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Sunrise in Obstructive Sleep Apnoea study (SOSA)

A comparison of the Sunrise mandibular movement monitoring device with overnight oximetry and WatchPAT in the diagnosis and management of obstructive sleep apnoea.

Version 1.1 April 2025

MAIN SPONSOR: Manchester Metropolitan University
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STUDY COORDINATION CENTRE: University Hospitals Bristol and Weston NHS Foundation Trust, Bristol Royal Infirmary Hospital.
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Team Members and Declaration of Roles:

Name	Role
Dr Virginia Hawkins	Chief Investigator (CI) Senior Lecturer and Academic Supervisor (Non – Clinical) Employed by Manchester Metropolitan University (MMU). MMU are the sponsors and the CI will have overall responsibility for the study. The CI will not be at the recruitment site and will remain in regular contact with the Principal Investigator and Co-investigator throughout the study period.
Rachel Pickersgill	Principle Investigator (PI) Lead Clinical Scientist and Higher Specialist Scientific Training (HSST) Trainee. Employed by University Hospitals Bristol and Weston NHS Foundation Trust. The PI is responsible for the daily operation of the study and raising any serious events that arise. The PI will analyse all data and present findings to the study team.
Dr Laura Buckley	Co-investigator Lead Clinical Consultant and clinical supervisor. Employed by University Hospitals Bristol and Weston NHS Foundation Trust. Lead medical clinician responsible for patient cohort and works at the study recruitment site. Will oversee the daily running of the study from a clinical perspective and aid in reporting any Serious Adverse Events.
Dr Joshua Butler	Clinical fellow – screening patients, consenting patients and triage patients post Sunrise test

	Employed by University Hospitals Bristol and Weston NHS Foundation Trust. Triage Sunrise results as part of the study, will be blinded to the oximetry and WatchPAT results.
Zoe Hamilton	Associate Physiologist to support with maintaining the database. Employed by University Hospitals Bristol and Weston NHS Foundation Trust. Database manager, ensure patient information is updated in the database and will have access to full data set. Ensure anonymised Sunrise reports, new patient questionnaire and Epworth Sleepiness Score are sent to PI and Clinical Fellow. Responsible for entering report results for oximetry, WatchPAT, Sunrise and Case Report Form into database as the PI will be blinded to oximetry and WatchPAT results.
Dr Elizabeth Hill	Clinical Specialist advisor, Senior Lecturer and Clinical Scientist. Employed by University of the West of England (UWE). Subject specialist mentor for PI and advisor to study design, protocol and thesis write up. Not directly involved with the recruitment or delivery of the study.
Professor Sonia Correa-Muller	Academic Supervisor, Professor of Neuroscience (Non – Clinical). Employed by Manchester Metropolitan University (MMU). Academic supervisor team member. Not directly involved with the recruitment or delivery of the study.
Amelia Herbert	Administrator Lead and Assistant speciality manager for the sleep service. Employed by University Hospitals Bristol and Weston NHS Foundation Trust. Responsible to ensure the PI and clinical fellow are not allocated patients enrolled in the study for oximetry or WatchPAT triage in the clinical pathway. Triage of oximetry and WatchPAT results are currently done in the existing clinical pathway.

Sponsor
Manchester Metropolitan University is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact:

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This protocol describes the Sunrise in OSA study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary, and won't be implemented without a formal amendment and approval to the regulatory bodies. Any changes will be circulated to investigators in the study and the sponsor. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

Contents

List of abbreviations

Abbreviation	Full text
AE	Adverse Events
AHI	Apnoea Hypopnoea Index
AI	Artificial Intelligence
APR	Annual Progress Report
ArI	Arousal Index
BMI	Body Mass index
BPM	Beats Per Minute
BRI	Bristol Royal infirmary
CI	Chief Investigator
CGM	Clinical Governance Meeting
CM	Centimetres
CPAP	Continuous Positive Airway Pressure
CRF	Case Report Form
CRPG	Cardio-Respiratory Polygraphy
DPIA	Data Impact Assessment Form
EEG	Electroencephalogram
EPR	Electronic Patient Record
ESS	Epworth Sleepiness Score
GDPR	General Data Protection Regulation
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
HSST	Higher Specialist Scientific Training
ICB	Integrated Care Board
ICF	Informed Consent Form
IG	Information Governance
IT	Information Technology

KG	Kilograms
ML	Machine Learning
MM	Mandibular Movement
MMU	Manchester Metropolitan University
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
ODI	Oxygen Desaturation Index
OPD	Outpatient Department
ORDI	Obstructive respiratory disturbance index (ORDI)
OSA	Obstructive Sleep Apnoea
OSAHS	Obstructive Sleep Apnoea Hypopnoea Syndrome
pAHI	Peripheral Arterial Tonometry Apnoea Hypopnoea Index
PAT	Peripheral Arterial Tonometry
PI	Principal Investigator
PPI	Patient and Public Involvement
PIS	Participant Information Sheet
PSG	Full Polysomnography
QR	Quick Reference
RDI	Respiratory Disturbance Index
REC	Research Ethics Committee
RERA	Respiratory effort related arousal
R&D	Research and Development
SAE	Serious Adverse Events
SE	Sleep Efficiency
SOL	Sleep Onset Latency
SOP	Standard Operating Procedure
SpO_2	Oxygen saturations
TST	Total Sleep Time
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust

1 INTRODUCTION

1.1 Background

What Is Obstructive Sleep Apnoea?

Approximately 1.5 million people in the United Kingdom and 1 billon globally suffer from Obstructive Sleep Apnoea (OSA) (Steier *et al.*, 2014; Benjafield *et al.*, 2019), a disorder where breathing stops for periods of 10 or more seconds during sleep due to repetitive collapse of the upper airway, reducing blood oxygen levels and causing brief awakenings, disturbing sleep throughout the night. Symptoms include snoring, tiredness and excessive daytime somnolence which can impact quality of life, cognition and mood (Bonsignore *et al.*, 2023; Grote, 2019). In addition, daytime sleepiness increases the risk of occupational or road accidents (Rejón-Parrilla, Garau and Sussex, 2014). OSA prevalence is expected to increase further with ageing populations and rising obesity rates (Kelly *et al.*, 2022; Benjafield *et al.*, 2019; Erridge *et al.*, 2021; Krefting *et al.*, 2023; Steier *et al.*, 2014).

OSA is frequently associated with other conditions including hypertension, cardiovascular disease, obesity, and type 2 diabetes, (Steier *et al.*, 2014; Benjafield *et al.*, 2019; Grote, 2019). OSA also imposes a socioeconomic burden, resulting in increased healthcare and economic costs, with indirect costs estimated at €1.9 billion in Europe and £1.6 million in the UK annually (Steier *et al.*, 2014). However, a significant proportion of patients remain undiagnosed because symptoms may be attributed to other conditions, and diagnosis of OSA often has long waiting times due to complex tests requiring considerable time to analyse. A British Lung Foundation commissioned report estimates 85% of OSA cases are undiagnosed and if all moderate to severe OSA diagnoses were treated the NHS could save £55 million annually (Rejón-Parrilla, Garau and Sussex, 2014). Treating undiagnosed OSA could alleviate this burden, but improved diagnostic and treatment strategies are also necessary (Benjafield *et al.*, 2019).

