**Predict&Prevent**

**Healthcare Professional Interview Study**

**Participant Information Sheet and Consent Form**

**What is the purpose of the Predict&Prevent Clinical Investigation?**

Patients with COPD have daily symptoms of breathlessness, cough and/or sputum production. These symptoms can progress and be made worse exacerbations, during which breathlessness increases and daily activities become more difficult to perform. If not suitably treated, these exacerbations can progress further so that a stay in hospital may be necessary.

There is no reliable solution at the moment that can help to monitor patients with COPD and predict when these exacerbations are going to occur.

The aim of our study is to try a monitoring solution which consists of a patient App (COPDPredictTM BASIC) which combines information from symptoms, spirometry and blood measurements that patients with COPD can perform at home, in conjunction with a web-based dashboard for a research team to monitor patients. This App will allow a patient to view their progress, receive information of a change in their health such as possible exacerbations and respond to self-management and treatment plans.

The dashboard will allow the research team to have access to patient information, monitor a patients’ health and also provide treatment recommendations via messaging, telephone or if necessary, to organise a nurse-led home visit. Hopefully this will prevent serious problems from developing and admission into hospital.

The Predict&Prevent Clinical Investigation is being conducted at your site, as you know, and we would like to invite you to provide consent for us to interview you to gain your opinions on:

1. How you found the COPD in CheckTM to use (technology acceptability usability/utility via questionnaires and interviews).
2. Acceptability of the intervention, including any implementation issues.

This will include an audio-recorded in-depth interview with one of the *qualitative researchers involved in the study.* Your participation in this qualitative research is voluntary. Under no circumstances will you be identified in any way in any report, presentation or publication arising from this or any other study.

The University of Birmingham is the Sponsor and will also act as the data controller for this study. This means that the University of Birmingham are responsible for looking after your information and using it appropriately. All information collected about you for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018 for health and care research and will be kept strictly confidential. All information collected will be archived for 25 years as per protocol.

All information collected by the Sponsor will be securely stored at the University of Birmingham on paper and electronically and will only be accessible by authorised personnel. The only people in the University of Birmingham who will have access to information that identifies you will be people who manage the study or audit the data collection process. In the Trials Office, you will be identified by a unique study number.

Analysis of the audio-recordings will be undertaken by the qualitative research team from University of Birmingham. Access to this data will be restricted to members of the research team at the University of Birmingham. The recordings will be made on an encrypted device (password protected) and saved using a study ID and not your name. You will never be identified in any publications but we may quote your words anonymously. All audio-recordings will be kept for 10 years after the end of the study. With your consent, we would like to keep audio-recordings indefinitely to help us with future training, teaching and research into randomised controlled trial (RCT) recruitment.

University of Birmingham and will keep identifiable information about you for at least 25 years after the study has finished, to allow the results of the study to be verified if needed

You can withdraw your consent to our processing of your data at any time. Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. Under the provisions of the General Data Protection Regulation (GDPR) 2018, you have the right to know what information the Trials Office has recorded about you. If you wish to view this information, or find more about how we use this information, please contact Legal Services at the address overleaf. Please note that a small fee may be payable to retrieve this information.

Legal Services

University of Birmingham

Edgbaston

Birmingham, B15 2TT

If you are worried about any part of this study or have a complaint, you should ask to speak to the researchers who will do their best to answer your questions. If you wish to complain formally, then the normal National Health Service complaints mechanisms will be available to you: please ask to speak to [insert local details of independent advice service as per local trust policies] or you can contact the trial office at [predictandprevent@trials.bham.ac.uk](mailto:predictandprevent@trials.bham.ac.uk) or telephone 0121 415 9133.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ***This form should be completed by the participant.*** | | ***Please initial each box:*** | | | | | |
|  |  |  | | | | | |
| 1. | I confirm that I have received enough information about this research and have had the opportunity to ask questions. These questions have been answered clearly and satisfactorily. |  | |  | | | |
|  | | | | | |
|  |  |  | | | | | |
| 2. | I agree to take part in an in-depth audio-recorded interview about my views on how COPD in CheckTM was to use ***(not all people will be asked to have an interview)*** |  | | |  | | |
|  |  |  | | | | | |
| 3.. | I understand that I am free to withdraw from the study at any time without giving a reason and that withdrawing from the study will not affect my legal rights. |  | | | |  | |
|  |
|  | ***For Statement 5 please tick Yes or No:*** | **Yes** |  | | | | **No** |
| 5. | I agree for my data to be retained for training, teaching and research purposes, now and in the future, with personal identifiers removed. |  |  | | | |  |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of participant Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Researcher Signature Date

1 copy for participant; 1 for research team