
- The TSC will monitor trial progress to ensure that it is conducted to high standards in accordance with the protocol, the principles of GCP, relevant regulations, guidelines and with regard to patient safety. This may involve reviewing the trial data set periodically to check for completeness.
- The study may be subject to inspection and audit by Newcastle Univeristy as the research sponsor. Participants will be informed of this in the PIS.

13 ETHICAL AND REGULATORY CONSIDERATIONS

13.1 Research Ethics Committee (REC) review & reports

- The CI will obtain a favourable ethical opinion from an NHS Research Ethics Committee (REC) prior to the start of the trial. All parties will conduct the trial in accordance with this ethical opinion.
- The CI will notify the Sponsor together with REC of any serious breaches of GCP or the protocol, urgent safety measures or USARs that occur during the trial.
- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- An annual progress report will be submitted each year to the REC by CI pm behalf of the sponsor until the end of the trial. This report will be submitted within 30 days of the anniversary date on which the original favourable ethical opinion was granted.
- The Chief Investigator will notify the REC of the early termination or end of trial in accordance with the required timelines.
- Within one year after the end of the trial, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

13.3 Data protection and patient confidentiality

- Before the start of the trial, approval will be sought from a REC for the trial protocol, informed consent forms and other relevant documents e.g. advertisements and GP information letters
- substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the trial (note that amendments may also need to be reviewed and accepted by the MHRA and/or NHS R&D departments before they can be implemented in practice at sites)
- all correspondence with the REC will be retained in the Trial Master File
- an annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended
- it is the Chief Investigator's responsibility to produce the annual reports as required.
- the Chief Investigator will notify the REC of the end of the trial
- if the trial is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination
- within one year after the end of the trial, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC

13.3.1 Participant confidentiality

- Personal data will be regarded as strictly confidential.
- To preserve anonymity, data leaving GP practices (screening data) will identify participants by a unique study identification code, the key which will be kept in the practice and not revealed to the research team. If a patient consents to taking part in the study, the research team will contact

the GP practice with the name and be given their unique identifier number. The key with the name and unique identifier will be stored at Newcastle separately from their other data.
- The study will comply with the Data Protection Act, 1998, GDPR 2018, and Caldicott Principles.
- All study records and Investigator Site Files will be kept at site (GP practice) in a locked filing cabinet with restricted access/ on password protected files on.

13.3.2 SMA attendee confidentiality

- Patients, family member carers that attend the SMA will be requested to sign a confidentiality agreement stating that they will not share personal information shared by others in the group with anyone outside the group.

13.4 Peer review

The study proposal has been peer reviewed by NIHR funding panel.

13.5 Public and patient Involvement

13.5.1 Design of the research

Seven PPI members were involved in the conceptualisation of the study proposal, providing input on the design and content of the trial and interventions. They recommended that both PSMAs and VSMAs were explored due to the experience of the pandemic. VSMAs were thought to be an easier, more convenient and potentially safer way for patients, and their families, to meet with their healthcare professional without the need to travel.

We conducted an online poll (hosted by the BLF) of 173 people with COPD regarding SMA attendance preferences. Most were unfamiliar with SMAs and expressed no specific interest in experiencing them, but those that did, favoured PSMAs over VSMAs. Reasons for less interest included confidentiality concerns, being too ill to attend, not seeing any additional benefit compared with existing peer support groups and/or pulmonary rehabilitation. One respondent was concerned that SMAs may be a cost-cutting exercise. As a result, the study recruitment strategy allows time to clearly describe the SMAs to potential participants.

Two people with COPD (from DE practices) discussed the study with the lead researcher, FG. Both of these individuals supported the idea of the proposal. One had attended an in-person SMA for COPD in the past 12 months and welcomed the opportunity to attend another, describing it as a positive experience. Both expressed safety concerns over PSMAs given the risk of contracting/spreading COVID-19, with a preference for VSMAs (June 2021). However, both expressed a desire to return to in-person practice appointments when possible. They explained that they were now more familiar with using tablets and phones but the need for family/technical support to attend sessions was important for some. As a result, we will ensure that written instructions are sent ahead of time to participants and telephone support is available, if needed. PPI representatives said the pandemic had increased feelings of isolation and their desire to interact with others now was strong, therefore they were more likely to engage in group activities than before the pandemic. If the pandemic situation improved, patients were amenable to attending a practice that wasn't their own provided it was accessible to them.

