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

Internal Reference Number / Short title: EASY-OSA

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	Nuffield Department of Medicine
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Chief Investigator Signature:	

There are no conflicts of interest to declare

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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1. KEY CONTACTS

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Funder(s)	NIHR Oxford Biomedical Medical Research Centre Nuffield Department of Medicine Oxford Sleep Research Fund 0189

2. LAY SUMMARY

Obstructive sleep apnoea (OSA) is a condition where the throat repeatedly closes during sleep, causing loud snoring and disrupted sleep. This leads to poor sleep quality, excessive sleepiness, and risk of car accidents. OSA also contributes to high blood pressure, heart problems, and higher mortality rates. Around 1 billion adults globally have OSA, including 8 million in the UK, but most are undiagnosed and untreated, risking serious health issues.

The best way to diagnose OSA is through an overnight sleep study in a lab or at home, which uses sensors to monitor breathing, oxygen levels, and heart rate. There is a shortage of capacity for sleep studies in the UK, with only 16,000 tests done monthly. At this rate, it would take decades to find everybody with OSA. There is a clear need for new diagnostic methods.

NICE is considering several new devices, including the Sunrise, AcuPebble, ResMed Night Owl, Brizzy, and WatchPAT devices. However, these devices often lack key features such as electrical heart rate activity and pulse oximetry, and they are less effective in detecting mild OSA. The University of Oxford's Biomedical Signal Processing & Machine Learning (BSP-ML) research group, part of the Institute of Biomedical Engineering (IBME), Department of Engineering Science has developed an ambulatory monitoring system (AMS) – for the virtual High Dependency Unit (vHDU) - initially used for COVID-19 patients. Their AMS system potentially overcomes the issues of other novel diagnostic tests by combining a chest worn patch (VitalPatch™, Vital Connect Inc, San Jose, CA, US) and a wrist-worn pulse oximeter (Nonin Medical Inc, Plymouth, MN, US) connected to a tablet via Bluetooth. This AMS can be worn for up to 7 days, the water-resistant chest patch allowing users to continue with their daily lives whilst being monitored.

Multi-parameter ambulatory monitoring systems, similar to the system mentioned above, have not yet been studied in a population with OSA. This study aims to provide proof of concept that an AMS can identify respiratory disturbances seen in OSA by comparing it to Respiratory Polygraphy (RP) in patients suspected of having OSA, potentially providing a more accessible and efficient diagnostic tool, with applicability at large scale.

3. SYNOPSIS

Study Title	Evaluating an ambulatory monitoring system in obstructive sleep apnoea: a proof-of-concept study
Internal ref. no. / short title	EASY-OSA
Study registration	TBC
Sponsor	University of Oxford Research Governance, Ethics and Assurance Joint Research Office Boundary Brook House Churchill Drive Headington Oxford OX3 7GB rgea.sponsor@admin.ox.ac.uk
Funder	NIHR Oxford Biomedical Medical Research Centre Nuffield Department of Medicine Oxford Sleep Research Fund 0189
Study Design	Single centre prospective pilot non-randomised comparison study of an ambulatory monitoring system to routinely collected clinical RP data
Study Participants	People with suspected obstructive sleep apnoea referred for clinical sleep studies
Sample Size	10
Planned Study Period	Each individual will be enrolled for a maximum of 7 nights (8 days) and the study will be conducted in 6 months. The study is planned to run between the 1st October to 31st December 2025
Planned Recruitment period	1st October to 31st December 2025

