FOUND

Finding Obstructive sleep apnoea Using a Novel Device

Trial title: Case finding of obstructive sleep apnoea in primary care using a novel device: a randomised controlled trial – FOUND

PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in this research trial; your participation is entirely voluntary. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us. Our contact details can be found at the end of this participant information sheet.

WHAT IS THE PURPOSE OF THE TRIAL?

Obstructive Sleep Apnoea (OSA) is a relatively common sleep disorder where the walls of the throat relax and narrow during sleep, interrupting normal breathing. This may lead to regularly interrupted sleep, which can have big impact on your quality of life and if untreated, leads to increased risk of developing certain diseases, such as obesity, diabetes, high blood pressure, heart attacks and strokes. More information about OSA can be found here: Sleep apnoea - NHS (www.nhs.uk)

The current practice of OSA screening varies across the UK with complex referral pathways to specialized clinics not available in all hospital across the country.

The FOUND trial will compare a new GP-based route using a device called AcuPebble with the current referral pathways for the diagnosis of OSA.

WHO IS ORGANISING AND FUNDING THE TRIAL?

The trial is being led by the University of Warwick in collaboration with the University Hospital Coventry & Warwickshire NHS Trust, the University of Oxford, the University of Birmingham and the Charity Hope2Sleep. This trial is funded by the National Institute for Health and Care Research Invention for Innovation (NIHR i4i) programme.

WHY HAVE I BEEN INVITED?

You have been invited to take part because you are aged between 50 and 70 years and according to your GP records have one or more of the following conditions which may increase your risk of OSA:

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- Type 1 or Type 2 diabetes
- High blood pressure
- A BMI (body mass index) >30kg/m^2

The University of Warwick did not have access to any of your personal or medical information as part of the invitation process. The University of Warwick collaborates with GP practices across the West Midlands, of which your practice is one, who help to identify people who may be suitable and interested in taking part in research.

DO I HAVE TO TAKE PART?

No, it is up to you whether you take part or not. You will be given time to think about whether you would like to take part in this trial. If you do decide to take part in the trial, you will be asked to sign a consent form at your first appointment. A member of the research team will go through the consent form with you and answer any questions you may have. You are free to withdraw at any time without giving a reason. A decision to withdraw from the trial will not affect your usual health care in any way.

WHAT WILL HAPPEN IF I WANT TO TAKE PART?

Informed consent

If you are interested in taking part, you will be invited to book an initial appointment at your GP practice with a member of the research team or a research nurse. They will ask you some questions to check if you are suitable for the trial and answer any questions you may have. The appointment should not take longer than 45 minutes. We will ask you to sign a consent form agreeing to take part in the trial. You will be able to keep a copy of your consent form. If you cannot come to your GP practice for this appointment, it may be possible to visit you at home.

Baseline questionnaires

After consenting to take part in the trial, you will be asked to complete short questionnaires about your quality of life and lifestyle.

Randomisation

You will then be randomly allocated to either the intervention group (using the AcuPebble) or the usual care group (control group), and notified of the next steps. This means that half the people who join the trial will use the AcuPebble device (intervention group) and the other half will continue with their usual care (control group)**.** You will not be able to choose which group you are in as this is decided randomly, like tossing a coin.

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Intervention group

If you are allocated to the intervention group you will receive by post an overnight sleep testing device, called an AcuPebble, from Acurable with instructions via a mobile app. The device is like a small plastic button the size of a 10p coin with an adhesive tape that allows it to be stuck to the skin at the level of the throat. You should stick it on before going to sleep and keep it on overnight, while you sleep. The app includes several animation videos that make the instructions very easy to understand. Acurable will provide user support to you if you need it. If you do not have a mobile phone one will be provided with the test device.

You will be asked to use the device for 1 night, on a night that is convenient to you, within a week of receiving the device. Should the test fail, you will be asked to repeat the test the following night using the same device and a new adhesive tape (spares provided in the pack) before the device is returned in pre-paid addressed envelope.

The data collected by the AcuPebble will be used in the study, but it will not be linked to any identifiable information about you. The results of the AcuPebble sleep test will also be sent to your GP, who will contact you if any further action is needed.

Control group

If you are allocated to the control group you will not have to do anything different. Your GP will continue to care for you as normal. That is, you will continue to access your GP for appointments should you feel you have the need to do so.

6 Month Follow-up

After six months, all participants (intervention and control group) will be asked to complete follow-up questionnaires. These can be completed online or on paper as you prefer. A pre-paid reply envelope will be provided for paper questionnaires.

Your medical records will also be reviewed for any information relating to possible OSA symptoms, diagnoses and treatment which have occurred during your time in the trial (i.e. since your first visit with the research team).

WHAT SHOULD I CONSIDER?

To be able to take part in the trial, we need to confirm that you do not have any of the following conditions:

- Known OSA,
- Known moderate-to-severe chronic obstructive pulmonary disease (COPD),

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- Known allergy to acrylate (clear rigid plastic).

If you agree to take part in the trial, you would need to:

- Follow your allocated trial group to the best of your ability,
- Allow us to collect data from you, depending which trial group you are in,
- Complete questionnaires at the initial (baseline) visit and again after 6 months.