Current NHS England (2024) sleep diagnostic waiting times are observing a monthly increase of 2.5% and services are unable to keep up with demand to reduce waiting times. Within Bristol Royal Infirmary Sleep service, referrals increased significantly from 2020-23, which resulted in waiting times of more than 52 weeks, a position reflected nationally. This required significant additional funding to reduce the backlog which is not sustainable, and therefore services need to explore innovations to streamline patient pathways.

Testing for OSA

In order to diagnose OSA, patients sleep overnight wearing monitors that record physiological signals such as oxygen saturations, respiratory movement and heart rate. National Institute for Health and Care Excellence (NICE) guidelines (2021) recommend cardio-respiratory polygraphy

(CRPG) as first line diagnostic test or overnight oximetry (oximetry) if access to polygraphy is limited. CRPG needs to be scored manually, which is time consuming and expensive. In contrast, oximetry does not require manual scoring, but lacks sensitivity and specificity (Netzer *et al.*, 2001)and further testing with CRPG or full polysomnography (PSG) may be required.

New innovative devices to diagnose OSA using alternative technology are now available and studies are auto-analysed, reducing reporting time while maintaining accuracy (Verma *et al.*, 2023). University Hospitals Bristol and Weston (UHBW) sleep department uses the Nonin WristOx$_2$ 3150 oximeter (oximetry) manufactured by Nonin Medical Inc, Plymouth, Minneapolis, USA (Nonin, 2023) and a novel test called Watch Portable Automated Test, abbreviated in clinical practice to WatchPAT 300 (WatchPAT) manufactured by Itamar Medical, Caesarea, Isreal (Itamar Medical, 2024) for initial OSA screening, both of which can be carried out at home. The result of the sleep test is reviewed by a senior clinician alongside a patient clinical questionnaire to determine whether the patient is referred directly for Continuous Positive Airway Pressure (CPAP), discharged, seen in clinic or a further sleep test requested. CPAP is a medical device used to treat OSA by delivering a constant flow of room air via a mask to keep the airway open and prevent pauses in breathing (apnoeas). CPAP is available on the National Health Service (NHS) to treat OSA and recommended by the National Institute for Health and Care Excellence (NICE) (NICE, 2021).

WatchPAT uses technology called peripheral arterial tonography to determine arousals from sleep, which combined with other measurements including oxygen saturations, heart rate and actigraphy can diagnose OSA. A systematic review by Moffa *et al.* (2023) reviewing overnight PSG and WatchPAT reported a sensitivity ranging from 87-96% and a specificity of 66-80%, suggesting WatchPAT is an effective diagnostic device for OSA. Although the data is auto-analysed, additional manual reporting is required, albeit requiring less time than CRPG. Local data demonstrated that 50% of patients under the age of 40 issued oximetry required additional testing due to negative results but a high clinical suspicion of OSA. A pilot pathway using WatchPAT rather than oximetry in patients under 40 years old resulted in improved diagnosis after first test, reduced appointments and cost. The department would consider using WatchPAT for all patients, but due to staffing shortages and increased clinical demand, staff are unable to analyse WatchPAT studies to meet demand, contributing to increased patient pathway time. Therefore the department is considering alternative novel devices with reduced analysis time following recent NICE guidelines (2024) 'Home-testing devices for diagnosing obstructive sleep apnoea hypopnoea syndrome' published 19th December 2024.

The Sunrise device (version 1), manufactured by Sunrise SA, Namur, Chaussée de Marche, Belgium, is a small, non-invasive sensor that sticks between the patient's chin and lips that can be used to diagnose OSA and is CE/UKCA marked for use in the UK (figure 1). Measurements are recorded via Mandibular Movement (MM) assessing linear acceleration and rotational rate of the mandible (Sunrise, 2022). Martinot *et al.* (2015) observed obstructive respiratory events were terminated by sharp MM associated with mouth closure on cortical arousals. This was further studied by Martinot *et al.* (2017) where MM and PSG demonstrated high concordance in identifying sleep disordered

breathing. Further studies demonstrated MM as a successful surrogate marker for oesophageal pressure, the gold standard for measuring respiratory effort, enabling the differentiation between obstructive and central apnoeas (Martinot *et al.*, 2019). The studies suggested MM monitoring could be used as a reliable screening tool for OSA at various severity cut-offs.

Sleep apnoea events, upper airway resistance and respiratory drive cause changes in MM which is recorded by the Sunrise device and results are sent via Bluetooth to the cloud where machine learning analyses the data, generating a report which needs no manual analysis (Sunrise, 2022). Data generated includes sleep stages, estimated apnoea-hypopnoea index and head position. The Sunrise device can be posted to patients and results uploaded via an app to be reviewed in the hospital. This could reduce the need for patients to travel to the hospital to collect and return the device, which would reduce days off work for the patient, travel time and cost.

Figure 1 Sunrise device attaches to the patients chin in the mentolabial sulcus. Taken from the Sunrise Clinical Compendium document. *(Sunrise, 2023)*

The Sunrise device has previously been validated in the literature in comparison to PSG both in laboratory and at the patient's home. Pepin *et al.* (2020) reviewed 376 adult patients comparing MM with PSG overnight in a sleep laboratory. This study demonstrated a Respiratory Disturbance Index (RDI) sensitivity accuracy of 92% with events of greater than 5/hour. A more recent study by Kelly *et al.* (2022) reviewed 31 patients using Sunrise in comparison to PSG in the patients' home. This study demonstrated a sensitivity of 88-100% depending on OSA severity. Both studies showed promising results and Sunrise has been recommended as a home-testing device to diagnose OSA in the NICE guidelines (2024), published 19th December 2024. The guidelines published draft versions for consultation prior to the final publication where concerns were raised over estimations of Sunrise accuracy in the published studies. The standard predefined AHI cutoff values to grade severity of OSA as recommended in the NICE (2021) guidelines where Mild OSA = 5 or more to less than 15 events per hour, Moderate OSA is 15 or more to less than 30 event per hour and Severe OSA is 30 or more events per hour. Pepin *et al.* (2020) did not use the predefined values and instead adjusted the cut off values to 7.63 events per hour, 12.65 events per hour and 19.85 events per hour. The draft guidance also highlighted that Kelly *et al.* (2022) did not use the thresholds from Pepin *et al.* (2020) and completed a post hoc analysis to determine the optimal cutoff for MM

obstructive respiratory disturbance index (ORDI). However, supporting documentation from Sunrise submitted to NICE during the consultation demonstrating Martinot *et al.* (2022) used the cut off values recommended in NICE 2021 to determine AHI. It was subsequently determined the risk of bias was low. Sunrise company also confirmed Sunrise reports AHI using standard cut off values (5, 15 and 30 events per hour) and the obstructive respiratory disturbance index uses the values established in the Pépin *et al.* (2020) study 7.63 and 12.65. Subsequently Sunrise is now recommended in the guidance, but much of what we understand about the device is limited to three published studies. As the Sunrise device has only recently been recommended by NICE, it has yet to be used extensively in clinical practice in the UK and within the NHS. There are currently no published studies comparing Sunrise to a third-party oximeter, which was recommended in the draft NICE guidelines. Furthermore, WatchPAT 300 devices are also widely used in the NHS, but they were also only recently recommended in December 2024 NICE guidelines, and there are no published studies comparing use of Sunrise to WatchPAT 300 devices in a clinical setting. Kelly *et al.* (2022) suggested future research evaluating the sunrise device in a variety of care pathways and reviewing patient experience.