	Objectives	Outcome Measures	Timepoint(s)
Primary	Investigate feasibility of using the Ambulatory Monitoring System (Chest patch and pulse oximeter) to detect overnight >3 % desaturations compared to clinical standard RP	Level of agreement between AMS and RP scored 3% desaturations. Level agreement will encompass the number of events, duration of events, and the relative timing.	Paired AMS and RP on night 1 of the study
Secondary	Investigate feasibility of using the Ambulatory Monitoring System (Chest patch and pulse oximeter) to detect apnoeas and hypopnoeas compared to clinical standard RP	Level of agreement between AMS scored decelerations and accelerations in respiratory rate compared to RP scored apnoeas and hypopnoeas (while also determining the optimal calibration thresholds for decelerations and accelerations in respiratory rate). Level agreement will encompass the number of events, duration of events, and the relative timing.	Paired AMS and RP on night 1 of the study
	To assess the feasibility and patient experience of using the ambulatory monitoring system	Participant rating of the ease and comfort of use the ambulatory monitoring system	Patient questionnaire at research visit 3
Exploratory	To compare sleep metrics (apnoea-hypopnoea index, oxygen desaturations index and hypoxic burden) between AMS and RP	The agreement between AMS and RP scored events.	Paired AMS and RP on night 1 of the study
	To explore the night-to-night variability of sleep apnoea severity measured by AMS	The agreement between multiple nights of AMS derived AHI	AMS on nights 1 to 5 of the study
Procedure	Ambulatory monitoring system which consists of a wireless non-invasive chest patch (VitalPatch, VitalConnect, USA) and a finger pulse oximeter (Nonin WristOx2 BLE OEM, Nonin Medical Inc., USA). Paired to tablet via Bluetooth		
Comparator	Clinically conducted home respiratory polygraphy		

4. ABBREVIATIONS

AHI	Apnoea Hypopnoea Index
AI	Apnoea Index

AMS	Ambulatory monitoring system
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
GP	General Practitioner
HI	Hypopnoea Index
HRA	Health Research Authority
ICF	Informed Consent Form
NHS	National Health Service
ODI	Oxygen Desaturation 3% Index
OSA	Obstructive Sleep Apnoea
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
PSG	Polysomnography
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
RES	Research Ethics Service
RGEA	Research Governance, Ethics and Assurance Team
RP	Respiratory polygraphy
SOP	Standard Operating Procedure

5. BACKGROUND AND RATIONALE

Obstructive sleep apnoea (OSA) is a condition that is characterised by loud snoring and pausing in breathing during sleep, which leads to intermittent hypoxia and sleep fragmentation. This has the consequent effects of causing excessive sleepiness, reducing quality of life, and increasing the risk of road traffic collisions. OSA causes hypertension and is associated with cardiometabolic complications, post-operative complications and increased mortality [1, 2].

OSA is common and is estimated to affect approximately 1 billion adults worldwide [3]. In the UK, it is estimated that there are 8 million adults with OSA [3], and 80% of these individuals are currently undiagnosed [2]. Individuals with undiagnosed OSA are not able to benefit from the highly effective treatments available for OSA and are at risk of serious health complications.

The gold-standard test for diagnosing OSA is an in-laboratory overnight polysomnography sleep study (PSG) [4]. PSG involves being fitted with multiple wires and electrodes to measure breathing effort, oxygen saturation, heart rate, as well as electroencephalography (EEG) for sleep staging. Whilst PSG is the gold-standard test, it is time consuming and requires highly skilled staff, making it expensive and limiting access. PSG is not necessary to diagnose OSA in most individuals and NICE recommend at home respiratory

polygraphy (RP) as the first line standard test for OSA [5]. RP includes the same wires to measure breathing effort, pulse oximetry to measure oxygen saturation and heart rate, but does not include EEG channels. Whilst RP is less expensive than PSG, it still requires highly-skilled staff to set-up and report studies [6].

Within the UK there is limited capacity for RP at home with approximately 16,000 sleep studies performed per month [7]. Currently, 1/3rd of sleep studies are not reported within the national target of six weeks, and it is estimated that it would take 40 years to identify all individuals with undiagnosed OSA with the current testing capacity within the UK. There is a clear need to develop new ways to identify OSA to manage the increasing demand for sleep studies in the UK.

