Title: Reliever inhaler monitoring using Smart Rescue
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Participant Information Sheet

Reliever inhaler monitoring using Smart Rescue

Full title: Exploring patients' use of reliever inhalers for asthma monitored using Smart Rescue: a mixed methods study

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand what the aim of the research is and what it will involve. This document contains important information that you should read before deciding to take part in the study. You are welcome to discuss the information with other people, and you may e-mail us to ask any questions if anything is unclear, or if you would like to request more information. Take time to decide whether you would like to take part.

What is the purpose of this study?

Patients with asthma use inhaler medications on a regular basis to reduce symptoms and prevent asthma flare-ups/attacks ('preventer' inhalers), or as needed when experiencing symptoms ('reliever' inhalers). 'Reliever' inhalers may be either an inhaler (usually blue) containing a single medicine used just for relief of symptoms, or it may be a combination inhaler that you use regularly for both prevention and relief (sometimes described as a MART (Maintenance and Reliever Therapy) regime), or just as needed (sometimes described as an AIR (Anti-Inflammatory Reliever) regime).

Typical blue reliever inhaler

Typical combined reliever inhalers (MART/AIR)

We know that higher use of reliever inhalers can be related to worse asthma control, which can lead to having more asthma symptoms, and more asthma flare-ups/attacks, which need extra treatment and can sometimes be serious needing hospital treatment.

Smart Rescue is a device and app which has been developed to track inhaler use, which means we can look in more detail at people's patterns of inhaler use. We are a group of researchers at the University of Oxford interested in finding out more about when and why people with asthma use their reliever inhaler, and how they have found using Smart Rescue to record this.

Why have I been invited to take part?

You have been invited to take part because you have responded to a notification on the Smart Rescue app informing you about the study. You can take part if you are 18 years old or over, have asthma and use 'reliever' inhalers (any regime/type), and are a Smart Rescue user. You

must also be UK-based and registered with a GP (we do not need their details). We are hoping to recruit 15-25 participants for this study.

Do I have to take part?
No. It is up to you to decide whether to take part. You can withdraw yourself from the research, without giving a reason, by advising us of this decision at any time before or during the interview. Shortly after you have completed the interview, your data will be combined anonymously with other data for analysis, so it will not be possible to withdraw it.

What will happen to me if I choose to take part in the research?
You will take part in an online or telephone interview e.g. using Teams/Zoom, arranged at a time to suit your schedule. This will be with the researcher (Manon Roberts) and will be audio-recorded (not video). In the interview we will ask you questions about your asthma and how you manage it, how you use your reliever inhalers and how you have found using Smart Rescue. We will use the information recorded by Smart Rescue as part of this discussion, so will either ask you to share it with us in advance of the interview, or for your permission to get it from the app developers using your Smart Rescue device ID. We will also record some basic information about you (age, gender, ethnicity, level of education, UK region) to ensure we are including a range of people in the study, as well as asking you questions from the Asthma Control Test, a commonly used questionnaire to assess how well controlled your asthma is.

You will be asked at the beginning of the interview to give consent to take part in the interview, and the researcher will make a written record of this. You will receive a copy of the signed consent form via e-mail.

Will I be reimbursed for my time?
To thank you for your time in taking part in our study, you will be offered a £30 Amazon gift voucher which will be sent to you via email after the interview has been completed. If you prefer not to receive an Amazon voucher, we can offer an alternative although there may be a delay in arranging this.

What are the advantages of taking part?
There are no direct advantages for you if you take part. Talking and reflecting on your asthma management might help guide how you manage your asthma or your future discussions with your usual asthma health care professional. The researcher doing the interviews is a medical student who is appropriately trained to do the interviews but can't give clinical advice about your asthma management, so any clinical concerns or queries about your asthma should be directed to your usual asthma care provider e.g. GP, practice asthma nurse or specialist asthma team. We will share with you your results of the Asthma Control Test score and share links to evidence-based resources about asthma management e.g. Asthma+Lung UK website.

Findings from the study will be used to help inform future strategies for delivering patient-centred asthma management, so taking part in the study could help other patients with asthma in future.

What are the possible disadvantages of taking part?
There are no real risks or disadvantages to taking part in this study. The main thing that you must consider is if you're happy to take part in an interview to discuss how you manage your asthma. This could involve discussion about your daily routine and what triggers your asthma, which may include discussion of your mental and physical health or stressful events. You do not need to answer any questions you don't want to.

What will happen to my data?
Smart Respiratory Ltd (who make Smart Rescue) have information on your inhaler use but this is completely anonymous (they can't identify you from it) which is why you have been invited by an app notification.
The device/app manufacturers will not have access to any additional personal data you provide: this will remain within the University of Oxford.

Your interview will be transcribed (typed up from the audio recording), but we will remove any identifiable information to make sure that you cannot be identified from the transcript. The transcript is important so that we can look back at the answers that you gave, to analyse and interpret it. Original audio recordings will be destroyed once analysis of interviews is complete and no more than one year after the interview. Transcripts of interviews and information about you gathered in the interview will be stored electronically for 5 yearson a secure University of Oxford server, and will be only identifiable by a unique participant identifier.

Your name will only appear on the consent form, which will be stored separate to your transcript/audio recording securely on University servers for five years after the interview has taken place.

Contact details for the purpose of this research such as your e-mail address, for arranging the interview and sending an online gift voucher, will be kept on a password-protected spreadsheet stored securely and deleted shortly after your interview has taken place. If you wish, we can also keep your e-mail address longer term on a separate password-protected spreadsheet to inform you of the study findings when they are reported or published (up to a maximum of 3 years).

The University of Oxford is the data controller with respect to your personal data and, as such, will determine how your personal data is used in the research. The University will process your personal data for the purpose of the research outlined above. Research is a task that we perform in the public interest. Further information about your rights with respect to your personal data is available from https://compliance.web.ox.ac.uk/individual-rights.

The University of Oxford has no control over, or responsibility for, the operation of the Smart Rescue app or how the data provided to it is used. The privacy policy for the Smart Rescue app can be found here https://smartasthma.com/privacy-policy-summary.

Who has reviewed this research?
This research has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee (ethics approval reference R93604/RE001).

Who is organising and funding the research?
This study is organised by Dr Helen Ashdown, who is a GP and Clinical Lecturer in the Nuffield Department of Primary Health Care Sciences, University of Oxford. The study is being carried out by Manon Roberts, a medical student at the University of Oxford, as part of her undergraduate degree. The research is funded through internal University of Oxford funding for student projects. Smart Respiratory Ltd have provided us with anonymous information about inhaler use and have sent app notifications on our behalf to invite people to take part in the study, but have no role in the funding or analysis of the study. None of the researchers involved have any financial or other interest in Smart Respiratory Ltd that would be a conflict of interest.

Who do I contact if I have a concern about the research, or if I wish to complain?
If you have a concern about any aspect of the research, please contact Dr Helen Ashdown (helen.ashdown@phc.ox.ac.uk), and she will do her best to answer any questions. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy and wish to make a formal complaint, please contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) team at rgea.complaints@admin.ox.ac.uk or on 01865 616480.

Further information and contact details
If you would like to take part in the study, or to discuss the research further, please contact manon.roberts@jesus.ox.ac.uk.