1.2 Rationale

Current diagnostic tests for OSA either lack sensitivity (oximetry) or require manual reporting (WatchPAT and CRPG). Sunrise has the advantage of requiring no reporting time and can be conveniently posted to patients and is therefore potentially a viable alternative test for the diagnosis of OSA, speeding up the patient pathway and reducing waiting times. The Sunrise device is now recommended for diagnosing OSA but as these guidelines were published 19/12/2024 there are few NHS services currently using the device and more research into how this can be utilised in an NHS setting is needed. The NICE guidance (2024) reviewing novel home testing devices for OSA highlights gaps in the research, including the need to review the accuracy in home testing devices at diagnosing and assessing OSA severity in patients with brown or black skin. UHBW receives referrals from all ethnic groups and our study will be inclusive and accessible for a range of ethnically diverse participants.

This study aims to compare the performance and diagnostic power of Sunrise with overnight oximetry and WatchPAT 300 devices in the assessment of patients with suspected OSA, to establish whether it would improve clinical practice if it were incorporated into a standard diagnostic pathway. We propose that the Sunrise device will be more effective than overnight oximetry and WatchPAT in the clinical diagnostic pathway. This could be by reducing number of patient visits, by reducing time to a clinical decision, and/or reducing staff time needed per patient referral.

<u>Impact and expected added value</u>

If our hypothesis is supported, this project could reduce patient pathway time, aiding faster diagnosis and reducing waiting lists as there is no analysis time for the Sunrise device in comparison

to WatchPAT 300. It may also be more sensitive than oximetry, reducing the need for additional tests in patients in whom oximetry is non-diagnostic. This study will also assess whether patients find Sunrise easier to use than existing equipment. Wearable devices to diagnose OSA are relatively new to the market and have been underutilised by NHS sleep departments due to lack of NICE guidance. With the recent NICE guidance recommending wearables, devices such as Sunrise may be utilised and departments will explore integration into sleep clinical pathways. Although not being tested in this study, Sunrise can be posted to patients, reducing the need for them to attend hospital to collect the device, reducing the need to travel to a city centre hospital or take time off work. This could improve patient experience and be beneficial to patients by reducing the need to travel to our city centre hospital with limited parking and within a fuel congestion zone. The Sunrise patient feedback questionnaire asks about mode of transport and any time taken off work to review our patient cohort and the possible impact posting devices to patient's homes may have in the future.

2 STUDY OBJECTIVES

2.1 Primary Objective

Research question

How does Sunrise compare to overnight oximetry and WatchPAT 300 for diagnosing and managing Obstructive Sleep Apnoea within an adult sleep clinical pathway?

Hypothesis

In the assessment of patients with suspected OSA, testing patients with Sunrise leads to a higher proportion of definitive management decisions (CPAP set up or discharge) than oximetry and is comparable to WatchPAT 300.

Null Hypothesis

In the assessment of patients with suspected OSA, testing patients with Sunrise does not lead to a higher proportion of definitive management decisions to testing with oximetry, and is not comparable with WatchPAT 300.

2.2 Secondary Objectives

- Assess the Sunrise outputs comparing them to current oximetry and WatchPAT 300 device testing platforms
- Evaluate Sunrise products ease of use for patients and healthcare professionals
- Assess the costs and efficiency of Sunrise implementation and using Sunrise compared to oximetry or WatchPAT 300

2.3 Primary endpoint/outcome

The proportion of patients for which a definitive management decision can be made when tested with Sunrise will be determined and compared to that of oximetry and WatchPAT 300.

2.4 Secondary endpoints/outcomes

Completion of our secondary objectives will be assessed by achieving the following endpoints/outcomes:

- Level of agreement in decision making between Sunrise and oximetry and Sunrise and WatchPAT 300
- Estimated Apnoea-hypopnoea index (AHI) derived from Sunrise compared with ≥ 3% oxygen desaturation index (ODI) derived from oximetry or ≥ 3% PAT-derived AHI (pAHI) from WatchPAT 300
- Respiratory Disturbance Index (RDI) derived from Sunrise compared to RDI from WatchPAT 300
- Sleep onset latency, sleep efficiency, total sleep time and time in supine or non-supine body position derived from Sunrise compared to WatchPAT 300
- Proportion of patients and health care professionals reporting Sunrise as easy to use; number of patients reporting difficulty using the test
- Proportions of failed tests and tests with inconclusive results for Sunrise
- Cost of Sunrise versus WatchPAT 300 and Sunrise versus oximetry.
- Comparison of staff time taken to analyse each type of diagnostic study.

3 STUDY DESIGN

This is a real-world study in which patients referred with suspected OSA will undergo testing with a Sunrise device in addition to their usual sleep testing with oximetry or WatchPAT. The results from the Sunrise test will be reviewed alongside clinical information to determine a hypothetical management plan, which will be compared to the actual clinical management plan determined from oximetry or WatchPAT 300. No additional patient visits will be involved in this study. The patient will use the Sunrise device at the same time as oximetry or WatchPAT 300 and will complete a patient feedback questionnaire which are the only two additional aspects to this study compared to the standard patient diagnostic pathway.

<u>Standard Procedure (current clinical pathway)</u>

- New patients referred into the clinical service are triaged by the clinical team for oximetry or WatchPAT 300. Patients ≤ 40 years old are triaged to WatchPAT 300 as part of the current pathway.
- Patients are issued an appointment to collect their equipment and are sent the New patient questionnaire and Epworth Sleepiness Score (ESS) via DrDoctor platform (Web based, no

version number), Lambeth, London, United Kingdom. This is completed by the patient and a copy of the questionnaire and ESS are uploaded to the patient CareFlow Electronic Patient Record (EPR) by the administrative team.

- Patient collects equipment, height, weight (Body Mass Index) and collar size measured.
- Patient returns their oximetry or WatchPAT 300 to the department.
- The oximetry report is downloaded but not analysed and uploaded to Careflow EPR by the clinical team.
- The WatchPAT 300 result is analysed and uploaded to Careflow EPR.
- Oximetry and WatchPAT 300 results are triaged as part of the clinical pathway based on ODI / pAHI and symptoms reported in the new patient questionnaire.
- Triage decisions are: i) CPAP set up; ii) further diagnostic testing; iii) discharge from sleep service or iv) clinic appointment for further discussion.

Study Procedure

- Patients will follow the above clinical process and be issued a patient study participant number. Patients will be informed of their participant number at this point.
- Patient will be issued a Case Report Form (CRF) and recruited into the study by the Principal Investigator.
- Participant numbers will be allocated on the patients CRF form, Sunrise patient feedback questionnaire and the study database.
- Patients recruited into the study will be issued the Sunrise device to use simultaneously for one night with oximetry or WatchPAT 300
- Patients will be issued the Sunrise Patient Feedback questionnaire via a QR code on the paper 'patient instructions for using Sunrise device' issued with the Sunrise equipment. For patients unable to access the questionnaire via a QR code, a paper copy will be provided
- The Principal Investigator (PI) will be blinded to the CRF after visit 1 to help ensure unbias analysis and triaging of Sunrise results. The database manager will complete the CRF after this point and update the study spreadsheet with the results.
- Patients will return the Sunrise device the same time as their oximetry or WatchPAT 300.
- Patient exits the study at this point. No further study requirements from the patient.
- Sunrise results will be triaged by the PI and the clinical fellow. Both will be blinded to the oximetry and WatchPAT 300 triage outcome.
- Hypothetical management plan following Sunrise Triage i) CPAP set up; ii) further diagnostic testing or iii) discharge from sleep service) iv) clinic appointment for further discussion.
- The patient referral letter and new patient questionnaire will be consulted after Sunrise data hypothetical managements are determined, to compare the patient's clinical pathway following current practice and a CRF completed.

