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| Digital therapeutics for long-term conditions**J:\Medicine\CTU\CTU Operation\01 Template CTU Documents and Logos\Logos\SCTU logo\Final-Logo copy.jpg**UKCRC Registered CTUs Logo - white |
| **Patient Information Sheet** |
| **Study Title:** A randomised controlled study to explore the safety and efficacy of the mySmartCOPD treatment re-alignment algorithm as part of a digital self-management app in patients with COPD  **Lay title:** Exploring the safety and effects of the mySmartCOPD system for COPD patients  **Chief Investigator:** Professor Tom Wilkinson  **Sponsor: University of Southampton** (Reference**:** ERGO 81603)  We would like to invite you to take part in the mySmartCOPD research trial run by researchers at the University of Southampton and My mHealth.  Please read the information below to understand why the research is being done and what it will involve. If anything is not clear or you would like more information before you decide to take part in this research, you can contact the trial team on: 02380 599194 |
| **Why are we doing the MySmartCOPD trial?** |
| We are studying a new digital tool (mySmartCOPD) to see whether it can help COPD patients get onto the right medication for their symptoms. Receiving the right medication can help patients control their symptoms, lower the risk of COPD flare-ups (exacerbations) and avoid side effects from over-medication. |
| **Who is this trial for?** |
| This trial is for COPD patients who have used the myCOPD app in the last 12 months. If you agree to take part, the information collected on the myCOPD app will be used by the trial team to ensure that the trial is suitable for you.  To take part in this trial ,all participants must be able to read and write in English without assistance. |
| **More about MySmartCOPD** |
| The mySmartCOPD system is the trial intervention. It is an additional feature to the myCOPD app that has been developed and tested by researchers at the University of Southampton and My mHealth.  mySmartCOPD will look at the data you enter in the myCOPD app, specifically your:   * + Monthly COPD Assessment Test (CAT) scores.   + Daily symptom scores (including rescue pack use and hospital visits).   + Regular COPD medication.   mySmartCOPD will compare your data to the standard guidelines for COPD medication and send you a notification to tell you whether you are on the best medication for your COPD symptoms. If you are not on the best medication, the myCOPD app will ask you to book a COPD medication review with your usual healthcare team (such as nurse or GP). Your healthcare team can then review the notification information on your app and discuss with you whether your regular COPD medication should be changed. |
| **Do I have to take part?** |
| No, it is entirely up to you to decide whether or not to take part, but the mySmartCOPD system is only available to trial participants. |
| **If I join the** **trial, will I have access to the mySmartCOPD system?** |
| This trial is a ‘randomised trial’. This means we put people into groups randomly, with one group using the new mySmartCOPD system as part of their myCOPD app (intervention group), and the other group continuing to use the current myCOPD app as usual (control group). The results are then compared to see if one is better. If you join the trial, you will randomly be put into one of these two groups for the duration of the trial. |
| **What will happen if I take part?** |
| You will be asked to use myCOPD as you usually would for the next 6 months, as well as complete some monthly questionnaires and contact your healthcare team if the myCOPD app suggests it.   |  | | --- | | Joining the trial   1. **Consent** - You will be asked to provide your consent to take part in the research being conducted. This will be done via the University of Southampton electronic consent system. We will also collect your month and year of birth and ethnicity to help us understand the characteristics of the people taking part in the trial. 2. **Eligibility** - Once your consent is received, a trial clinician will double check your data from the myCOPD app to make sure the trial is suitable for you. 3. **Randomisation** - If you can take part, you will then be assigned (or “randomised”) to either receive the mySmartCOPD system within your myCOPD app; or remain on the myCOPD app as normal. The myCOPD app will tell you which group you are in and provide further instructions to help you through the trial.   During the trial   1. **COPD Symptom Scores** – You will be asked to enter your COPD symptom scores daily. 2. **COPD Medication** – You will be asked to update your regular COPD medication if the medication changes. 3. **Questionnaires** – Once a month, you will be asked to complete:    * Short in-app trial questionnaires to see if there are any changes in your health since the start of the trial.    * An additional University of Southampton questionnaire to ask if you have seen your healthcare professional about your COPD; visited hospital; or feel that taking part in the trial has made you unwell.   End of trial   1. After 6 months on the trial, you will be asked to complete the final trial questionnaires and then your participation on the trial will be complete. 2. If you were in the intervention group, the mySmartCOPD system will be switched off on your account and you will return to the regular myCOPD app.   **Optional** – mySmartCOPD Discussions and the EQUATE trial  If you optionally consent, we would like to contact you between 3 to 12 months after starting the trial to talk about your experience using the mySmartCOPD system.  We are also working with researchers from the **University of Southampton EQUATE trial**, who are investigating how technology can help or make it more difficult to take part in health research. You can optionally consent for us to securely share your contact details and some information about yourself (age, gender, ethnicity) with the EQUATE team, who will then contact you and provide more details about the EQUATE trial. | |
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| **Help with the mySmartCOPD system - Patient Advocates** |
| If you are assigned to use the mySmartCOPD system and require help arranging a medication review or relaying information to your healthcare team, a team of non-medical advisers (called ’Patient Advocates’) working on the trial can help book COPD medication reviews for you and support you during the appointments. This is optional and it is completely up to you whether you want them to help.  These advisers are employed by my mhealth to help patients with new healthcare services and technologies. You can learn more about the patient advocates on page 4 of this information sheet. |
| **Are there any benefits in my taking part?** |
| The data you provide as part of the trial will help us understand the best ways of getting people with COPD onto the treatment that is right for them. We hope that this will improve the day-to-day symptoms of COPD patients and reduce the risk of hospitalisation due to COPD flare-ups. |
| **Are there any risks involved?** |
| The myCOPD app that you usually use has been given approval to be used in the UK and therefore, has a UKCA mark. The app that you will use during this trial does not have a UKCA mark as it is being tested in this trial. However, the mySmartCOPD system has been fully validated prior to the trial and will recommend the guideline-compliant medication for your symptoms. Additionally, all medication decisions will be made between you and your healthcare team. The mySmartCOPD system cannot make any changes to your medication on its own. |
| **What data will be collected and how will it be kept confidential?** |
| For us to conduct the trial, we will need to collect certain information about you, such as:   * Your name * Your contact details (telephone number, email address) * Your demographics (age, gender, ethnicity)   Information about your GP practice.  We will also use the data you enter into the myCOPD app or trial questionnaires to see the impact of the mySmartCOPD system, or to compare against if you are in the control group.  We will let your GP know that you are taking part in this trial. Other than that, your participation and the information we collect about you during the course of the research will be kept strictly confidential.  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. All data used for analysis will be de-identified. This means that any data that could identify you is replaced with a code or number. No identifiable data such as your name and contact information will be shared outside of those staff who require it to conduct the trial unless you provide your explicit consent for us to do so. De-identified research data will be retained for 20 years in keeping with regulatory requirements.  Any identifiable data collected on the University of Southampton electronic consent system will be stored securely on the University of Southampton servers and will not be stored with any health data received from the myCOPD app or in the trial questionnaires.  Staff from Southampton Clinical Trials Unit and patient advocates working on the trial will see information such as your name, contact details and outcomes of medication reviews within the myCOPD app and may contact you to help with trial activities. You do not need to accept this help if you do not want to.  People will use this information to do the research or to check your records to make sure that the research is being done properly. 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.   |  | | --- | | **Where can you find out more about how your information is used?** |   You can find out more about how we use your information   * By accessing the Health Research Authority website at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/) * From the leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch) * by asking one of the research team by sending an email to **mysmartCOPD@soton.ac.uk** or ringing us on 02380 599194. * By emailing the Sponsor’s Data Protection Officer [**data.protection@soton.ac.uk**](mailto:data.protection@soton.ac.uk)   For information about how the University of Southampton collects and uses your personal information when you take part in one of our research projects, please see our Privacy Notice:  <https://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf> |
| **What happens if I change my mind?** |
| You have the right to change your mind and withdraw at any time without giving a reason and without your use of the myCOPD being affected. To withdraw, contact the trial team on: 02380 599194    If you withdraw from the trial, we will keep the research data we have already obtained for the purposes of achieving the objectives of the trial only, unless you state otherwise. We will also keep a copy of your consent form to confirm your initial consent to take part in the trial. |
| **What will happen to the results of the research?** |
| The results will be analysed and presented at national and international meetings; and will also be published in a medical journal. A simple summary of the findings will be sent to all trial participants.  The information collected about you may be used to support other ethically-approved research in the future and may be shared in a de-identified form with other researchers.  The results of the trial will be used to apply for UKCA marking for the mySmartCOPD system. |
| **What happens if there is a problem?** |
| All research is looked at by a Research Ethics Committee, to protect your interests. This trial has been reviewed and given a favourable opinion by RECXXXXXXXXXX, REC ID: XX/XX/XXXX. Furthermore, this trial has received Professional Indemnity and Clinical Trials Insurance from the University of Southampton, should something go wrong.  If you have a concern about this trial, please contact the researchers via telephone 02380 599194 or email ([mysmartcopd@soton.ac.uk](mailto:mysmartcopd@soton.ac.uk)). If you have a complaint, please contact the University of Southampton Research Governance Office (023 8059 5058, [rgoinfo@soton.ac.uk](mailto:rgoinfo@soton.ac.uk)). If you are harmed due to someone’s negligence, then you may have grounds for legal action but you may have to pay legal costs. |

