

CAN SHARED MEDICAL APPOINTMENTS SUPPORT PEOPLE LIVING WITH COPD?

PARTICIPANT INFORMATION SHEET

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

PURPOSE OF STUDY



Chronic Obstructive Pulmonary Disease (COPD) is a lung condition that affects over a million people in England.

We are trying to find better ways to help people manage their COPD themselves, by monitoring symptoms, using inhalers and other medication correctly and by seeking help when needed.



To support patients, some general practices are trying shared medical appointments (SMAs), where a group of 6-8 patients, with the same condition, share a longer appointment lasting about 60 -90 minutes. Patients can ask staff questions and share their experiences within the group.

We do not know how well SMAs work for patients with COPD or whether it is more costly than usual care. Recently, more care is being delivered by video, but we do not know if this is possible in groups of patients.



This research will test these shared medical appointments in a small study to help decide if a larger trial is possible in the future.

WHAT IS INVOLVED?

We will recruit 132 patients with COPD and allocate them, at random, to one of three groups:



Group 1 will attend a SMA in person (PSMA)



Group 2 will attend a SMA by videocall (VSMA)



Group 3 will not attend a SMA but will receive care as usual

We will:

1. Measure the number of patients that take part and remain in the study
2. Interview patients about their experiences in the study
3. Test how to collect information from patients about NHS use
4. Interview staff about how well shared medical appointments work
5. Test how to collect information about time and money needed to run SMAs

WHY ME?

Your GP practice has identified you as someone who is suitable to take part in this study.

DO I HAVE TO TAKE PART?

No, it is your decision to take part or not. You do not have to give a reason.

HOW WILL TAKING PART IN THE RESEARCH STUDY AFFECT MY CARE?


Your usual care will not be affected in anyway. You will still be able to access all healthcare services as usual during and at the end of the study. Your general practice will invite you to attend an annual review appointment as usual during the 12 month study period.

WHAT WILL HAPPEN IF I TAKE PART?

A researcher will contact you to discuss the study. If you would like to take part you will be asked sign and return the consent form enclosed to show you have understood what is involved and have agreed to take part. Or if you prefer, we can take a recording of your verbal consent by telephone.


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Questionnaire 1




You will be asked to complete some questionnaires about your health, wellbeing and use of healthcare services. You can complete them by post/telephone or online.
- 2


Attend either an in-Person SMA, online Video SMA or usual care







- 3

Questionnaire 2




You will be asked to complete the same questionnaires after 6 months.
- 4

Interview (optional)



You may be invited to take part in a one-to-one interview (face-to-face/ by telephone or video-call) with the research team about your experience of taking part in the study.
- 5

Questionnaire 3



You will be asked to complete the same questionnaires after 12 months.

Once the study has finished we will send you a summary of our research findings if you wish. With your consent, we will tell your GP that you are taking part in this study but they will not see your questionnaire responses or know what you say in the interview.

WHAT ARE THE BENEFITS OF TAKING PART?

By taking part in this study you will help us better understand how well these shared appointments work and who they work for. If you attend an SMA as part of the study you will receive support from healthcare professionals and other people living with COPD. If you attend usual care as part of this study you are helping to provide us with important information that allows us to compare SMAs with usual one-to-one appointments. If SMAs are found to be as good as or better than usual appointments, they might become a part of routine COPD care in future.

WHAT ARE THE RISKS OF TAKING PART?

You may find completing study questionnaires, attending a SMA and/or an interview time consuming. If you attend a SMA you may find seeing those with more severe forms of the condition distressing. If you become distressed during the session you can speak with a member of the healthcare team who will be able to sign post you to support. You may feel uncomfortable discussing your health condition in front of people with COPD. You can choose not to share information about yourself during the session if you wish. Everyone that participates in the study is required to agree not to discuss the health issues of others with people outside the group. All participants attending in-person SMAs will follow general practice guidelines to prevent COVID-19.

WILL I RECEIVE PAYMENT?

You will receive a £10 high street voucher for your time to take part in the study. You will receive a second £10 high street voucher if you take part in an interview. If you attend a SMA in person, your travel costs will be reimbursed. If you attend a VSMA, you will be provided with equipment and technical support as required. This includes the loan of a university insured tablet/ prepaid internet enabled device to be returned after the VSMA.

HOW WILL WE USE INFORMATION ABOUT YOU?

