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Testing a home sleep monitoring system for sleep apnoea

Submission date
04/11/2025

Recruitment status
No longer recruiting

Registration date
06/11/2025

Overall study status
Completed

Last Edited
27/02/2026

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Obstructive sleep apnoea (OSA) is a common condition where the throat repeatedly closes during sleep, causing disturbed sleep and drops in oxygen levels. It increases the risk of high blood pressure, heart problems and accidents. The usual test for diagnosing OSA is a home sleep study. Home sleep studies use several sensors and access to testing is limited. This study aims to find out whether a new ambulatory monitoring system (AMS), which uses fewer sensors with only a small chest patch and wrist-worn pulse oximeter, can detect breathing and oxygen changes as accurately as the current used home sleep tests.

Who can participate?
Adults aged 18 years and over who have been referred to the Oxford Sleep Unit because their doctor suspects sleep apnoea can take part. People with an allergy to medical adhesive used for the chest patch cannot take part.

What does the study involve?
Participants will use both the new AMS and the standard home sleep test on the same night, followed by up to five more nights using the AMS alone. They will attend up to three short visits at the Oxford Sleep Unit to receive and return equipment and complete short questionnaires about comfort and ease of use. All monitoring is non-invasive and done at home during normal sleep.

What are the possible benefits and risks of participating?
There is no direct benefit to participants, but their involvement will help test a new, simpler way to diagnose sleep apnoea that could improve access to testing in the future. Risks are very low: the devices are CE-marked and widely used. A small number of people may experience mild skin irritation from the adhesive patch.

Where is the study run from?
The study is being conducted at the Oxford Sleep Unit, Churchill Hospital, Oxford, and led by the University of Oxford (UK).

When is the study starting and how long is it expected to run for?
September 2025 to March 2026

Who is funding the study?
The study is funded by the NIHR Oxford Biomedical Research Centre and the Oxford Sleep Research Fund (UK).

Who is the main contact?
Dr Chris Turnbull, christopher.turnbull@ndm.ox.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Integrated Research Application System (IRAS)
350021

Protocol serial number
66154

Study information

Scientific Title
Evaluating an ambulatory monitoring system in obstructive sleep apnoea: a proof-of-concept study

Acronym
EASY OSA

Study objectives

Primary objective:
To investigate the feasibility of using an Ambulatory Monitoring System (AMS) which consistents of a chest patch and pulse oximeter) to detect overnight >3 % desaturations compared to clinical standard respiratory polygraphy (RP)

Secondary objectives:
1. To investigate the feasibility of using an AMS (chest patch and pulse oximeter) to detect apnoeas and hypopnoeas compared to clinical standard RP
2. To assess the feasibility and patient experience of using an AMS

Exploratory objectives:
1. To compare sleep metrics (apnoea-hypopnoea index, oxygen desaturations index and hypoxic burden) between AMS and RP
2. To explore the night-to-night variability of sleep apnoea severity measured by AMS

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/09/2025, North East - Newcastle & North Tyneside 2 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; N/A; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 25/NE/0168

Study design
Single-arm prospective cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Obstructive sleep apnoea

Interventions
This is a single-centre, prospective, non-randomized pilot study designed to assess the feasibility of using a novel ambulatory monitoring system (AMS) to detect respiratory disturbances in people with suspected obstructive sleep apnoea (OSA).

Each participant will undergo a paired overnight comparison between the AMS and standard home respiratory polygraphy (RP) on night 1. The AMS will then continue recording for up to 5 additional nights (maximum of 7 nights total).

The AMS comprises a wireless chest patch (VitalPatch™, VitalConnect Inc.) measuring ECG, respiratory rate, posture, and movement, and a wrist-worn pulse oximeter (Nonin WristOx2 BLE, Nonin Medical Inc.) measuring oxygen saturation and pulse rate. Both devices connect via Bluetooth to a tablet for data upload. RP will be performed as part of routine clinical care.

Intervention Type
Other

Primary outcome(s)
The feasibility of using an Ambulatory Monitoring System (AMS) which consists of a chest patch and pulse oximeter to detect overnight >3 % desaturations compared to clinical standard respiratory polygraphy (RP). This will be assessed on night 1 of the study.

Key secondary outcome(s))
1. The feasibility of using an AMS (chest patch and pulse oximeter) to detect apnoeas and hypopnoeas compared to clinical standard RP, assessed on night 1 of the study.
2. The feasibility and patient experience of using an AMS, assessed on day 5-7 of the study, at the final study visit.

Exploratory objectives:
1. Sleep metrics (apnoea-hypopnoea index, oxygen desaturations index and burden) of AMS and RP assessed on night 1 of the study.
2. Night-to-night variability of sleep apnoea severity measured by AMS on nights 1-5 of the study (all nights up to the final study visit, visit 3)

Completion date
01/03/2026

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation in the study
2. Aged 18 years or above
3. Referred with required suspected obstructive sleep apnoea

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Allergy or intolerance to hydrocolloid adhesive used for AMS chest patch attachment

Date of first enrolment
13/11/2025

Date of final enrolment
20/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Churchill Hospital
Old Road
Headington
Oxford
England
OX3 7LE

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Funder Name
Oxford Sleep Research Fund

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon reasonable request after all analysis have been complete, no later than one year after the planned end of study date. Please c ontact Chris Turnbull (christopher.turnbull@ndm.ox.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	01/08/2025	06/11/2025	No	Yes
Protocol file	version 1.0	01/08/2025	06/11/2025	No	No