ISRCTN16982033 https://doi.org/10.1186/ISRCTN16982033

A randomised controlled trial to identify Obstructive Sleep Apnoea (OSA) in primary care

Submission date
21/06/2023

Recruitment status
No longer recruiting

Registration date
03/07/2023

Overall study status
Completed

Last Edited
20/10/2025

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Obstructive Sleep Apnoea (OSA) is a sleep problem which causes the breathing tubes to become slightly or completely blocked during sleep. The brain, detecting low blood oxygen levels, sends signals that cause the person to wake up, restoring normal breathing. OSA increases the risk of dying from heart disease and stroke. It often causes daytime sleepiness and increases the risk of road traffic accidents.
Awareness levels of OSA in the UK are low. It is estimated that up to 85% of people with OSA remain undiagnosed and untreated. Currently, a patient with symptoms that indicate OSA needs a GP referral to specialist hospital services to attend hospital, collect and be instructed on how to use the overnight sleep study equipment, return it the next day and wait for data analysis and hospital follow-up appointment. Pre-pandemic, the waiting time for a referral to a sleep clinic in Coventry was over 4 months. The AcuPebble SA100, the first medical device to obtain official product approval for the automated diagnosis of OSA, can be posted to a patient; with results immediately calculated and sent to the hospital Sleep Specialist. The British Lung Foundation estimated the annual savings to the NHS in the UK would be £28 million if all people with moderate to severe OSA were diagnosed and treated.
Our research aims to find out if the AcuPebble can be used in a General Practice setting for moderate-to-severe OSA diagnosis.

Who can participate?
Patients aged 50 -70 years with diabetes and/or high blood pressure and BMI over 30 kg/m².

What does the study involve?
We will invite patients who may be at higher risk of OSA (overweight, have hypertension, diabetes or both) to take part in the study and split into two groups. One group (intervention) will complete a home overnight sleep study using the AcuPebble. The other (control) group will continue as normal (referred to hospital via the traditional pathway if presenting a sleep study need). Individuals diagnosed with OSA in either group will be referred to treatment through existing pathways.
We will compare the number of diagnoses of OSA in the two groups, looking at how well this new approach works compared to the current hospital-based referral route, and whether it is value for money for the NHS. If this strategy is successful in detecting moderate-to-severe OSA,

it can be rolled out in primary care to improve the detection and treatment of OSA. Better detection would reduce risks and improve health and wellbeing with fewer long-term health conditions.

What are the possible benefits and risks of participating?
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.
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 the 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 any distress.

Where is the study run from?
University of Warwick (UK)

When is the study starting and how long is it expected to run for?
November 2022 to October 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Emma Scott, e.j.scott@warwick.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Emma Scott

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Additional identifiers

Integrated Research Application System (IRAS)
323422

Central Portfolio Management System (CPMS)
56660

National Institute for Health and Care Research (NIHR)
203393

Study information

Scientific Title
Case finding of obstructive sleep apnoea in primary care using a novel device: a randomised controlled trial (FOUND)

Acronym
FOUND

Study objectives
Current study hypothesis as of 26/06/2024:

We propose, with the support of the Coventry and Warwickshire CCG/ICS and the associated sleep service at University Hospital Coventry and Warwickshire NHS Trust, to test the feasibility of moving the testing for OSA into a General Practice setting using the AcuPebble device and to trial a targeted moderate-to-severe OSA case finding programme.
Aims:
1. To determine if it is feasible to move testing for moderate-to-severe OSA from the hospital-based sleep centres into general practice using the validated AcuPebble device.
2. To determine if case finding using the AcuPebble device in a general practice setting increases the detection rate of moderate-to-severe OSA.
3. To determine if general practice-based screening is cost-effective.

Objectives:
1. To determine if using this device would increase the detection of moderate-to-severe OSA in high-risk groups within general practice.
2. To assess the cost-effectiveness of screening for moderate-to-severe OSA with AcuPebble in primary care versus usual care in people at high-risk.
3. To compare a hospital-based referral route with a new general practice-based route for the diagnosis of moderate-to-severe OSA.