NICE is currently considering novel diagnostic tests including the Sunrise (https://us.hellosunrise.com/), AcuPebble (https://acurable.com/en), ResMed Night Owl (https://nightowlsleeptest.com.au/), Brizzy (https://nomicscare.com/en/products/brizzy/), and WatchPAT (https://www.itamar-medical.com/professionals/) devices. These tests vary in the measurements that they record, including movement, sound, chin EMG, and peripheral artery tonometry. Whilst there are therefore are several developed novel diagnostics tests, none of these include ECG monitoring, few contain pulse oximetry data, and few can stage sleep. These devices have lower sensitivity and specificity for mild OSA than RP and have not been thoroughly evaluated in people with central sleep apnoea [8, 9].

The Biomedical Signal Processing & Machine Learning (BSP-ML) group, part of the Institute of Biomedical Engineering (IBME), Department of Engineering Science, University of Oxford has developed an ambulatory monitoring system (AMS), initially for use in the COVID-19 pandemic on a virtual high-dependency unit. The AMS consists of the wearable devices, a chest patch (VitalPatch, VitalConnect, US) and a finger-worn pulse oximeter (WristOx2R 3150 BLE, Nonin, US) which are linked via Bluetooth to an Android tablet [10]. The AMS system has been shown to detect physiological deterioration 2-3 hours earlier than conventional observations in patients with COVID-19 [11].

The Oxford AMS enables continuous recording of respiratory rate, single-lead ECG, accelerometry for body movement (all from the wearable chest patch) and includes pulse oximetry monitoring data (oxygen saturation and pulse rate), collected wirelessly via Bluetooth by software running on an Android tablet. The AMS consists of the non-invasive adhesive chest patch that can be worn for up to 7 days, the pulse oximeter and its finger probe which is worn during the night, and the Android tablet which collects the data from both devices via Bluetooth. It has the advantage over the recently assessed novel diagnostics in that it includes impedance pneumography (using the ECG electrodes) to derive respiratory rate (only AcuPebble contains this) and pulse oximetry data which is not available on all devices.

The Oxford AMS and associated algorithms have yet to be evaluated for the diagnosis of OSA. This study aims to generate proof-of-concept data that this AMS system can identify respiratory disturbances that are relevant to OSA including desaturations, apnoeas and hypopnoeas. We will conduct a proof-of-concept study which will compare retrospectively the level of agreement between the ambulatory monitoring system and RP in patients undergoing clinical assessment for suspected OSA.

6. OBJECTIVES AND OUTCOME MEASURES

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary:		
Investigate feasibility of using the Ambulatory Monitoring System (Chest patch and pulse oximeter) to detect overnight >3 % desaturations compared to clinical standard RP	Level of agreement between AMS and RP scored 3% desaturations. Level agreement will encompass the number of events, duration of events, and the relative timing.	Paired AMS and RP on night 1 of the study
Secondaries:		
Investigate feasibility of using the Ambulatory Monitoring System (Chest patch and pulse oximeter) to detect apnoeas and hypopnoeas compared to clinical standard RP	Level of agreement between AMS scored decelerations and accelerations in respiratory rate compared to RP scored apnoeas and hypopnoeas (while also determining the optimal calibration thresholds for decelerations and accelerations in respiratory rate). Level agreement will encompass the number of events, duration of events, and the relative timing.	Paired AMS and RP on night 1 of the study
To assess the feasibility and patient experience of using the ambulatory monitoring system	Participant rating of the ease and comfort of use the ambulatory monitoring system	Patient questionnaire at research visit 3
Exploratory:		
To compare sleep metrics (apnoea-hypopnoea index, oxygen desaturations index and hypoxic burden) between AMS and RP	The agreement between AMS and RP scored events.	Paired AMS and RP on night 1 of the study
To explore the night-to-night variability of sleep apnoea severity measured by AMS	The agreement between multiple nights of AMS derived AHI	AMS on nights 1 to 5 of the study

7. STUDY DESIGN

We will conduct a single centre prospective pilot non-randomised study with fully paired comparison of an ambulatory monitoring system to routinely collected clinical RP data. Patients with suspected OSA referred to the Oxford Sleep Unit will be invited to participate.

