Title: Comparing peak flow meters (Monitoring study)
Ethics reference: R89259/RE001
V1.0 (24th October 2023)
PI: Helen Ashdown helen.ashdown@phc.ox.ac.uk

UNIVERSITY OF OXFORD
NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Participant Information Sheet (Monitoring Study)

Comparing peak flow meters

Method comparison of digital vs. mechanical peak flow meters in an in vivo and real-world setting

You are being invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether you wish to take part.

Why is this research being conducted?

Peak flow meters are widely used in health care to measure how quickly air can be blown out of the lungs. They are particularly used in the diagnosis and monitoring of asthma, where the airways can become narrowed and peak flow is reduced. Normal peak flow varies by age, sex and height and in asthma may be reduced compared to predicted values.

Mechanical peak flow meters have been used for many years, but more recently a digital peak flow meter (Smart Peak Flow) has become available which records results electronically on an individual's smart phone app (Smart Asthma) and allows data sharing with health professionals. It is available to purchase by individuals via Amazon and has been provided to patients in some health care settings, but is not yet widely used. It has been tested in laboratories, which showed good performance, but the accuracy compared to traditional peak flow meters has not been tested in real people.

In this study we want to test how accurate the new Smart Peak Flow meter is, compared to a mechanical peak flow meter, over a period of time in people with asthma, and gather feedback about how they have found using it. This will give further information about whether it is sufficiently accurate to use in routine health care and recommend to patients.

Mechanical peak flow meter

Smart Peak Flow digital peak flow meter

Title: Comparing peak flow meters (Monitoring study)
Ethics reference: R89259/RE001
V1.0 (24th October 2023)
PI: Helen Ashdown helen.ashdown@phc.ox.ac.uk

UNIVERSITY OF OXFORD
NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Why have I been invited to take part?

You have been invited to take part because you have responded to an advertisement for the study or have been asked if you would be willing to take part after participating in another linked study about Smart Peak Flow. Anyone aged 18 years or older can take part (or 17 or older if you are a registered student at the University of Oxford) if you have asthma requiring regular treatment with inhalers (every day, not just occasionally) and have a smart phone on which you can download the Smart Asthma app. We are hoping to recruit 10-20 participants for this study. You cannot take part if you are not able to perform peak flow testing, have an active respiratory infection or a chronic respiratory disease other than asthma.

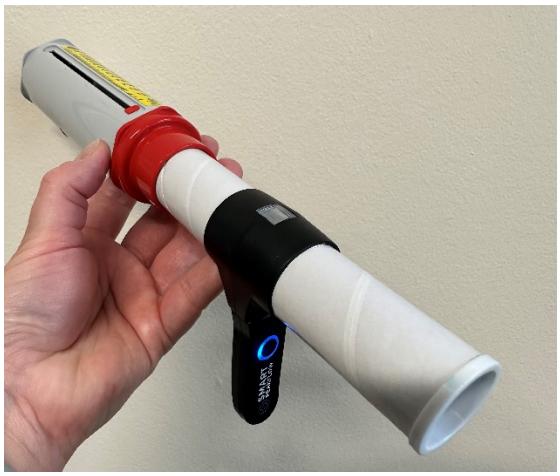
What will happen to me if I take part in the research?

If you decide to take part, the researcher will arrange a mutually convenient time and place to go over the study and answer any questions you may have, check you can take part and, if you are still happy to take part, ask you to sign an informed consent form. There are two parts to the study – initial recording of peak flow measurements (which you may have done already as part of another linked study), and a monitoring study that you do at home over a period of two weeks completing a study diary booklet (which can be returned by post, so only one in-person meeting needed).

(1) *Initial recording of peak flow measurements*

We will ask for a few details about you: your age, sex assigned at birth (as this is most closely related to adult lung size), estimated height and whether your asthma is controlled or uncontrolled. We will then show you how to perform peak flow measurements using the mechanical peak flow meter. This involves blowing out as hard and fast as possible into a tube, either standing or sitting upright. It sometimes takes a few tries to get the technique right.

We will then ask you to perform further peak flow measurements into the digital peak flow meter, which will be connected to the mechanical peak flow meter, as shown below.



We will record three blows, allow a 30 second pause, another three blows, a further 30 second pause, and then a final three blows (nine blows in total). We will change the mechanical peak flow meter between each three sets of blows. These measurements should take less than five minutes in total.

(2) Monitoring study

The researcher will provide you with a new mechanical peak flow meter and new Smart Peak Flow meter (including manufacturer product information). The researcher will help you install the Smart Asthma app and connect the Smart Peak Flow meter to your smart phone, and show you how to connect the two meters together, and provide some spare connectors.