In addition to this, the CI, PPI lead and co-applicant held two meetings with PPI representatives at the VOICE research support group at Newcastle University. The first meeting (November 2022) focused

on the participant information sheet that had been prepared in advance. The meeting captured several the initial impressions of potential participants regarding the concept of shared medical appointments. The group also highlighted key elements of the information sheet that required clarification and re-wording.

The second VOICE support group (December 2022) highlighted the importance of the way in which potential participants would be introduced to the study and the concept of shared medical appointments. The group said that it was important to highlight the potential benefits to participants not only of what the intervention itself could bring but the importance of the research study itself. As such a carefully worded script for practice staff who would be making the initial approach to potential participants to obtain consent to be contacted by the research team was created and reviewed by the newly formed PPI group. The group was also provided with draft versions of the questionnaires and interview topic guide that participants were to be provided with and asked to comment on the length of the questionnaires, whether the questions were what they expected based on the information provided in the information sheet. They were also asked to comment on the terminology of ‘telemedicine’ and what ‘remote’ consultations meant to them.

A third meeting was held with PPI reps the Policy Research Unit in Behavioural Science at Newcastle University. PPI reps were presented with the questionnaires included in the funding application, along with the additional questionnaires proposed by the reviewing panel committee. The EQ-5D-5L questionnaire was preferred over the short form survey in which used American terminology that they thought study participants may struggle to answer i.e. one question is about ones’ ability to walk ‘blocks’. The SGRQ was considered preferable to the CAT but felt that participants were already asked a lot of questions and that it would be helpful to indicate how long the participant should expect to spend completing the questionnaires.

13.5.2 Management of the research

OM will lead and coordinate PPI activities, acting as a single point of contact for all public contributors involved in the research. Working with our public co-investigator (SE), she will develop and deliver the PPI strategy and implement appropriate evaluation, monitoring, and reporting e.g., using GRIPP2 guidance and UK Standards for Public Involvement. OM and SE will attend steering group meetings from the outset, to provide input to protocol development, study conduct, data interpretation, feedback to participants and support for wider PPI activities. They will be involved in preparing documentation for ethical review and ensuring PPI input is sought throughout the project.

Four additional PPI representatives from the NENC have been recruited to form a PPI group. The PPI group will attend 2 meetings per year, chaired/facilitated by SE. They have and will be consulted on matters requiring PPI input and tasked with a range of activities including; co-creation of participant-facing documentation, guidance on patient recruitment processes, interpretation of the findings, creation of policy briefs and research summaries for participants and other stakeholders to support engagement and dissemination.

At the PPI meetings, OM will update PPI members on the project status and provide feedback on PPI activities and their impact. OM will work with public contributors to develop and support their training needs. SE will undertake training to support the evaluation of PPI activities. OM and SE will work with

British Lung Foundation-Asthma UK, who have agreed to support our PPI activities and the development of a nationwide survey to contextualise the findings of the trial and advise on whether SMAs should be taken forward how they ought to be adopted into practice (See letter of support attached). We will agree with PPI Group members how they wish to be kept informed of progress, SE will establish a WhatsApp group (or similar) as an informal channel for the group to stay in contact, ask ad hoc questions etc. This approach has proved a popular and successful of maintaining engagement, enthusiasm and inclusion in other research projects.

13.5.3 Analysis of results

PPI members will attend the PMG meetings and will discuss the qualitative data collected from patient interviews to help to sense check and validate the findings.

13.5.4 Dissemination of findings

PPI members will attend the dissemination workshop and share research summaries via the networks of patient groups in the North East. Our PPI members may also attend TSC meetings and support the production of the study protocol of a future definitive trial if deemed appropriate.