Participants will undergo a single night of RP as part of their standard clinical care and at least five nights of sleep study via AMS, with the first night paired to respiratory polygraphy (RP). The total duration of the study for any participant will be a maximum of seven nights. Participants will attend for two visits as part of their standard clinical care to set up and will undergo research assessments alongside these visits (the day prior to the first night of study to set up RP and AMS equipment and the following day to return equipment). After at least 5 nights of AMS participants will attend a research visit to complete questionnaires on AMS monitoring, safety assessments and to return study equipment.

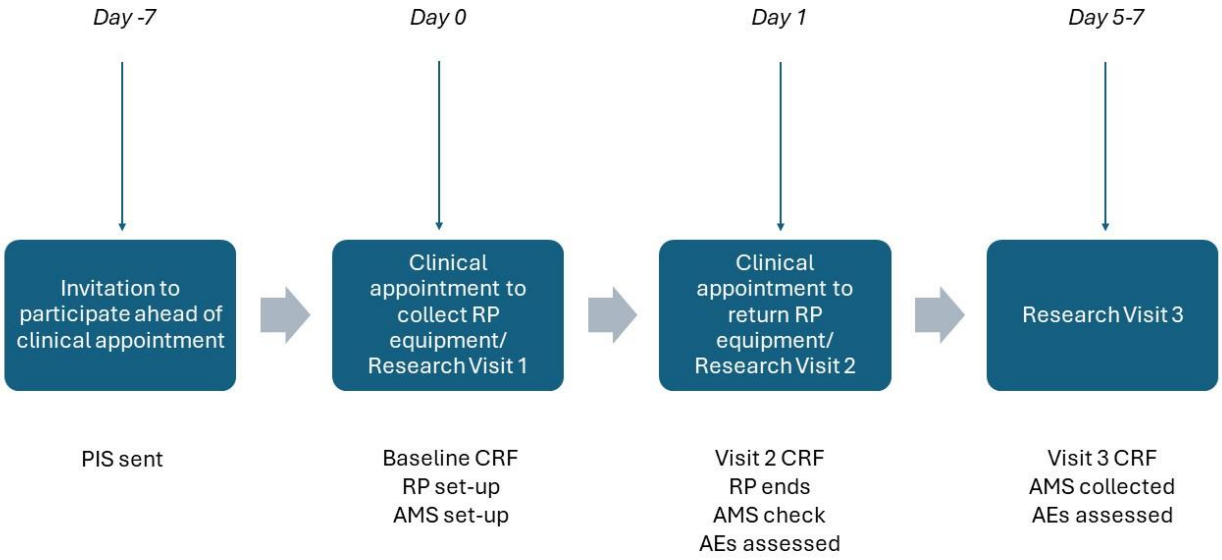

Figure 1: Flow chart of study activities. AMS=ambulatory monitoring system, CRF=case report form, PIS=patient information sheet, RP=respiratory polygraphy. Baseline CRF assessments will include medical history, medications, and anthropometric measurements (height, weight, neck circumference). Subsequent CRFs will include questionnaires on comfort and tolerability of RP and AMS.

8. PARTICIPANT IDENTIFICATION

8.1. Study Participants

Participants will be adults referred to the Oxford Sleep Unit for suspected OSA undergoing RP as part of their clinical assessment.

8.2. Inclusion Criteria

- Willing and able to give informed consent for participation in the study.
- Aged 18 years or above.
- Referred with required suspected obstructive sleep apnoea

8.3. Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

- Allergy or intolerance to hydrocolloid adhesive used for AMS chest patch attachment

9. PROTOCOL PROCEDURES

The schedule of procedures is shown below:

Procedures	**Day -7**	**Day 0**	**Day 1**	**Day 5-7**
	Invitation	**Visit 1**	**Visit 2**	**Visit 3**
Invitation phone call	✕			
Informed consent		✕		
Demographics		✕		
Medical history		✕		
Physical examination		✕		
Eligibility assessment		✕		
Home respiratory polygraphy set-up		✕		
Ambulatory monitoring system set-up		✕		
Home respiratory polygraphy collection			✕	
Ambulatory monitoring data collection				✕
Questions about tolerance			✕	✕