The processes of participant recruitment, passage through the study and data collection are described in the study flow diagram below:

TELEPHONE CALL AND VERBAL DISCUSSION

- Identification from exclusion / inclusion criteria
- Patient called to discuss study and ask questions
- If patient agrees to participate, the study process and requirements will be explained.

VISIT 1: DEVICE COLLECTION

- Consent process completed
- CRF completion
- Height and weight measured
- Patient collects oximeter and Sunrise or WatchPAT and Sunrise equipment from sleep unit reception. QR code for patient feedback questionnaire included. Paper copy available.

Patient uses equipment at home.
Patient completes new patient form, Epworth sleepiness score and patient feedback questionnaire.

VISIT 2: RETURN DEVICE

- Patient returns both devices and questionnaires to the sleep unit reception
- Confirm questionnaires have been completed
- If electronic questionnaires not completed, paper questionnaire available.

Patient exits the study at this point and continues on existing clincial pathway.

POST DIAGNOSTIC TRIAGE

- Oximetry and WatchPAT 300 results downloaded and triaged as per clinical pathway by the clinical team
- Triage options: CPAP set up, discharge from service, clinic appointment or further diagnostic testing.
- Patient continues on current clinical pathway.

SUNRISE TRIAGE

- The Sunrise results will be triaged by the PI and Clinical fellow who are blinded to the oximetry and WatchPAT results
- The triage will not affect patient treatment or diagnostic pathway
- Results and questionnaires analysed
- CRF completed

END OF STUDY

4 STUDY SETTING

This is a single centre study that will be conducted at Bristol Royal Infirmary (BRI) Sleep Unit. Participants will collect the sleep study equipment from the Sleep Unit department. The sleep study equipment will be used overnight in the patient's usual home residence. Patients with suspected OSA referred into BRI sleep service from primary or other secondary care providers, who meet the eligibility criteria, will be approached for recruitment into the study. Patients will follow the standard care pathway for this study and no additional hospital visits will be required for patients who consent to participating. If patients decline to participate, this will not affect their standard care pathway.

5 ELIGIBILITY CRITERIA

5.1 Inclusion Criteria

- Adults (aged ≥18 years old) referred with suspected Obstructive Sleep Apnoea
- Patient has capacity to provide informed consent
- Patient has access to a smartphone with Bluetooth and WiFi or internet data to download the Sunrise app and to transmit the Sunrise results to the Sunrise portal. UHBW Trust Wi-Fi available to the patient at equipment collection and return if needed.
- Willing and able to comply with the study-specific procedures
- Ability to read and comprehend English or understand simple device user instructions with guided pictures in English.

5.2 Exclusion Criteria

- Suspected diagnosis of a sleep disorder other than OSA (including central sleep apnoea, parasomnias, narcolepsy, idiopathic hypersomnia)
- Suspected chronic hypercapnic respiratory failure (history of acute hypercapnic respiratory failure, raised CO_2 or serum bicarbonate)
- Patients with unstable cardiovascular disease or non-arteritic anterior ischaemic optic neuropathy
- Patients with beards who are unwilling to shave the area below their lip (the soul patch)
- Patients with conditions affecting the rotation of the condyle in the temporo-mandibular joint
- Unable to consent or lacks capacity to provide informed consent
- In-patient referrals
- Unwilling or unable to comply with the study-specific procedures.
- Patients who have requested in their medical notes not to be involved in research or not to receive digital communication

5.3 Withdrawal Criteria

A patient can choose to withdraw from the study at any time up until the end of the study.

If a patient did not wish to use the Sunrise device they would continue on their existing clinical diagnostic pathway as with current practice. Their diagnostic pathway or treatment options would not be affected by withdrawal from the study.

If the patient wanted to withdraw after using the Sunrise device, they would be removed from the Sunrise analysis and triaged by their WatchPAT 300 or oximetry results, following the existing clinical pathway and their treatment would not be delayed.

If a patient wishes to withdraw, they will be given the opportunity to speak to the PI or database manager to confirm their withdrawal and the participant does not need to give a reason for withdrawal. This will be noted on the Case Report Form (CRF).

Patients who do not want to continue with any diagnostic sleep test within the service will be discharged from the service and the study, following current protocol.

The study may be prematurely stopped if any field safety notices relating to the Sunrise device are issued, or the Sunrise device is withdrawn by the manufacturers.

6 STUDY PROCEDURES

6.1 Recruitment

Patients with suspected OSA, including urgent pathway patients referred to the adult sleep service will be triaged to undergo either oximetry or WatchPAT 300 assessments based on the current clinical pathway. All patients 40 years of age and under are automatically triaged to WatchPAT based on previous internal audits. The study will aim to recruit a range of demographics representative of our current patient cohort and our randomisation process aims to do this. Ethnicity data will be recorded to assess our participant representation in the study. Eligible patients will be sent to the PI in date order of referral and the PI will screen and recruit in order from the top of the list. If screened and recruited patients are not representative of a range of demographics, the lead administrator can filter the list of referrals based on sex and age.

The PI, co-investigator or clinical fellow, will assess whether patients referred to the service meet inclusion / exclusion criteria by reviewing referral letters and patient demographics. The PI, co-investigator and clinical fellow are clinical members of staff employed by the Trust and already have access to the patient electronic record and are involved in the triaging process and part of the existing clinical care team. No additional screening is required beyond meeting the inclusion/exclusion criteria.

Patients eligible to participate to the study will be added to the study spreadsheet on the Trust Information Technology (IT) system. Names and hospital numbers of eligible patients will be sent to the administrator lead who is involved in the administrative side of the triaging process in their current role. No additional access is required.

Patients will only be recruited by the above method and not through adverts or posters. Whether patients are eligible or not, they will all follow the existing clinical pathway as standard.

Eligible patients will be sent via post a covering letter and the Patient Information Sheet (PIS) and appointment letter for their oximetry or WatchPAT collection. Seven days after the letter is sent, the patient will be contacted by telephone to discuss eligibility by the PI, co-investigator or clinical fellow. Their telephone number will be available on the Trust Care Flow electronic patient record system (EPR). Eligible patients who verbally agree to participate at the initial telephone call will be added to the study database by the PI, co-investigator, clinical fellow or database manager. When the patient attends the sleep department to collect their diagnostic study (oximetry or WatchPAT 300 will be prepared by the clinical team as part of the existing clinical pathway), the PI, co-investigator, clinical fellow or database manager will discuss the study and consent paperwork with the patient. If the patient still wishes to proceed with the study and signs the paperwork, the PI, co-investigator, clinical fellow or database manager will allocate the Sunrise device, issue study specific paperwork (patient feedback questionnaire, Sunrise instructions). Consent paperwork will be completed by the PI, co-investigator, clinical fellow or database manager with the patient when they attend the department to collect their equipment and they will be recruited into the study. Any patients who verbally agree to participate but do not wish to complete consent paperwork or have changed their mind will be removed from the study database. Once the consent paperwork has been completed, the Sunrise device will be allocated to the patient. All clinical staff have access to the electronic patient records as part of their Trust access and no additional patient information or access is required.