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Previous study hypothesis:

We propose, with the support of the Coventry and Warwickshire CCG/ICS and the associated sleep service at University Hospital Coventry and Warwickshire NHS Trust, to test the feasibility of moving the testing for OSA into a GP setting using the AcuPebble device and to trial a targeted OSA case finding programme.
Aims:
1. To determine if it is feasible to move testing for OSA from the hospital-based sleep centres into general practice using the validated AcuPebble device.

2. To determine if case finding using the AcuPebble device in a general practice setting increases the detection rate of OSA.
3. To determine if GP-based screening is cost-effective.

Objectives:
1. To determine if using this device would increase the detection of OSA in high-risk groups within general practice.
2. To assess the cost-effectiveness of screening for OSA with AcuPebble in primary care versus usual care in people at high-risk.
3. To compare a hospital-based referral route with a new GP-based route for the diagnosis of OSA.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/06/2023, South Central Oxford A (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 207 1048276; oxford.rec@hra.nhs.uk), ref: 23/SC/0188

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Case finding of obstructive sleep apnoea in primary care

Interventions
Current interventions as of 26/06/2024:

WP1: Feasibility.
The study will include an internal feasibility phase to assess the fidelity of the delivery of the new device in General Practice and its acceptability to patients and primary care teams. We will review recruitment of practices, participant recruitment and randomisation, baseline data collection, and completion of AcuPebble overnight study, allowing modifications to the main trial before its recruitment starts.

WP2: Randomized trial.
Trial design.
Randomised controlled trial of case-finding of moderate-to-severe OSA in primary care using a novel MHRA-registered device (AcuPebble® SA100) compared to usual care, with internal feasibility phase to assess fidelity of delivery of the device, acceptability to patients and primary care team. After eligibility screening, consent and baseline assessment, 1,426 eligible participants randomised 1:1 to Intervention or Control group. Due to the nature of the

intervention, participants and General Practitioners will not be blinded to the allocation. However, the primary outcome assessment will be automated.
Participants will be followed up at 6 months.

Interventions.
Participants randomised to the Intervention Group will receive by post the overnight sleep testing device, including an Epworth Sleepiness Score questionnaire. No hospital attendance is required, and use of the device does not require training. The test is comfortable and non-invasive. It uses a small device about the size of a 2p coin which is attached to the throat with small piece of medical adhesive tape. There are no leads or wires. Most participants will only need to wear the device for one night. A repeat test may be required if the first test fails for any reason but the device has a <1% failure rate.
Participants in the Control Group will continue with usual care.

Baseline data collection.
All participants will have their height and weight measured, complete the EQ-ED-5L (5 questions plus visual analogue scale) and Client Service Receipt Inventory (CSRI). They will also be asked to self-identify their ethnicity.

Randomisation.
Participants will be randomised (1:1) to receive the intervention or usual care using a validated web-based randomisation programme (Sortition). Randomisation will be minimised with a non-deterministic minimisation algorithm to ensure site, age, sex, ethnicity, BMI, diabetes (yes/no), hypertension (yes/no) are balanced across the two groups. Individual randomisation is appropriate because the risk of contamination is very low since the device is sent to participants directly. Due to the nature of the intervention, participants and the GPs will not be blinded to the allocation of intervention. The primary outcome assessment, however, will be automated minimising risk of bias.