9.1. Recruitment

Potential participants will be identified by the members of the clinical team in the Oxford Sleep Unit. Potential participants will be individuals referred for suspected obstructive sleep apnoea who are scheduled to undergo an at-home sleep study as part of their routine clinical care. They will be contacted by telephone approximately one week ahead of their scheduled appointment by a member of the clinical

team to invite them to take part and if they are interested, they will be sent an invitation letter and patient information sheet via email or post. Interested participants will be asked for their verbal consent to share their contact details with the research team.

9.2. Screening and Eligibility Assessment

Study eligibility will be assessed against the inclusion and exclusion criteria. No exceptions will be made regarding eligibility. There are no study screening procedures.

9.3. Informed Consent

Interested potential participants will be invited to a research visit on the same day as their clinical RP (Day 0). Participant informed consent will be performed in person and will take approximately 20 minutes.

Written and verbal versions of the Participant Information Sheet and Informed Consent will be presented to the participants detailing no less than: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant-dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site. A copy of the signed informed consent will be scanned and uploaded to their electronic medical record

9.4. Registration

This is a non-randomised study. Participants will be registered as enrolled at visit 1 following informed consent.

9.5. Blinding and code-breaking

Not applicable.

9.6. Description of study intervention(s), comparators and study procedures (clinical)

Not applicable.

9.6.1. Description of study procedure(s)

Visit 1

At visit 1 participants will be asked questions about demographic (age at study entry, gender, sex at birth, ethnicity, current occupation) and medical history (past medical history, concomitant medications, smoking history). Participants will have a physical examination detailing height in centimetres, weight in kilograms, neck/waist/hip circumferences in centimetres, Mallampati score, and tonsil size recorded as per a standard operating procedure. Participants will undergo eligibility assessment.

Participants will be supplied with home RP equipment and be shown how to use this equipment as part of routine standard clinical care as per standard operating procedures. This involves attending a 15-minute group talk with other patients explaining how to use the equipment.

Participants will be supplied with the AMS and shown how to use this 1:1 with a researcher. The AMS consists of a wearable non-invasive chest patch (VitalPatch, VitalConnect, USA) and a finger pulse oximeter (Nonin WristOx2 BLE OEM, Nonin Medical Inc., USA). These are CE marked devices being used as per the manufacturers description. The researcher will attach the chest patch at research visit 1 and turn the device on. The device will remain on for the duration of the study (maximum of 7 nights from study onset); it is attached non-invasively using a medical-grade hydrocolloid adhesive which is part of the patch. It is water-resistant enabling the patch to be worn whilst showering but not submerged during the study. The finger pulse oximeter is worn around the wrist and participants will be shown how to turn this on and off and instructed to use this device only during the night when sleeping for each night of the study. The finger pulse oximeter has a battery life of 24 hours when sampling at 1Hz and has battery warning indicators. Participants will be supplied with spare AAA batteries and instructed to fit these after three nights of usage. The finger pulse oximeter device will store pulse rate and oxygen saturation data at 1Hz for up to 270 hours. The participants will be supplied with a computer tablet for use during the study. Both the chest patch and finger pulse oximeter devices transmit data via Bluetooth-Low-Energy to the tablet at the participant's bedside where data is stored for upload to the University of Oxford's based AMS cloud, once Internet connectivity is available to the tablet.

From the finger pulse oximeter, we will collect the pulse rate, peripheral oxygen saturation (both at a sampling rate of 1 Hz) and near-infrared photo-plethysmography waveform (at a sampling rate of 75 Hz). From the chest patch, we will collect the heart rate and respiratory rate (both at a sampling rate of 0.25 Hz), participant posture (e.g., standing, sitting, lying down, etc.), number of steps (at a sampling rate of 1 Hz), single-lead ECG and body movement from 3-axis accelerometer waveforms (at sampling rates of 125 and 62.5 Hz, respectively). Both devices compute signal-quality indices and display battery status.