13.6 Regulatory compliance

- Before any site can enrol patients into the study, the Chief Investigator will ensure that appropriate approvals from participating organisations are in place – i.e. organisation information document, confirmation of Capacity and Capability as advised from NIHR CRN NENC and Letters of Access (issued by NECS) as advised by the Health Research Authority.
- For any amendment to the study, the Chief Investigator in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment.
- The Chief Investigator or designee will work with sites (NECS, as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

13.7 Protocol compliance

Accidental protocol deviations will be documented on relevant forms and reported to the CI and Sponsor immediately.

13.8 Notification of Serious Breaches to GCP and/or the protocol

- A “serious breach” is a breach which is likely to effect to a significant degree –
  (a) the safety or physical or mental integrity of the participants of the trial; or
  (b) the scientific value of the trial

- the sponsor will be notified immediately of any case where the above definition applies during the trial conduct phase

13.9 Data protection and patient confidentiality

All investigators and trial site staff will comply with the requirements of the Data Protection Act 1998 GDPR 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act’s core principles.

(See data management plan)

13.10 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

- None of the investigators or committee members have any conflict of interest to declare.
- If a conflict of interest arises, the trial steering committee will be informed.

13.11 Indemnity

- The NECS has liability for clinical negligence that harms individuals toward whom they have a duty of care.
- NHS Indemnity covers NHS staff involved in the trial (interventionists) for potential liability in respect of negligent harm arising from the conduct of the study.
- Newcastle University have provided indemnity insurance for the design, management and conduct of the study.

13.12 Amendments

If there is a need to make an amendment to the protocol (for example, change in CI, study documentation) the CI will complete the notification of tool and send it to the study sponsor. This form will indicate whether it is a substantial or non-substantial amendment. It is the sponsors responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the MHRA and/or REC for review and approval.

If it is a substantial amendment, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice.

The CI and study sponsor will be responsible for notifying NECS (the host NHS organisation in England) and trial sites (GP practices) of any amendments via email using the template emails provided by the HRA.

The amendment history will be tracked by ensuring that the title of the documentation are saved with the version and date each time.

13.13 Post-Trial Care

Participants will be sent a summary of the research findings upon completion of the study. They will continue to receive care as usual.

13.14 Access to the final trial dataset

Only the CI and co-investigators involved in data analyses (FG, RA, MYT, AD, TB) will have access to the full dataset. This will help to ensure that the overall results are not disclosed prior to the main publication. Site investigators will not have access to the full dataset unless a formal request describing their plans is approved by the trial management group

14 DISSEMINIATION POLICY

14.1 Dissemination policy

- Newcastle University owns the data arising from the trial
- With participant permission, study data will be tabulated and made available in an open data repository where it will be archived from at least 10 years.

- There are no time limits or review requirements on the publications.
- NIHR will be acknowledged within the publications
- NIHR have review and publication rights of the data from the trial.
- Participants of the trial will be provided with a written lay summary of the research findings.
- Research participants will not be provided with information about their personal specific results.
- The trial protocol will be made publicly available in an open science database repository and registered on ISRCT upon HRA approval having been obtained.

14.2 Authorship eligibility guidelines and any intended use of professional writers

- Authorship of publications will be based on the criteria outlined by the International Committee of Medical Journal Editors.
- It is anticipated that FG will be the lead author on most outputs from this study.