The researcher will give you a study diary booklet and the researcher will go through with you how to complete this, but there will also be reminder instructions in the booklet. The booklet will include some questions about you and your asthma, and spaces to record your peak flow readings. We will ask you to record your peak flow readings, 3 times on each occasion in quick succession, twice daily for two weeks (14 days). This is the recommended frequency of monitoring when home peak flow monitoring takes place in routine clinical practice, and does not have to be at a strict time. You should record these readings in your study diary, along with recording if/when you have used your reliever inhaler. The researcher will e-mail you to check how you are getting on during the two weeks and can answer any questions.

At the end of the two weeks, we will also ask you to complete a survey (found at the end of the study booklet. This is an Asthma Control Score (a widely used scale for monitoring asthma control) and a survey about how you have found using the peak flow meters. We will then ask you to return the study booklet, which can either be by post (the researcher can provide you with a stamped address envelope at the initial study visit) or arrange a mutually convenient time for collection.

What are the possible disadvantages or risks in taking part?
There are no risks or disadvantages in taking part. Peak flow measurements require forced breaths out, which some people find uncomfortable and/or can cause them to cough. All data will be anonymised, and participants will not be identifiable from the data we record.

The Smart Peak Flow meter and mechanical peak flow meter (the MiniWright) are CE-marked and licensed for use in clinical practice. Disposable mouthpieces will be used and non-disposable parts will be cleaned with medical disinfecting wipes between each participant, so there is no risk of cross-contamination of devices between participants. Those with an active respiratory infection will not be eligible to take part to reduce spread of infection to the environment through coughing/forced breaths.

We can share your initial peak flow readings with you if you wish, however this is not a diagnostic test or a way of receiving health care input on your asthma management. Peak flow readings vary

between individuals by age, sex, height and technique and we will not be able to calculate your predicted peak flow at the time of the study (online calculators exist for this). If you identify as having uncontrolled asthma, or if you are experiencing respiratory symptoms, we would advise you to seek advice from your health care professional in the usual way. You are welcome to make a copy of your study booklet before returning it, for your own records and/or to share with your health care professional if you should wish.

In order to use the Smart Peak Flow meter at home, you will need to download and register for the Smart Asthma app – this is free but requires an e-mail address for set-up, and asks your gender, year of birth, height, country and basic information about your asthma as part of the set-up process, and agreement to the app's terms and conditions. You can provide additional information on the app if you wish but this is not necessary for use of the device. The researcher can help with set-up.

Are there any benefits of taking part in the research?
There will be no direct or personal benefit to you from taking part in this research. However, testing accuracy of peak flow meters will help inform their use in routine health care practice in future in the diagnosis and monitoring of asthma. There is no payment for participating in this study. However, you may keep the two peak flow meters if you wish, which retail for £10 (MiniWright) and £50 (Smart Peak Flow).

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 during the study. After you have completed the study and submitted your study diary, your data will be combined anonymously with other data for analysis, so it will not be possible to withdraw it.

What will happen to the results of the research?
The findings from the research will be written up as part of a student project. We expect them to be presented in conference presentations and/or published in academic journals. It will not be possible for participants to be identifiable from the outputs of this research, and if we use any free text comments from your survey we will ensure that there is nothing which could potentially identify you. If you would like to find out about the results of the study, you may write your e-mail address in the space on the consent form (entirely optional).

What will happen to my data?
We will collect research data as described above, but this will not be linked to your name or any identifiable details. Your name will only appear on your consent form which will be stored separately. Your results data will only be linked to a number. The anonymous data will be stored electronically on study databases stored on secure computers and servers. We will keep a copy of your consent form but this will be kept separate to any research data, in a locked filing cabinet in a University of Oxford department, for three years after publication. If you choose to give your e-mail address to be informed of study results, this will be transcribed from your consent form to

a secure password-protected document not linked to study ID number and used only for this purpose and deleted afterwards, and kept for a maximum of 3 years after the end of the study. The researcher will separately keep your contact details for keeping in touch during the two week study, which will be stored in a password-protected file. These details will be removed after return of the study booklet or up to two months after its expected return.

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 Asthma app or how the data provided to it is used. The privacy policy for the Smart Asthma app can be found here https://smartasthma.com/privacy-policy/.

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 reference: R89259/RE001).

Who is organising and funding the research?
The research is organised by Dr Helen Ashdown who is a GP and Clinical Lecturer in the Nuffield Department of Primary Care Health Sciences, University of Oxford. The research is being carried by Eldona Kupa who is a medical student, as part of her undergraduate research project. The research is funded through internal University of Oxford funding for student projects. The Smart Peak Flow meters are being provided at cost price by the manufacturer and they have reviewed the plans for the study, but they have no role whatsoever in the conduct or analysis of the study.

Who do I contact if I have a concern about the research, or I wish to complain?
If you have a concern about any aspect of this research, please contact Dr Helen Ashdown (helen.ashdown@phc.ox.ac.uk) and she will do her best to answer your query. She will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible: ethics@medsci.ox.ac.uk; Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford OX3 7GB.

Further Information and Contact Details
If you would like to discuss the research further or to get in touch to take part, please contact: eldona.kupa@new.ox.ac.uk.