Subsequent Visits

Visit 2

Participants will be followed up at visit 2 when they return their clinical home RP equipment as part of their standard clinical care. Data will be downloaded from their clinical RP and anonymised for research purposes. RP will then be manually double scored by two qualified scorers. Means of the two values will be taken unless the coefficient of variation is greater than 10%, where the scorers will meet to discuss and review the studies. Participants will be assessed by an investigator and will be asked to complete a paper questionnaire assessing the ease of use and tolerability of the ambulatory monitoring system and home sleep study.

Visit 3

Participants will attend a final visit 5-7 days after visit 1. At this visit participants will return all remaining equipment for data downloading and will have their chest patch removed. The researcher will complete a study CRF and participants will be asked to complete a questionnaire assessing the ease of use and tolerability of the ambulatory monitoring system.

9.7. Sample Handling

No biological samples are being collected in this study.

9.8. Early Discontinuation/Withdrawal of Participants

During the course of the study a participant may choose to withdraw early from the study at any time. This may happen for several reasons, including but not limited to:

- The occurrence of what the participant perceives as an intolerable event.
- Inability to comply with study procedures
- Participant decision

Participants may choose to stop study assessments but may remain on study follow-up.

Participants may also withdraw their consent, meaning that they wish to withdraw from the study completely. Participants withdrawing from the study will have the following options;

1) Participants can withdraw from the study but permit data up until the point of withdrawal to be retained for use in the study analysis. No further data would be collected after withdrawal.

2) Participants can withdraw completely from the study and withdraw the data collected up until the point of withdrawal. The data already collected would not be used in the final study analysis.

In addition, the Investigator may discontinue a participant from the study treatment at any time if the Investigator considers it necessary for any reason including, but not limited to:

- Pregnancy
- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with treatment regimen or study requirements
- Clinical decision

Withdrawn participants will have no further follow-up as withdrawal will represent the end of the study.

The type of withdrawal and reason for withdrawal will be recorded in the CRF.

Participants who withdraw will be replaced in the sample size as outlined in the section sample size calculation below.

9.9. Definition of End of Study

The end of study is the point at which all the study data has been entered and queries resolved.

10. SAFETY REPORTING

We are not collecting safety monitoring data as the ambulatory monitoring system is non-invasive, has an established risk profile, demonstrated through its routine use in clinical practice, and is being used in accordance with its CE mark, ensuring compliance with stringent safety and performance standards.

Any adverse event related to the CE marked devices, discovered during the study will be added to the MHRA yellow card system (https://yellowcard.mhra.gov.uk/).

10.1. Definition of Serious Adverse Events

Not applicable

10.2. Reporting Procedures for Serious Adverse Events

Not applicable

11. STATISTICS AND ANALYSIS

11.1. Statistical Analysis Plan (SAP)

A separate detailed statistical analysis plan will be produced prior to data lock and prior to analysis of the study. A summary of the statistical aspects of the study are summarised here.

11.2. Description of the Statistical Methods

Detailed descriptions of the statistical methods will be reported in the statistical analysis plan. Briefly, Continuous data will be assessed for normality using a combination of normality tests and histograms. Descriptive statistics will be expressed as number and percentage for categorical variables and as either median and interquartile range or mean and standard deviation for continuous variables were non-parametrically and parametrically distributed respectively. The primary and secondary outcomes will assessed using a combination of proportions, correlation coefficients and Bland-Altmann plots.

11.3. Sample Size Determination

As this is a feasibility study, no formal power calculation has been conducted. The recruitment target is 10 participants with complete AMS and RP studies from night 1. Local prevalence data from individuals referred for a sleep study shows a prevalence of 60% of OSA for those referred for a sleep study, with published UK validation studies showing a prevalence of 46%. Those without OSA will still provide helpful information as they will have obstructive events below the threshold for diagnosis of OSA. The primary outcome is the level of agreement in desaturation events between AMS and RP. Secondary and exploratory outcomes will provide proof of concept data for the determination of apnoeas, hypoponeas, overall sleep metrics, and the night-to-night variability of AMS measurements.