Data collection.
For the intervention group only, the AcuPebble device will record sleep study data to enable the automated diagnosis of moderate-to-severe OSA. As part of the routine data collected for the sleep study, they will also complete the Epworth Sleepiness Scale and some brief questions about their experience of using the AcuPebble. These are standard questions presented on the AcuPebble platform.
Data from the sleep study will be reviewed by the clinical co-applicant. Participants who test positive for OSA will be contacted via their general Practitioner with their results and referred to the hospital for treatment. Participants with borderline results or any other cause for clinical concern will be referred to the hospital for further investigation. Any subsequent visits and treatment by the GP or Sleep Clinic are not part of the research and represent a return to the usual care pathway postdiagnosis.
At six month follow up, all participants will be asked to complete the EQ-5D-5L and CSRI again. They will also be asked some brief questions relating to OSA symptoms, diagnosis and treatment. Participants will be given the choice of completing these questionnaires online or on paper, both versions will be sent to them to complete at home by email or post, according to their preference. GP patient notes will be reviewed for those in the intervention group who received a positive diagnosis of moderate-to-severe OSA following their sleep study to establish if treatment has commenced, when it commenced and what treatment is being given. Any patients who were referred for further investigation following their sleep study will also have their notes reviewed to determine whether there has been a subsequent moderate-to-severe

OSA diagnosis. GP notes will be reviewed for all participants in the control group to check for diagnoses of moderate-to-severe OSA since randomisations and for those diagnosed, if and when treatment has commenced and what treatment is being given.

Economic analysis.
An economic evaluation will assess the cost-effectiveness of screening for moderate-to-severe OSA with AcuPebble in general practice compared to referral to a hospital for a home respiratory polygraph. The analysis will be undertaken from the NHS and Personal Social Services (PSS) perspective. Should additional information on productivity loss resulting from time off paid employment become available, we would consider additional analyses that include these wider costs. We will conduct a systematic literature review to identify existing economic evidence regarding OSA diagnosis and treatment. Insights from this, and input from clinical experts will inform the structure of a de novo decision model to be used to assess the cost-effectiveness of the compared options.

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Previous interventions:

WP1: Feasibility.
The study will include an internal feasibility phase to assess the fidelity of the delivery of the new device in GP and its acceptability to patients and primary care teams. We will review recruitment of practices, participant recruitment and randomisation, baseline data collection, and completion of AcuPebble overnight study, allowing modifications to the main trial before its recruitment starts.

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Interventions.
Participants randomised to the Intervention Group will receive by post the overnight sleep testing device, including an Epworth Sleepiness Score questionnaire. No hospital attendance is required, and use of the device does not require training. The test is comfortable and non-invasive. It uses a small device about the size of a 2p coin which is attached to the throat with small piece of medical adhesive tape. There are no leads or wires. Most participants will only need to wear the device for one night. A repeat test may be required if the first test fails for any reason but the device has a <1% failure rate.
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For the intervention group only, the AcuPebble device will record sleep study data to enable the automated diagnosis of OSA. As part of the routine data collected for the sleep study, they will also complete the Epworth Sleepiness Scale and some brief questions about their experience of using the AcuPebble. These are standard questions presented on the AcuPebble platform.
Data from the sleep study will be reviewed by the clinical co-applicant. Participants who test positive for OSA will be contacted via their GP with their results and referred to the hospital for treatment. Participants with borderline results or any other cause for clinical concern will be referred to the hospital for further investigation. Any subsequent visits and treatment by the GP or Sleep Clinic are not part of the research and represent a return to the usual care pathway postdiagnosis.
At six month follow up, all participants will be asked to complete the EQ-5D-5L and CSRI again. They will also be asked some brief questions relating to OSA symptoms, diagnosis and treatment. Participants will be given the choice of completing these questionnaires online or on paper, both versions will be sent to them to complete at home by email or post, according to their preference. GP patient notes will be reviewed for those in the intervention group who received a positive diagnosis of OSA following their sleep study to establish if treatment has commenced, when it commenced and what treatment is being given. Any patients who were referred for further investigation following their sleep study will also have their notes reviewed to determine whether there has been a subsequent OSA diagnosis. GP notes will be reviewed for all participants in the control group to check for diagnoses of OSA since randomisations and for those diagnosed, if and when treatment has commenced and what treatment is being given.