**Thank you for taking the time to read this Patient Information Sheet**

If you have questions about any aspect of the Patient Information Sheet, please contact the trial team on: 02380 599194

**Additional Information**

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| **Description of Patient Advocate role in the mySmartCOPD Trial**  **Who are patient advocates?**  Patient advocates are employees of my mhealth, which is the company behind the MyCOPD app. Patient advocates are not medical professionals and have no clinical training. For this trial, patient advocates are employed to help participants who are assigned to use the mySmartCOPD system.  **How can patient advocates help?**  Patient advocates are there to support you with the mySmartCOPD trial, but only if you decide that you would like their support. In the trial, if you are allocated to use the mySmartCOPD system, you may receive messages from the app telling you the outcome of the medication review that mySmartCOPD performs for you. The outcome of this will be either that it suggests you book an appointment with a healthcare team to discuss your medication, or that you do not need to do this. The patient advocate can help you in three ways:   1. They can help you to understand this message and what you need to do once you receive it. 2. They can help you to book an appointment with a healthcare team. 3. They can help you to discuss the message from the app with the healthcare team during the appointment.   **What will the patient advocates know about me?**  Patient advocates will have access to a list of patients using mySmartCOPD, including:   1. Patients’ names 2. Patients’ email address and phone number 3. Patients’ GOLD grouping (this explains how severe patients’ COPD symptoms are for the medication review) 4. The outcomes of the medication reviews that the app has performed for patients 5. Whether patients have already discussed the medication review with their healthcare team and, if so, when this was.   **What contact will I have with the patient advocate?**  The patient advocate will contact you if their list shows that you have not yet spoken to a healthcare team about the medication review that might be suggested by the app. They will contact you by phone or email and they will ask if you would like support in arranging an appointment and/or talking to the healthcare team. **It is up to you if you would like this support, as we understand that you may prefer to do this yourself.** **You may choose to not have their involvement.**  If any of the above information isn’t clear or you have any questions, please contact the trial team for more information on 02380 599194 |