Any withdrawals or dropouts will be replaced until there are 10 participants with complete AMS and RP studies from night 1.

11.4. Analysis populations

All participants who are registered and whom have complete data from RP and AMS night 1 will be analysed.

11.5. Decision points

There are no planned interim analyses.

11.6. Stopping rules

There are no formal stopping rules given the small sample size.

11.7. The Level of Statistical Significance

Formal statistical tests will be considered significant when p-values are less than 0.05.

11.8. Procedure for Accounting for Missing, Unused, and Spurious Data.

We will not impute missing data and will only analyse those with complete data from night 1 RP and AMS monitoring, replacing those with incomplete data in the sample.

11.9. Procedures for Reporting any Deviation(s) from the Original Statistical Plan

Any deviation from the statistical analysis plan will be described and justified in the protocol and/or final report. They will also be recorded in any publications arising from this study.

11.10. Health Economics Analysis

Not applicable

12. DATA MANAGEMENT

The plan for the data management of the study is outlined below. There is not a separate Data Management document in use for the study.

12.1. Source Data

Source documents are where data are first recorded, and from which participants' CRF data are obtained. These include, but are not limited to, hospital records (from which medical history and previous and concurrent medication may be summarised into the CRF), clinical and office charts, laboratory and pharmacy records, diaries, microfiches, radiographs, and correspondence.

CRF entries will be considered source data if the CRF is the site of the original recording (e.g. there is no other written or electronic record of data). All documents will be stored safely in confidential conditions.

On all study-specific documents, other than the signed consent, the participant will be referred to by the study participant number/code, not by name.

12.2. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

12.3. Data Recording and Record Keeping

All trial data will be entered into the REDCap research data management system in the form of an electronic case report form (eCRF).

The participants will be identified only by a unique trial-specific code in all electronic records created for the trial. The name and any other directly identifying detail will NOT be included in any trial data stored on the electronic database. Details linking the study ID to participant identifiable information will be stored on informed consent forms and within the participants medical records. Paper copies of the informed consent forms will be stored within locked secured filing cabinets within the site (Oxford University Hospitals NHS Foundation Trust) for the duration of the study. Participants will be asked if they are willing to be contacted to consider participation in future research. For those consenting to consider participants in future research, consent forms will be held securely until such a time as details are removed from the database. For those not consenting they will be archived following completion of the study (see section 19). A copy of the paper consent form will be kept in participants medical notes for as long as these records are held.

For the purposes of participant expenses, bank details will be stored for 7 years in accordance with University of Oxford financial policy.

Data will be held on a secure, backed-up server for the duration of the trial and will then be archived (see section 19). Access to view and/or enter data will only be available via the data management system for authorised personnel (validated by individual user credentials, with different permissions granted as appropriate). The system will maintain an audit trail of all entries/modifications/deletions made to the data.

AMS Data will be 'downloaded' automatically to the University of Oxford's Institute of Biomedical Engineering (IBME) server once the tablets have internet connectivity. All communication between the tablet and IBME is encrypted. For additional security the data is transmitted and stored in de-anonymised format. The trial ID is only transmitted once, at registration, and is then subsequently encrypted and stored in a separate database table. Once the data is received and acknowledged by the IBME server, the data is automatically deleted from the tablet within 24 hours. The IBME server is behind the University's firewall and monitored by the University's IT systems for security compliance.

There is a backup option to download the AMS data manually from the tablets via a USB cable - this is only possible after user authentication on the tablet with a code that changes daily. This procedure will only be used to retrieve missing data at visit 3

The AMS system is built in-house by the study co-investigators, all members of University of Oxford with Oxford University Hospitals honorary contracts, which allows full control of the data pipeline with no third-party involvement - co-investigators will have access to the pseudo-anonymised data for debugging purposes. Once the trial finishes, the data will be linked with the external variables (e.g. Respiratory Polygraphy outcomes) and exported in anonymised format for analysis.

13. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

13.1. Risk assessment

A risk assessment and monitoring plan will be prepared before the study opens and will be reviewed as necessary over the course of the study to reflect significant changes to the protocol or outcomes of monitoring activities.

13.2. Study monitoring

Regular monitoring will be performed according to the study specific Monitoring Plan. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents as these are defined in the study specific Monitoring Plan. Following written standard operating procedures, the monitors will verify that the clinical study is conducted, and data are generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements.

13.3. Study Committees

As this is a small proof of concept study there are no trial oversight committee.

14. PROTOCOL DEVIATIONS

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from Good Clinical Practice (GCP) or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file.

15. SERIOUS BREACHES

A “serious breach” is a breach of the protocol or of the conditions or principles of Good Clinical Practice which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or

(b) the scientific value of the research.

In the event that a serious breach is suspected the Sponsor must be contacted within 1 working day. In collaboration with the C.I., the serious breach will be reviewed by the Sponsor and, if appropriate, the

Sponsor will report it to the approving REC committee and the relevant NHS host organisation within seven calendar days.

16. ETHICAL AND REGULATORY CONSIDERATIONS

16.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

16.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

16.3. Approvals

Following Sponsor approval, the protocol, informed consent form, and participant information sheet will be submitted to an appropriate Research Ethics Committee (REC), and HRA (where required) and host institutions for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

16.4. Other Ethical Considerations

It is possible that the AMS may detect OSA or cardiac arrhythmias which are not detected by RP as the AMS will be utilised for up to 7 days, with RP being used for a single night only. Where these are detected, the investigators will inform the participant as soon as possible of the finding, notify their GP of the finding, and make onwards referrals as appropriate – for example to the clinical Sleep Unit if OSA is detected outside of the RP night.

16.5. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the host organisation, Sponsor and funder (where required). In addition, an End of Study notification and final report will be submitted to the REC Committee, HRA, host organisation, Sponsor and funder (where required).

16.6. Transparency in Research

Prior to the recruitment of the first participant, the trial will have been registered on a publicly accessible database.

Where the trial has been registered on multiple public platforms, the trial information will be kept up to date during the trial, and the CI or their delegate will upload results to all those public registries within 12 months of the end of the trial declaration.

16.7. Participant Confidentiality

The study will comply with the UK General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s), apart from the patient consent form (which will include the participants name) which will be secured within a locked filing cabinet. All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

16.8. Expenses and Benefits

Reasonable travel expenses for any visits additional to normal care will be reimbursed on production of receipts, or a mileage allowance provided as appropriate.

17. FINANCE AND INSURANCE

17.1. Funding

This research is funded by the NIHR Oxford Biomedical Medical Research Centre and the Nuffield Department of Medicine who support all salaries for staff involved in running this study and the Oxford Sleep Research Fund 0189 will be utilised to reimburse patient travel expenses and database hosting.

17.2. Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London). NHS indemnity operates in respect of the clinical treatment that is provided.

17.3. Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

18. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the NIHR Oxford Biomedical Medical Research Centre and the Nuffield Department of Medicine. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

19. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Ownership of IP generated by employees of the University vests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the trial.

19. ARCHIVING

The study documents (including the Trial Master File (TMF), including the study database will be s archived electronically on a secure, backed up, access restricted server for 5 years. The Oxford University Hospitals site will be responsible for archiving their site file and consent forms as per their local arrangements for 5 years. This will either be on site in a secure, access restricted and lock filing cabinet or offsite in a professional secure archive facility.

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21. APPENDIX A: STUDY FLOW CHART

This is embedded in the text.

22. APPENDIX B: SCHEDULE OF STUDY PROCEDURES

This is embedded in the text.

23. APPENDIX C: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee and HRA (where required).