ARE THERE ANY POSSIBLE DISADVANTAGES OR RISKS FROM TAKING PART?

This trial uses a sleep study device that is already used in hospitals and will be used in line with its current approvals. Although there are no known serious risks associated with the device, some people using the device may experience mild discomfort. The control group will receive usual care. Therefore, there are no known serious risks involved in taking part in this trial.

Most of the questionnaires we will use in this trial have been previously used in other studies and we do not expect these would cause you any distress.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Your participation will help us understand how best to identify people who may have OSA and protect their health for the long-term**.** From this trial we hope to find out whether using the hospital-based referral route (usual care) or the new GP-based route using the AcuPebble device (intervention) is most effective for the identification of OSA.

WILL I BE REIMBURSED FOR TAKING PART?

We will be unable to provide expenses or payments as part of this trial.

WILL MY GENERAL PRACTITIONER/FAMILY DOCTOR (GP) BE INFORMED OF MY PARTICIPATION?

Your GP has invited you to take part in this study and will be aware of your participation. If you are allocated to the intervention group, your GP will receive the findings of your AcuPebble test. If this indicates that you have OSA, your GP will notify you and he/she will refer you to your local sleep clinic. If your test does not show OSA, your GP will notify you that no further action is needed.

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If you are allocated to the control group, your GP will be informed that you are part of the trial and your GP will continue to care for you as normal.

Taking part in the trial will not affect care you receive from your GP for any other unrelated conditions.

Will my taking part in the trial be kept confidential?

Any information that is collected about you during the course of the research will be kept strictly confidential. We will use codes to avoid identifying you with your name.

Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the trial to ensure that the research is complying with the appropriate regulations.

What will happen to my data?

The University of Warwick and the University of Oxford have standard procedures set up to store all your information securely.

We will need your contact information to contact you at six months. Your contact details will be stored separately from the other information we collect about you to make sure no one can identify which information is yours. Once the trial is finished, we will anonymise all the data collected (i.e. you will only be identified by a code number), so that it is not possible to know that the data came from you.

UK General Data Protection Regulation (GDPR) requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Warwick (the sponsor for this trial, based in the United Kingdom) is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records in order to undertake this trial and will use the minimum personally-identifiable information possible. We will keep identifiable information about you until after the trial has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Warwick for 10 years after the end of the trial. You will not have to do anything for us to collect this information.

AcuPebble is a registered NHS device and data will be stored in the UK. Fully anonymised trial data only accessed by registered users, will be stored on regularly backed up, university password-accessible data drives, in accordance with GDPR and your consent.

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Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice

You can find out more about how we use your information by contacting GDPR@warwick.ac.uk.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE TRIAL?

Your participation is voluntary. If you decide you do not want to take part in the research at any point that is fine, and you can withdraw at any time without giving a reason. We will give you the opportunity to tell us the reason for withdrawing if you would like to. Your current and future medical care will not be affected.

If you wish to withdraw from the intervention, we would like to ask you to continue in the follow-up so the true reflection of the impact of the intervention on the outcomes of the trial can be maintained.

If you wish to withdraw from the follow-up, we will use the data that has been collected up to the point at which you decide to withdraw from the trial. We would continue to use this anonymised data after your withdrawal from the trial.

WHAT WILL HAPPEN TO THE RESULTS OF THIS TRIAL?

The trial results will be presented at scientific meetings and published in a scientific journal. You will be not identified in the presentations and publications.

We will also communicate the trial findings through the Hope2Sleep network, Sleep Apnoea Trust and media engagement in order to increase the awareness of OSA within the primary care community and public. A stakeholder engagement dissemination event will be held at the end of the trial.

WHAT IF SOMETHING UNEXPECTED IS FOUND?

Your results/findings will be sent to your GP for review, and he/she will be in touch if anything unexpected was found.

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WHAT IF THERE IS A PROBLEM?

The University of Warwick, as Sponsor, has appropriate insurance in place in the very unlikely event that you suffer any harm as a direct consequence of your participation in this trial. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this trial, you should contact the co-chief investigators, Dr Michelle Miller on 02476 575104 or Professor Francesco Cappuccio on 02476 573129 or FOUND@warwick.ac.uk or you may contact the University of Warwick Research and Impact Services office sponsorship@warwick.ac.uk or on 02476 575733.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research trial. If you wish to get in touch with the PALS team please contact them at PALS@ouh.nhs.uk.

HOW HAVE PATIENTS AND THE PUBLIC BEEN INVOLVED IN THIS TRIAL?

Patients with OSA and representatives from the sleep charities Hope2Sleep and the Sleep Apnoea Trust Association were involved in the design of this trial. Members of the public tested the device and provided feedback to the study team. Three public contributors are members of committees overseeing the trial and will provide input from the patient and public perspective throughout the trial.

WHO HAS REVIEWED THE TRIAL?

All research in the NHS is reviewed by an independent group of people called the Research Ethics Committee, who protect your rights, safety, wellbeing and dignity. This trial has been reviewed and given favourable opinion by South Central – Oxford A Research Ethics Committee.

FURTHER INFORMATION AND CONTACT DETAILS:

If you want to discuss the trial in more detail please contact us on:

Tel: 02476 574654

Email: FOUND@warwick.ac.uk

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