If a patient does not wish to participate or withdraws after being recruited into the study, they will continue to follow the existing patient pathway and no delays will occur to diagnosis or treatment.

There are no additional screening tests to the patient's existing clinical pathway. Patients will have the below recorded or checked as part of the current patient pathway:

- Sex: Male (M) or Female (F)
- Age: years old
- Height: centimetre (cm)
- Weight: Kilograms (kg)
- Body Mass Index: (BMI) kilograms / metre squared (kg/m^2)
- Collar size: centimetre (cm)
- Ethnicity

6.2 Consent

- Seven days after a letter and PIS have been sent to eligible patients, the PI will contact the patient via telephone. If the patient is interested in participating in the study, the nature and objectives of the study will be discussed, and the process if they were to participate.
- The patient will have the opportunity to ask questions during the initial phone call and when they collect and return the equipment to the department.
- A patient requires capacity to consent to this study. This will be determined by their medical notes, the referral letter and when speaking to the patient. This is within the recommended guidance of the Mental Capacity Act 2005, NICE (2018) guidance and compliant with UHBW Trust safeguarding.
- Written consent will be obtained from the patients when they collect their oximetry and Sunrise or WatchPAT 300 and Sunrise device from the sleep clinic.

The PI, co-investigator, clinical fellow and database manager have completed Good Clinical Practice (GCP) training. The PI has also completed the MMU Research Integrity Training.

6.3 Blinding

- The unblinded investigators within UHBW will be the co-investigator and the trial database manager. Unblinded investigators will have access to the complete data set including oximetry and WatchPAT 300 results throughout the study recruitment. They will not be involved in any blinded tasks which include triaging the Sunrise report.
- The PI and clinical fellow who will be triaging the Sunrise result will be blinded to the results of the WatchPAT 300 or oximetry result, and the clinical management decision made based on the WatchPAT 300 or oximetry result.
- The database manager will save the Sunrise report, new patient questionnaire, Epworth Sleepiness Score (ESS) and original patient referral letter in the Sunrise research folder under the patient's study number and inform the PI and clinical fellow when reports are ready. The PI and clinical fellow will triage each Sunrise report independently and blinded to each other's triage results. The PI and clinical fellow will save their triage outcome on independent Excel spreadsheets which the database manager and co-investigator have access to. The database manager will populate the results on the master database which has all information on including the oximetry and WatchPAT 300 results.
- Study participants will not be blinded as they will visually see whether they are issued oximetry or WatchPAT 300 plus Sunrise device.

6.4 Unblinding

Once data collection and triaging has finished, the oximetry and WatchPAT 300 result and the clinical management decision made on those results will be made available to the PI to analyse the study outcomes.

6.5 Baseline Data

Patient demographics

The below patient data will be collected for the study and will be either checked when the patient collects their equipment or will be available on their referral letter or electronic patient records (EPR). All information will be recorded in the CRF. The measurements will be recorded once and not repeated as part of this study:

- Sex: Male (M) or Female (F) – recorded from referral letter or EPR. Ensuring both male and female participants are represented for statistical analysis.
- Date of birth: recorded from referral letter or EPR. Ensuring a range of ages are represented for statistical analysis.
- Ethnicity: recorded from referral letter or EPR. Prevalence and severity of OSA can vary between ethnic groups. Recording ethnicity ensures research findings can be represented across our typical patient cohort and across diverse populations.
- Age: years old – recorded from referral letter or EPR. The risk of developing OSA increases with age but we have several younger patients referred into the service and intend to record ages for statistical analysis.
- Height: centimetre (cm) – measured at device collection. This measurement is used to calculate Body Mass Index.
- Weight: Kilograms (kg) – measured at device collection. One of the most significant risk factors for obstructive sleep apnoea is obesity and weight is used to calculate Body mass index.
- Body Mass Index: (BMI) kilograms / metre squared (kg/m^2) – measured at device collection. Increased BMI is associated with increased OSA severity.
- Collar size: centimetre (cm) – measured at device collection. Neck circumference can be used as a predictor of OSA in adults.

Epworth Sleepiness Score (ESS)

The ESS is a standardised self-reported questionnaire to assess patients' daytime sleepiness. There are eight questions asking the likeliness of dozing or falling asleep in various daily situations including sitting and reading, watching television, sitting inactive in a public place, as a passenger in a car for an hour without a break, lying down to rest, sitting talking to someone, sitting quietly after lunch without alcohol, in a car while stopped for a few minutes in traffic. Each question is answered with a score 0-3 with a maximum score of 24 (0= would never doze, 3 = high chance of dozing). A score ≥11 usually indicates excessive sleepiness. This questionnaire is routinely issued to all new patients referred into the sleep service and repeated after a treatment intervention to assess if sleepiness has reduced.

Oximetry derived parameters

Overnight oximetry is a simple non-invasive diagnostic test used during sleep to monitor oxygen levels in the blood and heart rate as a screening test for OSA. Oximetry is worn on the wrist like a watch with a probe on the finger, the probe uses a pulse oximeter which measures the percentage of oxygen in the blood measured as oxygen saturations or SpO_2 and heart rate.

Oxygen saturation (SpO2) refers to the percentage of haemoglobin carrying oxygen in the blood. SpO2 levels between 95-100% are considered the normal range and SpO2 which reduces and increases by ≥3% or below 90% can indicate sleep disordered breathing such as OSA or issues with oxygen absorption. Changes in heart rate correlated with oxygen desaturations can be associated with OSA.

Oximetry is a convenient, non-invasive and affordable test which can be used in patient's homes and is simple to download and generate results. However as only two channels are measured and sleep staging cannot be recorded, there are limitations to this test and users must be aware of these limitations as recommended in NICE (2021) guidance. Oximetry does not measure sleep parameters such as body position, sleep stages, snoring and can underestimate mild OSA or OSA in younger patients.

The following parameters will be analysed:

Oxygen desaturation index (ODI) ≥3%: ODI is the frequency of signal changes on the oximetry channel. This study will analyse the number of desaturation changes ≥3% as recommended by the American Academy of Sleep Medicine (AASM) scoring guidelines (American Academy of Sleep Medicine, 2023).

Median Heart Rate beats per minute (bpm): heart rate can fluctuate during sleep due to awakenings, apnoeas, hypopnoeas or body position changes. Using the median heart rate reduces the influence in transient values and provides a stable representation of heart rate throughout the night offering a more consistent metric to evaluate cardiovascular health during sleep.

Heart rate variation > 6 beats per minute (bpm): The number of times the heart rate increases by more than 6bpm. Changes in heart rate are paired with oxygen desaturations which are used to diagnose OSA.

Median SpO_2: Represents oxygen levels overnight. Using median SpO_2 reflects overall oxygen levels during sleep. Using the median reduces the impact of outliers of minimum and maximum SpO_2 levels and reduces the influence of transient abnormalities.