15 STUDY MILESTONES

Data will be collected at baseline, 3 months post intervention (up to 6 months from baseline), and then again 9 months post intervention (up to 12 months from baseline). Summarised below

Study month	
0-6	*study preparation, approvals, participant identification*
7-12	*patient recruitment, randomisation, baseline data collection*
10-15	*SMAs will be scheduled and patients will receive the intervention within 3 months of baseline data collection*
13-18	*Follow up data will be collected from patients 3 months after the intervention (mid-point)*
22-27	*Follow-up data will be collected 9 months after the intervention (end-point)*
29-36	*Dissemination and definitive trial development*

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18. APPENDICIES

18.1 Appendix 1- Responsibilities of trial management (groups and individuals)

18.1.1 Trial Steering Committee

A trial steering committee has been formed to review study milestones and advise on progression to future work. The chair of the committee is independent researcher based at Oxford university. The steering committee includes experts and patient representatives including:

Chair: Dr Chrysanthi Papoutsi- University of Oxford	Primary Care Health Sciences specialist (conducting SMA research at present- see here)
Prof Samantha Harrison- Teesside University	COPD and pulmonary rehabilitation specialist
Mr Malcolm Cairns	Person living with COPD in NENC
Alexander Moore	Community Pharmacist and Senior Lecturer in Clinical Pharmacy
Dr Andrew Finney	Independent, interested in SMAs in primary care
Dr Fiona Graham	CI
Dr Theo Bigirumurame	Statistician

Chloe Thompson	Administrator

The committee will meet once per year and will send a short report to the study sponsor to advise on study progression. The recruitment, quality of data and safety of participants will be reviewed at each trial steering committee. They will meet at the end of the study and will assess whether the progression criteria to process to a definitive trial have been met.

18.1.2 Data Monitoring (and ethics) Committee

The decision has been made not to have a data monitoring and ethics committee. We do not expect there to be any serious adverse effects amongst those receiving the intervention. As this is a feasibility study, we are collecting information about recruitment, data quality, collection methods and adherence. We are collecting information about hospital visits and medical appointments and referrals as secondary outcome measures and will review these data and the safety of participants at each PMG meeting. Safety of participant will also be reviewed by the TSC annually too.

18.1.3 Project Management Group (PMG)

The PMG will consist of all co-applicants who will produce the study protocol and oversee the progress and achievement of project milestones. The PMG will meet monthly via Zoom for the first 6 and last 6 months of the study and every 3 months in between unless more frequent meetings are needed.

Our PPI co-applicant (SE) and PPI lead (OMcG) will be part of the PMG and will be responsible for ensuring PPI activities are planned and executed. They will recruit additional PPI members at the start of the study who will meet as a group to undertake PPI activities during the project and also join the PMG meetings by telephone or Zoom when appropriate.

18.1.4 Responsibilities of chief investigator (FG) supported by (EK)

- Obtaining local Research and Development and abiding by the polices of research governance.
- Ethics committee approval/communications re: amendments
- Ensuring that no participant is recruited into the study until all relevant regulatory permission and approvals are obtained
- Documenting appropriate delegation of tasks to other study personnel
- Maintaining study documentation and compliance with reporting requests from NIHR and sponsor
- Ensuring that members of the research team are qualified and adhere to the GCP principles
- Financial probity
- (Sponsor) Indemnity, compensation and insurance
- Available for audit, inspections and relevant inspection preparation activities
- Archiving research data
- Responsible for appropriate and relevant reporting as specified in the study protocol (i.e. to authorities, sponsor, CI etc.) Others, as locally applicable

18.1.5 Responsibilities of Research Associate (FG supported by RA)

- The day-to-day management of the trial
- Responsibility of screening and recruitment of primary care practices to the study (FG, JW, JC) and patients
- Informed consent- posting out information to participants
- Completion of Informed Consent Form over the phone/ audio recording.
- Notifying patient's GP of their involvement in the study
- Randomisation allocation to intervention and informing GP practice.
- Maintaining trial master file including copies of study approval, lists of patients and practitioners and their signed informed consent forms
- Ensuring data collected is accurate, timely and complete (including quality checks)
- Provides updates on the progress of the trial
- Ensuring study patients are aware of who to contact should they experience problems during the study (before and after the intervention).

