"A qualitative study exploring patients' acceptability and practical responses to the Predict and Prevent AECOPD to self-manage COPD"

Patient Information Sheet

You are invited to take part in a research interview about your experiences of being involved in the Predict and Prevent trial. Before you decide, you need to understand the purpose of the research and what it will involve if you decide to take part. Please take time to read the following information carefully and feel free to ask the researcher any questions you may have.

Why have I been invited?

You have been invited to participate in this study because you are taking part in the Predict and Prevent AECOPD trial and you agreed that you were happy to be contacted about participating in the interview study.

What is the purpose of the study?

The study aims to understand your perceptions and experiences of being involved in the Predict&Prevent AECOPD trial. The overall goal is to explore any benefits and challenges you might have encountered while self-managing your condition.

What will I be asked to do if I agree to participate in the study?

You will be asked to take part in a discussion with a researcher from the project (a "research interview") that will be audio recorded. This interview will last about an hour and could take place face-to-face, on the telephone or via online software such as Skype or Zoom. Before you take part, you will be asked to sign a consent form. We will then ask you some basic information about yourself such as gender, age and ethnicity. We may use this information when we write up the study results, but we will never do so in a way that identifies you.

What will happen during the interview(s)?

The researcher will ask you some questions about your experiences living with COPD, using technologies to help self-manage your condition and your views of being involved in the Predict and Prevent study. The researcher will have a list of topics that they wish to cover during the discussion, but these are only a guide.

If you are asked any questions in the interview that you would rather not answer, please say so and the interviewer will move on to a different question.

The interview will take place at a date, time and place that is convenient for you. It may take place face-to-face, online on a video conferencing system such as zoom, or on the telephone, according to your preferences and the current government guidelines on social distancing due to COVID-19.

What are the possible benefits of taking part?

This study will help us to find out if supporting patients at home using information entered into mobile devices, such as electronic tablets, is better at helping patients manage their COPD symptoms. There may be no immediate benefits to you by taking part, but the aim is to improve the care for patients with your condition in the future.

What are the possible disadvantages and risks of taking part?

We do not anticipate any risks or disadvantages as a consequence of taking part, only the use of your time.

What if I do not want to take part?

It is up to you to decide whether or not to take part. It is entirely your choice. With any aspect of the study you can always change your mind and it will not affect any other aspect of your care. If you do decide you want to take part, the researcher will have given you a copy of this information sheet to keep and you will be asked to sign a consent form.
You can change your mind about your participation ("withdraw") any time before or during your interview and up to two weeks afterwards, without needing to give a reason and without any negative impact on the care you receive. After two weeks we will no longer be able to link you to the recorded and typed versions of your interview (they will be anonymised) so we will not be able to remove you from the study after that time.

What happens when the research study stops?

The results of this research will be used to guide the potential use of mobile devices by individuals with COPD and better inform health professionals about the challenges that face people who live with COPD so they can improve care.

Who is organising and funding the research?

The study is sponsored by the University of Birmingham (meaning The University of Birmingham has accepted certain legal and ethical responsibilities for the study), is being coordinated by the Birmingham Clinical Trial Unit (BCTU) and is funded by the government through the NIHR Invention for Innovation (i-4-i) programme.

Who has reviewed the study?

All clinical research that takes place in the NHS is looked at by an independent group of people which protect patient interests. This group is called a Research Ethics Committee (REC) and Predict&Prevent AECOPD has been reviewed and given a favourable opinion by London-Stanmore Research Ethics Committee.

Will my taking part in this study be kept confidential?

All information about you will be handled in confidence. All information provided throughout this research is protected under the General Data Protection Regulation and the UK Data Protection Act (2018). The data (including the recordings) will be held by the University of Birmingham and will be securely stored. The study will do its utmost to keep your information confidential, therefore your name will not be mentioned in any report of this research.

We will ask your permission to record the study interview using a secure audio recorder. After a two-week period (where we wait to check that you are happy for your data to be used), we then ask a reputable company to produce a written version of the recording called a transcript. The company will need to sign a confidentiality agreement before they do so. We then remove all identifying information from the transcript (such as names and places). After this, we will delete the original recording. It will then no longer be possible to link you to your data, i.e. it will be completely anonymous.

The data from your interview will be anonymised *before* it is analysed. The research team who will be involved in analysing the data include professional qualitative researchers, clinical experts and patient representatives, but they will not know your name or any other personal details about you that could identify you. We will only use anonymised quotes from the transcript in any publication or report.

It may be necessary to allow authorised personnel from government regulatory agencies or the Sponsor to have access to your research records. This is to ensure that the study is being conducted to the highest possible standards. Anonymised data from this study may be used for teaching or shared with other researchers for research purposes. If you would prefer that your anonymized data was not used for any purposes other than for this particular study, then you can indicate this on the consent form.

Very occasionally, interviews bring to light information about a participant that could affect their welfare or the welfare of others (such as safeguarding concerns). If this happens during your interview then the researcher may have a legal or professional obligation to disclose this information to the relevant authority/agency, which overrides issues of confidentiality.

What if something goes wrong?

We do not envisage any problems occurring as a result of your participation in the study. If you have any concerns or questions about this study, please contact the research team (details can be found at the end of this information sheet). Alternatively, you can discuss these with the member of the research team who will conduct the interview. Please feel free to ask any further questions before deciding to take part in the interview. If you are harmed in any way, insurance is in place to deal with any negligence.

What will happen to the results of the research study?

The findings from this study will be analysed by the research team and published in peer reviewed journals and presented at conferences/events/meetings, without any reference to any named/identifiable individual. If you would like to know the results of the research, we are happy to provide you with a summary. Please let the research team know when you sign the consent form that you would like to be informed of the final results.

Contact Information

If you would like to speak to someone about the study please contact:

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Or

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