WatchPAT 300 derived parameters

WatchPAT 300 is a home-based non-invasive sleep diagnostic test used to assess OSA. WatchPAT 300 is worn on the wrist with a probe on the finger while the patient sleeps (similar to oximetry), which continually monitors a range of physiological parameters including: pulse oximetry, heart rate,

movement, airflow, Peripheral arterial tone (PAT), an indication of the sympathetic nervous system activity. The device measures changes in the peripheral arterial tone which reflects variations in blood flow related. Following an apnoea, there is an arousal from sleep which results in increased arterial tone and heart rate which is detected by the WatchPAT 300 and termed a "reciprocal pattern". When a reciprocal pattern is associated with a change in oxygen saturations, an apnoea-hypopnoea (AHI) event is recorded by the WatchPAT algorithm. WatchPAT 300 is portable and simple for the patient to use in their own home, and has been clinically validated as an alternative to PSG to diagnose OSA (Ichikawa *et al.*, 2022; Iftikhar *et al.*, 2022). The WatchPAT software auto analyses but this needs manual editing by a trained clinician before the results can be finalised and used in the diagnostic pathway.

The following parameters will be analysed:

Peripheral Arterial Tonometry Apnoea Hypopnoea Index (pAHI): PAT is used with SpO_2 and heart rate to calculate the Apnoea Hypopnoea Index (AHI) by detecting changes in blood flow associated with arousals from sleep due to sleep apnoea. The AHI is the total number of apnoeas (complete cessation of airflow) (apnoeas are categorised into obstructive, central and mixed) and (hypopnoeas (partial reduction in air flow) during sleep divided by the total sleep time. A higher AHI indicates higher severity of OSA.

Oxygen desaturation index (ODI) ≥3%: ODI is the frequency of signal changes on the oximetry channel. This study will analyse the number of desaturation changes ≥3% as recommended by the American Academy of Sleep Medicine (AASM) scoring guidelines (American Academy of Sleep Medicine, 2023).

Peripheral Arterial Tonometry Respiratory Disturbance Index (pRDI): An index reporting respiratory events during sleep including respiratory effort related arousals (RERAs), hypopnoeas and apnoeas. RERAs cause disruptions to sleep but do not meet the criteria to be classed as apnoeas or hypopnoeas. pRDI is calculated using oxygen desaturation ≥3%: RDI = (RERAs + Hypopnoeas + Apnoeas) / TST (in hours).

Sleep Onset Latency (SOL): The time taken to transition from wakefulness to sleep after lying down. This is important as if SOL is measured incorrectly, this will influence the AHI.

Total Sleep Time (TST): The number of hours and minutes the patient is asleep while using the device. Measuring TST is important as calculating AHI needs to be the total amount of sleep not including time in bed when the patient is falling asleep.

Sleep Efficiency (SE): percentage of time spent asleep while in bed. SE is calculated by dividing the total sleep time by the total amount of time in bed.

Sleep time per body position: detected using a 3-axis accelerometer monitoring movement and orientation of the chest sensor during the night. The device can detect patterns of restlessness or

sleep positional changes. This is important to assess if OSA severity increases in a particular sleep position.

Sunrise derived parameters

The Sunrise OSA device has been described earlier in the protocol. The device does not have a flow sensor and the AHI is derived from a number of metrics. When an apnoea or hypopnoea occur, the change in breathing causes an arousal (a mini awakening detected in the Electroencephalogram (EEG) in a PSG study. Wearable devices do not have EEGs. The arousal index (ArI) recorded on the Sunrise corresponds to the number of awakenings (if the arousal lasts more than 15 seconds) and arousals (sleep interruptions lasting 3-15 seconds) per hour of sleep. The ArI indicates sleep fragmentation (disturbance) during sleep. Another parameter is the Obstructive respiratory disturbance index (ORDI) which correlates to the number of obstructive and mixed apnoeas, obstructive hypopnoeas and respiratory effort-related arousals per hour of sleep.

The following parameters will be analysed:

Estimated Apnoea Hypopnoea Index (AHI): Version 1 of the Sunrise device does not have an SpO2 sensor. The AHI is the number of obstructive, mixed and central apnoeas per hour of sleep. The estimated AHI for Sunrise is extrapolated from the metrics derived from MM signal analysis (including TST, ORDI and ArI in combination with gender, age, BMI and neck circumference data).

Respiratory Disturbance Index (RDI): An index reporting respiratory events during sleep including respiratory effort related arousals (RERAs), hypopnoeas and apnoeas. RERAs cause disruptions to sleep but do not meet the criteria to be classed as apnoeas or hypopnoeas. RDI = (RERAs + Hypopnoeas + Apnoeas) / TST (in hours).

Sleep Onset Latency (SOL): The time taken to transition from wakefulness to sleep after lying down. This is important as if SOL is measured incorrectly, this will influence the AHI.

Total Sleep Time (TST): The number of hours and minutes the patient is asleep while using the device. Measuring TST is important as calculating AHI needs to be the total amount of sleep not including time in bed when the patient is falling asleep.

Sleep time per body position: detected through an accelerometer and gyroscope.

Sleep Efficiency (SE): percentage of time spent asleep while in bed. SE is calculated by dividing the total sleep time by the total amount of time in bed.

Number of failed studies: If the Sunrise device is used but does not generate data, there is less than 4 hours of study recording, the patient was unable to use the device, or there is a fault with the device, this will be recorded as a failed study assessment.

6.6 Patient Assessments

- Telephone call 1
  - Eligible patients will be called to determine whether they would be willing to participate in the study.
  - If patients agree, the study will be explained to them and they will be able to ask any initial questions.
  - If patients decline to participate, they will continue to have oximetry or WatchPAT 300 as part of their clinical pathway and their diagnostic pathway will not be altered.

- Visit 1
  - Patient attends to collect sleep test (oximetry or WatchPAT 300) as part of usual pathway. Written instructions are given to the patient as part of this collection with access to an oximetry instructions video via a Quick Response (QR) code.
  - Questionnaires (Epworth sleepiness core, sleep history questionnaire) issued electronically or in paper format
  - Consented for study – paper consent form signed.
  - A patient feedback questionnaire will be issued with the Sunrise device via Microsoft forms accessible via a QR code. A paper form will be offered if patients are unable to access the Microsoft form or data has not been completed upon returning the device. A QR code on the patient instructions will also direct the user to a step-by-step video to set up the Sunrise app and use the device. This is in addition to paper instructions provided by Sunrise.
  - Height and weight will be taken and BMI calculated
  - Collar size will also be measured

- Visit 2 (appointment booked 2 days after visit 1)
  - Patient returns oximetry/WatchPAT 300 and Sunrise device
  - Oximetry or WatchPAT 300 and Sunrise data will be downloaded.
  - If a patient was unable to complete the feedback questionnaire on Microsoft forms, they will be issued a paper form to complete this.

6.7 Long term follow-up assessments

There is no long-term assessment or follow up as part of this study. Once the equipment has been returned, this is the end of the patient's involvement in the study. The patient will follow the existing clinical pathway and a clinical management decision will be made according to their oximetry or WatchPAT 300 results alongside clinical information. This will be based on the post diagnostic triage pathway as part of the current pathway (Appendix 3). This process was agreed at the department clinical governance meeting. The existing clinical care pathway will then continue.

6.8 Qualitative assessments – nested studies

The patient will be issued a feedback questionnaire to review ease of use of Sunrise at the time of issuing the device. Questions will also cover patient satisfaction and if the patient had any difficulty using the Sunrise device. These answers will be reviewed as part of the secondary objectives.

If any data is missing from the questionnaire, the PI and database manager will contact the patient via telephone and ask if they will answer any missing questions over the phone and explain this will be added to their questionnaire answers.