18.1.6 Responsibilities of Co-investigators

- JC and KM will be responsible for delivering the training to healthcare professionals recruited to the study and the intervention delivery and integrity with support from FG and the PMG.
- JC, KM and AS will be responsible for ensuring good quality clinical care and raising and handling medical safety issues that arise during the study.
- FG and a Research Assistant (RA) in Newcastle University (recruited at the start of the study) will be responsible for data collection. FG, RA, MYT, will be responsible for qualitative data analyses overseen by more experienced qualitative researchers (AO and JW) with implementation science expertise (AO).
- TB will be responsible for quantitative data analyses, drawing upon advice from an experienced health economist LV.
- All co-applicants will be involved in the interpretation of the findings and the dissemination via their networks.

18.1.7 Responsibilities of PPI Lead and Public Co-applicant

- OM will lead and coordinate PPI activities, acting as a single point of contact for all public contributors involved in the research. Working with our public co-investigator (SE), she will be responsible for development and delivery of the PPI strategy and will implement appropriate evaluation, monitoring, and reporting e.g., using GRIPP2 guidance and UK Standards for Public Involvement.
- OM and SE will attend steering group meetings from the outset, to provide input to protocol development, study conduct, data interpretation, feedback to participants and support for wider PPI activities. They will be involved in preparing documentation for ethical review and ensuring PPI input is sought throughout the project.

18.1.8 Responsibilities of local collaborator (GP/ Practice manager in practice or their delegate)

- Ensure all staff delegated to work on trial are:
  - Qualified by education, training & experience
  - Thoroughly familiar with study protocol
  - Aware of, and compliant with GCP and any applicable regulatory requirements pertaining to clinical trial conduct or management
- Aware of relevant SOPS relating to SMA delivery
- Documenting adverse events and signing AE forms
- Timely Serious Adverse Events (SAE) reporting and signing of SAE forms
- Screening of patients (Administrator) and confirmation of eligibility (GP)
- Completion and return of eCRFs/CRFs and data queries (practice manager)
- Initiation of and ensuring training is in place for new trial personnel
- Organisation of SMAs

18.1.9 Responsibilities of interventionists

- Attend training in delivering the SMAs
- Be familiar with the SOPs for SMAs
- Deliver the SMA as trained
- Take a register of patients that attend the SMA (attended/did not attend/was not brought) and record if any leave the session early and for what reason
- Complete the fidelity checklists and return to the research team

18.2 Appendix 2 – Authorisation of participating sites

18.2.1 Required documentation for participating sites

- Research passport of CI
- IRAS
- HRA and NHS Ethics approvals
- Insurance certificates
- Local study information pack (Organisation information document- data sharing contract)

18.2.2 Procedure for initiating/opening a new site

The local CRN will identify suitable candidate practices. The CI and/or RA will have an initial meeting (in person/via videoconference) with GPs and practices managers regarding the involvement of their staff and patient in the study. The intervention (SMA) will be delivered by a trained team of healthcare professionals external to the GP practice in which they will be delivered. They will receive training in

delivering the SMA in person and by video. They will be given a SOP that has been created by the CI and co-investigators.

18.3.3 Principal Investigator responsibilities

Practice managers will act as the PI/local collaborator at each GP practice. The PI will attend the initiation meeting/teleconference and be responsible for the training of new members of the trial team in the protocol and its procedures, ensuring that the ISF is accurately maintained, dissemination of important safety or trial related information to all stakeholders within their site, safety reporting within the timelines etc.

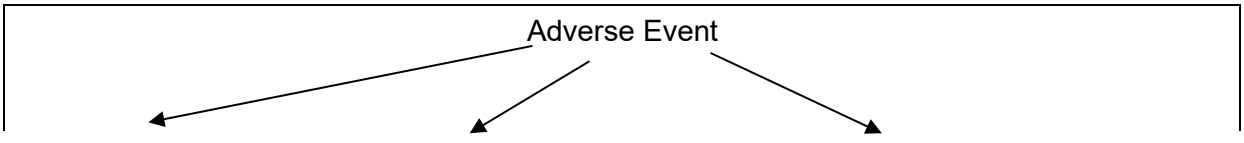
18.3 Appendix 3 – Schedule of Procedures