We will need to use information from you/from your medical records for this research project. This information will include your:

- Contact details (NHS number, name, phone number and home address)
- Gender, age, ethnicity, educational attainment and employment status.
- COPD severity, for example the number of flare ups in the last 12 months, medication use
- Healthcare service use, for example the number of visits to GP practice in past 12 months

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your name and contact details will be stored separately from your other data which will have a code number instead of your name. We will keep all information about you safe and secure on university owned computers. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason. To do this please contact the research team by email (fiona.graham@newcastle.ac.uk) or by phone where you can leave us a message or speak to us in person (07511046947). If you choose to stop taking part in the study, we will keep information about you that we already have unless you tell us not to. After the data has been analysed we will not be able to remove your information from the findings. However, data will be anonymous- it will not be possible to identify you. Should you lose capacity to consent during the study, we will delete your name and address. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

WHAT WILL HAPPEN TO THE RESULTS?

The results of the study will be published in research reports and in scientific journals. We will not publish anything that could be used to identify you. With your consent, we will keep your contact details for up to 12 months once the project has finished so we can share with you our research findings. After this your details will be deleted.

To support future research and decision making, information collected from you during this study, such as questionnaire responses and interview transcripts, will be anonymised and stored for up to 10 years. A code will be used instead of your name and anything that could identify you will be removed from the data. With your permission, this anonymous data will be shared with other researchers via an online public database.

WHO IS ORGANISING AND RESPONSIBLE FOR THIS RESEARCH?

The research project is organised by a team of researchers at Newcastle University and the NHS North of England Commissioning Support Unit (which is part of the NHS responsible for ensuring best use of NHS resources). The study sponsor and data controller is Newcastle University.

This study has been reviewed by The North of Scotland (1) Research Ethics Committee.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?

You can find out more

- by asking one of the research team or calling us on 07511046947
- at www.hra.nhs.uk/information-about-patients/
- by contacting Newcastle University Data Protection Officer: rec-man@ncl.ac.uk

CLOSER LOOK: WHAT WILL HAPPEN IF I TAKE PART?

Everyone that takes part will be asked to complete a set of 3 questionnaires on three different occasions: when you join the study, 6 months after you join and 12 months after you join.

You will have the option to complete them by post (they will be posted to your home address with a free post return envelope). Alternatively, a member of the research team can give you a call and complete them over the phone. Or if you prefer we can email you a link so you can complete them online.

Questions will be about your COPD symptoms, physical and mental health and how you manage your COPD. We will also ask you about your use of healthcare services. For example, how many times have you visited the general practice/ accident and emergency in the last 12 months about your COPD

In-person shared medical appointment (PSMA)

Some people will be invited to attend a PSMA. This will involve attending a general practice close to you where you live and joining an appointment with 6-7 other people with COPD. You will receive a letter from the GP detailing the time and location of the session. The appointment will be run by a healthcare team from your local area. There will be group discussion about living with COPD which will be followed by individual consultations with a healthcare professional (pharmacist/nurse practitioner) with others listening-in. You can share as much or as little as you wish. The appointment may last 90 mins.

Video shared medical appointment (VSMA)

Some people will be invited to attend a VSMA. This will involve joining an online video call from a private space (for example your home) using your smart phone, computer or tablet (these will be provided as needed). You will receive an e-mail and/or letter (according to your preference) from your GP detailing the date and time of the session, with a link and accompanying instructions on how to join.

When you click on or type the link, you will be taken to an online forum where you will be able to interact with the healthcare team, and other patients with COPD in the group. There will be group discussion about living with COPD which will be followed by individual consultations with a healthcare professional (pharmacist/nurse practitioner) with others listening-in. You can share as much or as little as you wish. The appointment may last upto 90 mins.

Interview (optional)

Some people will be invited by the research team to take part in an interview that will last around 60 minutes (depending on how much you have to say). It will be in person, by phone or videocall, you can choose. Questions will be about your views and experiences of SMAs including: what you like, what you don't like. There are no right or wrong answers. We would like to record the interview using an audio recorder. Your name will be removed from the audio file before it shared securely with a UK transcription company who will type up the interview so we can analyse what was said. This company will handle your data securely in line with General Data Protection Regulation.

What if something goes wrong?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions, call 07511046947. If you remain unhappy and wish to complain formally, you can do this by contacting Newcastle University Research Integrity and Governance team at: research.integrity@ncl.ac.uk.

In the event that something goes wrong, you may have grounds for compensation against Newcastle University or via the NHS indemnity scheme, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.