6.9 Withdrawal Procedures

A patient can choose to withdraw from the study at any time. They can request this either in person or by contacting the study team by emailing the PI or database manager using the contact details available in the PIS. Once notification to withdraw has been received all data relating to the patient who wishes to withdraw from the study will be removed from the study database and any digital forms completed deleted. Any corresponding paper documents will be destroyed through the Trusts confidential waste disposal system. This will be carried out by the PI, database manager, clinical fellow or co-investigator.

Patients will be made aware if they choose to withdraw from the study this will not affect their clinical treatment or pathway. Patients will then be replaced by recruiting other patients from the current waiting list to ensure study reaches its planned recruitment.

The study may be prematurely stopped if any field risk notices relating to the Sunrise device are issued, or the Sunrise device is withdrawn by the manufacturers.

7 ADVERSE EVENTS

7.1 Definitions

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

1 Results in death
2 Is life-threatening – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe
3 Requires hospitalisation, or prolongation of existing inpatients' hospitalisation
4 Results in persistent or significant disability or incapacity
5 Is a congenital anomaly or birth defect

7.2 Reporting procedures

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

7.2.1 Non serious Adverse Event (AE)s

All such events, whether expected or not, should be recorded using a file note and stored in the study master file.

Non serious AEs do not need to be reported to the sponsor. They will be managed locally by the research team, co-investigator, PI and UHBW.

Any adverse events will be noted on the patient's CRF and if appropriate the incident would be reported on a clinical incident reporting tool (Datix) as per standard Trust protocol. The sponsor would also be informed.

Any safeguarding queries will be managed in accordance with the Trust's safeguarding policy and concerns raised through the Trust safeguarding department.

The study follows the existing patient pathway at UHBW Sleep Unit and will not make any changes to existing clinical protocols and existing pathways will be followed. There are no invasive procedures in this study. In addition, patients will wear the Sunrise device which is a non-invasive test that is licensed for medical use. Should the device be uncomfortable while worn on the mandible, or the patient's wishes to stop using the device, it can be removed by the patient at any time.

7.2.2 Serious AE (SAE)s

For any SAEs the PI and medical consultant co-investigator are on site at UHBW and will be notified immediately via email. A SAE form will be completed and emailed to the Chief Investigator (CI) within 24 hours.

All SAEs will be reported to the REC that approved the study within 15 days of the CI becoming aware of the event and follow any recommendations and actions they state where in the opinion of the Chief Investigator, the event was:

1 'related', ie resulted from the administration of any of the research procedures; and
2 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the National Research Ethics Service SAE form for non-Investigational Medicinal Products studies. The Chief Investigator must also notify the Sponsor of all SAEs.

Contact details for reporting SAEs

CI responsible for reporting / co-investigator medically responsible Email: v.hawkins@mmu.ac.uk, attention Dr Virginia Hawkins (CI). Email: laura.buckley@uhbw.nhs.uk, attention: Dr Laura Buckley co-investigator.

Please send SAE forms to: v.hawkins@mmu.ac.uk

Tel: +44(0)161 247 1092 (Mon to Fri 09:00-17:00)

8 STATISTICS AND DATA ANALYSIS

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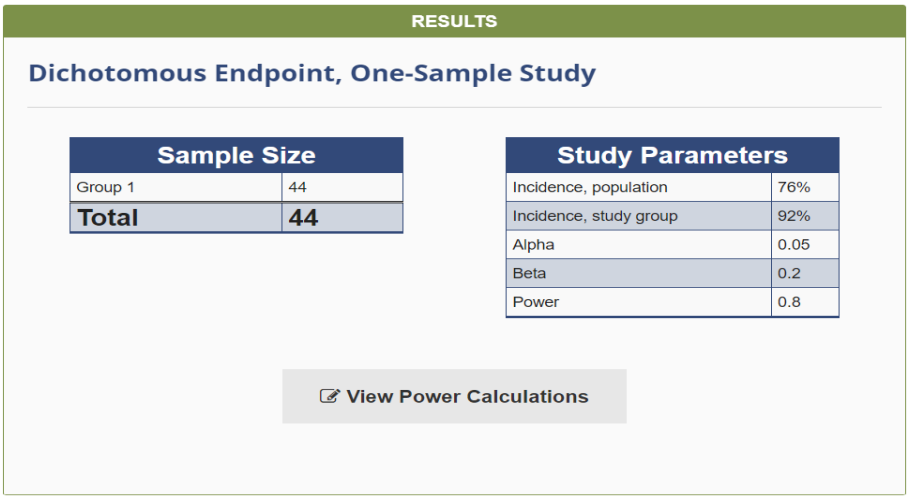
8.1 Sample size calculation

A sample size of 100 patients (50 patients undergoing oximetry and 50 WatchPAT 300) was selected based on power (90%) and type I error (5%) considerations for the primary endpoint of the proportion of patients in whom there is a definitive management decision made following testing with Sunrise compared to oximetry or WatchPAT 300.

Data from a pilot study in the department reviewing patients who underwent oximetry to diagnose OSA showed that 76% of patients reached a management decision following the initial test. Sunrise has demonstrated a 92% accuracy in comparison to Polysomnography (Pepin *et al.*, 2020). This study was selected as in-laboratory PSG was used and it has the largest sample size. We calculated that a sample size of 44 patients undergoing oximetry and 44 undergoing WatchPAT 300 would be required and plan to recruit 50 patients from each group (total 100) to allow for test failure or loss to follow up.

The sample size was calculated via an online sample size calculator ClinicCalc (2024).


RESULTS

Dichotomous Endpoint, One-Sample Study

Sample Size	
Group 1	44
Total	**44**

Study Parameters	
Incidence, population	76%
Incidence, study group	92%
Alpha	0.05
Beta	0.2
Power	0.8

View Power Calculations

8.2 Planned recruitment rate

The UHBW sleep unit receives on average 30 referrals per week.

There is only one recruitment site and department. Based on average numbers of new patients referred to the service, we expect approximately 60% of patients (18 per week) referred to be eligible for the study.

Expected recruitment rate would be approximately five to six patients per week over 16 – 20 weeks to achieve total recruitment of 100 patients. The PI and co-investigator determined this number based on current resources of clinical and research staff time, where the PI has dedicated time in addition to their clinical role for completion of the study.

- During the recruitment phase, the administrator lead will send 16-20 patients per week to the PI, clinical fellow and co-investigator to screen from the current patient waiting list. Patients will be selected randomly by selecting them in order of referral date (16-20 with the oldest date of referral). If there are not enough patients eligible in the first set of patients sent due to exclusion / inclusion criteria, the administrator lead will then send an additional shortlist of patients for screening in order of referral date at the PI's request. This list of patients has already been triaged for oximetry or WatchPAT in the clinical pathway. Equal numbers of patients triaged to oximetry or WatchPAT will be sent e.g. eight oximetry and eight WatchPAT patients for even recruitment rate in each group. If required, the administrator lead can filter the referrals based on sex and age to ensure there is even distribution across all groups.
- If a Sunrise study fails, this study will be recorded as a test failure and a new patient will be recruited.