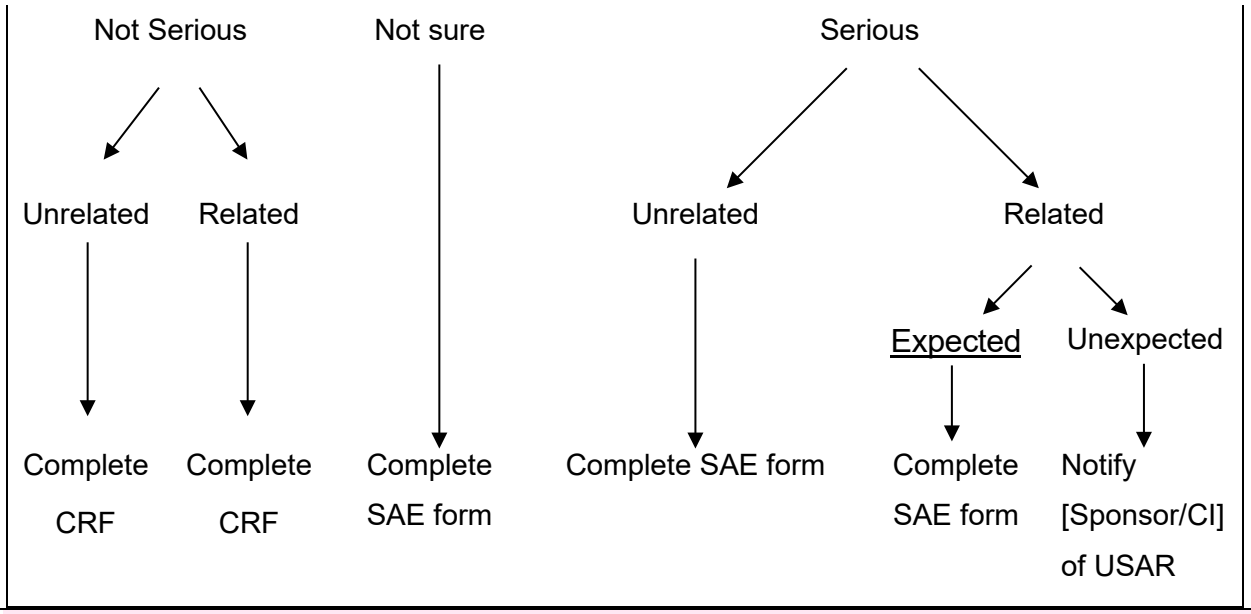
Procedures	Screening	T1 Baseline	Treatment Phase	T2 Post intervention period (4-6 weeks)	T3 Follow Up one (3 months post intervention)	T4 Follow up two (9 months post intervention)
Eligibility assessment by GP	GP review patient records					
Screening logs	Admin call and completion of logs					
Invitation to participate (Eligibility assessment)	Patient contact 1 (by research team)					
Informed consent		Contact 2				
Time point 1 questionnaires incl PCUQ and demographic form (baseline)		Contact 2				
Patient questionnaire (Demographics and group/research experience)		Contact 2				

Randomisation allocation and invite to SMA		Contact 3				
Attendance at SMA			Visit 1 (in person/ online)			
Time and Travel Q1				Patient contact 4		
Patient interview arrangement				Patient contact 4		
Patient interviews				Patient 5		
Practice staff invite to interview				Staff contact 1		
Practice staff interviews				Staff contact 2		
Time point 2 questionnaires incl PCUQ (6 months)					Patient follow-up 1	
Time point 3 questionnaires incl PCUQ (12 months) Time and Travel Q2 (8 months)						Patient follow-up 2 (completion of PCRF form by practice staff)
Resource use questionnaire						Practice staff complete resource use qnaire

PCRF- Patient case report form completed by practice staff

18.4 Appendix 4 –Safety Reporting Diagram





Contact details for reporting SAEs and USARs

Please send SAE form(s) via email to Fiona.graham@newcastle.ac.uk

Or

Call 07511046947

18.5 Appendix 5 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made