Economic analysis.
An economic evaluation will assess the cost-effectiveness of screening for OSA with AcuPebble in GP compared to GP referral to a hospital for a home respiratory polygraph. The analysis will be undertaken from the NHS and Personal Social Services (PSS) perspective. Should additional information on productivity loss resulting from time off paid employment become available, we would consider additional analyses that include these wider costs. We will conduct a systematic literature review to identify existing economic evidence regarding OSA diagnosis and treatment. Insights from this, and input from clinical experts will inform the structure of a de novo decision model to be used to assess the cost-effectiveness of the compared options.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
AcuPebble® SA100

Primary outcome(s)

Current primary outcome measure as of 26/06/2024:

To compare the detection rate of moderate-to-severe OSA in high-risk groups within General Practice between the intervention and usual care groups between randomisation and 6 months follow-up general practice notes review.

Previous primary outcome measure:

Number of participants diagnosed with moderate-to-severe OSA, defined as an AHI reading of 15 to 30 (moderate) or >30 (severe) episodes per hour from the AcuPebble report (intervention group) or GP notes review at six months (control group).

Key secondary outcome(s)

Current secondary outcome measures as of 26/06/2024:

1. To compare the duration of time to diagnose moderate-to-severe OSA between the intervention and usual care groups between randomisation and diagnosis of moderate-to-severe OSA. Baseline, 6 months general practice notes review.
2. To compare the duration of time to diagnose individuals with evidence of EDS/OSAS between the intervention and usual care groups between randomisation and date treatment starts. Baseline, 6 months general practice notes review.
3. To compare the duration of time to test for OSA/OSAS in high-risk groups within general practice between the intervention and usual care groups between randomisation to completion of testing for OSA/OSAS.
4. To compare the duration of time to start treatment between the intervention and usual care groups between randomisation to treatment start.
5. To compare the incremental cost-effectiveness of the intervention over usual care from both the NHS and societal perspectives using Health Care resources EQ-5D-5L and CSRI at baseline and 6 months general practice notes review.
6. To compare the detection rate of OSA (mild, moderate or severe), in high-risk groups within general practice between intervention and usual care groups.
7. To compare the detection rate of OSAS in high-risk groups within general practice between intervention and usual care.

Feasibility: To assess fidelity of the delivery of the new device in General Practice. Looking at:
1. Acceptability to patients
2. Acceptability to primary care team
3. Number of practices recruited
4. Number of participants recruited
5. Data completion at baseline, 6 months, GP notes review

Previous secondary outcome measures:

1. Time to diagnosis of OSA (for those with a positive diagnosis) from OSA questionnaire and GP notes review at six months.
2. Time to start treatment (for those with a positive diagnosis) from OSA questionnaire and GP

notes review at six months.
3. Health-related Quality of Life is measured using the EQ-5D-5L and the accompanying visual analogue scale (VAS) at baseline and six months.
4. Incremental cost-effectiveness of the intervention over usual care from both the NHS and societal perspectives using data from the EQ-5D-5L and CSRI at baseline and 6 months.

Feasibility: To assess fidelity of the delivery of the new device in General Practice. Looking at:
1. Acceptability to patients
2. Acceptability to primary care team
3. Number of practices recruited
4. Number of participants recruited
5. Data completion at baseline, 6 months, GP notes review

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. Age 50 - 70 years
2. BMI>=30 kg/m² as of GP records in the last 3 years
3. Diabetes (type 1 or 2) OR hypertension (office BP > 140/90 mmHg or on treatment) OR both diabetes and hypertension

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
1427

Key exclusion criteria
1. Patients with known OSA
2. Patients with known moderate-to-severe COPD
3. Those deemed unable to take part by their GP (e.g. terminally ill)
4. Patients with known allergy to acrylate

Date of first enrolment
01/07/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Warwick
University House
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from michelle.miller@warwick.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/07/2024	29/07/2024	Yes	No
Participant information sheet	version 1.0	09/06/2023	03/07/2023	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes