

# Testing a home sleep monitoring system for sleep apnoea

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<b>Registration date</b> 06/11/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/11/2025	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 at 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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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
350021

**ClinicalTrials.gov (NCT)**  
Nil known

**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 consists 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**

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## **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**

Adult

## **Lower age limit**

18 years

## **Sex**

All

**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

United Kingdom

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 contact 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?
<a href="#">Participant information sheet</a>	version 1.0	01/08/2025	06/11/2025	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version 1.0	01/08/2025	06/11/2025	No	No