8.3 Statistical analysis plan

8.3.1 Summary of baseline data and flow of patients

Variable	Type of variable	How this will be reported
Age	Continuous	Mean ± standard deviation if normally distributed or median interquartile range (IQR) if not normally distributed
Sex	Categorical	Percentage
BMI	Continuous	Mean ± standard deviation if normally distributed or median interquartile range (IQR) if not normally distributed
Weight	Continuous	Mean ± standard deviation if normally distributed or median interquartile range (IQR) if not normally distributed

Height	Continuous	Mean ± standard deviation if normally distributed or median interquartile range (IQR) if not normally distributed
Collar Size	Continuous	Mean ± standard deviation if normally distributed or median interquartile range (IQR) if not normally distributed
Ethnicity	Categorical	Percentage
Epworth Sleepiness Score	Continuous	Mean ± standard deviation if normally distributed or median interquartile range (IQR) if not normally distributed

8.3.2 Primary outcome analysis

Statistical analysis

Chi squared test will be used to analyse the primary outcome.

- Any missing data will be gathered by the PI and database manager.
- If oximetry or WatchPAT 300 fails, patients will be offered a repeat study as part of their clinical pathway. A repeat Sunrise study will not be offered and this will be recorded as a failed test.
- If a patient withdraws from the study or the Sunrise device fails, their data will not be used in the final analysis.
- If the Sunrise device fails, the device failure will be recorded in the results as a secondary outcome. An additional patient will be recruited to ensure the n number is achieved.

8.3.3 Secondary outcome analysis

Objective	Statistical analysis
Level of agreement in management decision between Sunrise and oximetry or WatchPAT 300	Cohen's kappa
Estimated Apnoea-hypopnoea index (AHI) derived from Sunrise compared with ≥ 3% oxygen desaturation index (ODI) derived from oximetry or ≥ 3% PAT-derived AHI (pAHI) from WatchPAT 300 Respiratory Disturbance Index (RDI) derived from Sunrise compared to RDI from WatchPAT 300	Bland Altman and Intraclass Correlation (ICC)

Sleep Onset Latency Sleep Efficiency Total Sleep Time Sleep time per body position (*derived from Sunrise compared to WatchPAT* 300)	
Proportion of failed / inconclusive tests. Proportion of patients reporting Sunrise as easy to use; number of patients reporting difficulty using the test.	Chi Squared
Analysis time for Sunrise, WatchPAT 300 and Oximetry. Cost of Sunrise device versus WatchPAT 300 and Sunrise versus oximetry device.	2-sample t-test for normal distribution or Mann-Whitney for non-normally distributed data
Patient feedback questionnaires	Likert scale for semi-qualitative analysis with free text boxes for patient feedback. Data will be collated to inform future practice.

8.4 Subject population

The participant population will be patients referred into the adult sleep service for suspected OSA at the Bristol Royal Infirmary aged ≥18 years old.

8.5 Procedure(s) to account for missing or spurious data

- To ensure missing data is minimised, when patients collect the sleep study equipment, they will be informed of the QR code to complete the questionnaire. If they are unable to access the QR code a paper format of the patient questionnaire will be provided. When returning the equipment, the patient will be asked if there were any issues with the equipment or the questionnaire. If the electronic patient questionnaire has not been completed, the patient will be provided with a paper copy. If there is any missing data from the patient questionnaire, the PI will contact the patient to complete any missing questions over the phone.
- If the result of both Sunrise and oximetry or WatchPAT 300 is not available, the patient will be excluded from the study
- If any qualitative or quantitative data cannot be collected, the reason will be recorded on the CRF and patient database.

8.6 Qualitative analysis

The patient and clinician feedback forms will be reviewed. The qualitative data will be analysed by collating the patient answers from the Likert scale and reviewing written answers to consider themes or patient recommendations.

The patient and clinician feedback questionnaires are included in the supporting evidence.

9 DATA HANDLING

9.1 Data collection tools and source document identification

- Data will be collected from the oximetry, WatchPAT 300 and Sunrise reports and recorded in the CRF and database. Oximetry is downloaded via the Stowood Limited (Oxford, United Kingdom) software Visi-Download (version 1.0) and WatchPAT 300 is downloaded via CloudPAT (Version 3.14). Both software platforms are already installed on the Trust IT system and compliant with Trust General Data Protection Regulation (GDPR) and information governance. As part of this study the Sunrise cloud has been installed to enable access to the Sunrise results. A Data Protection Impact Assessment (DPIA) was completed.
- Data will be collected from the ESS which is a standardised tool used nationally in sleep medicine departments.
- The new patient questionnaire is already being used in the clinical pathway and was agreed and signed off at the department's Clinical Governance Meeting (CGM). The sleep history questionnaire includes information regarding symptoms, sleep routine, social history (smoking and alcohol consumption), driving status.
- The Sunrise Patient Feedback Questionnaire will be answered via the patient scanning a QR code or via paper copy if they are unable to access the QR code. The first question on the questionnaire will require the patient to add their participation ID e.g. 001, 002, 003. They will be informed of this Identification (ID) number when they collect their equipment for the study.
- The clinicians involved in the study will complete a clinician feedback questionnaire on the use of the Sunrise device and portal.
- Each patient will have a CRF containing non identifiable personal demographics, patient questionnaires, pdf of diagnostic reports and consent forms. Each patient will have an electronic folder where all information, bar the consent form is saved, the file will be named their patient allocation number e.g. 001, 002, 003. The electronic folders will be saved within the UHBW Sleep Unit drive which contains confidential information within the department and is secure. The study folder will have restricted access to UHBW staff named in this protocol. Patient identification numbers will be assigned within the database. Any paper copies of questionnaires or consent forms will be scanned onto the electronic file by the PI and database manager. A lever arch file will be available to also store original paper copies of CRF, consent forms and any paper copies of the patient questionnaires completed. This will be kept in a locked, secure location in the sleep unit. The database will be managed by the PI and the database manager. Consent forms will be saved away from the study data so the patient cannot be linked to the participant ID. Results of the WatchPAT 300 and

oximetry will be blinded from the PI by the database manager until after the Sunrise triage decision.

- Sunrise user data is saved in the Sunrise portal when the user (the PI, clinical fellow or database manager) creates the Sunrise account. New data will be added when the patient sets up their Sunrise account via the app and new data is stored when the Sunrise device is used which will include the RAW data from the night of the sleep study. No data backup will be stored locally on the app during the test. Once the Sunrise test has been completed, RAW data (sleep study results) will be sent to the cloud for analysis.

9.2 Data handling and record keeping

- Data including the patient referral letter, sleep history questionnaire, Epworth sleepiness score, WatchPAT 300 and oximetry results will be stored on CareFlow EPR and backed up every 24 hours onto UHBW servers.
- The above and the Sunrise pdf reports will be saved in the patient's electronic folder and saved in a locked file within the Sleep Unit secure drive which is backed up through the Trust IT servers.
- The database will be a Microsoft Office 365 Excel file. The database will be stored in a secure folder on the Sleep Unit IT drive. This folder will have restricted access authorised by UHBW IT team. The PI, database manager, co-investigator and clinical fellow have entry access.
- The PI, database manager and co-investigator are responsible for the data entry and quality
- The PI and co-investigator are responsible for the data analysis
- If CareFlow EPR (the UHBW electronic patient record) had a data breach, this would be managed by UHBW Cyber team. A data protection impact assessment (DPIA) form has been completed for Sunrise as part of this project which covers data breaches.
- Anonymised (participant ID numbered) datasets will be shared with the CI using a secure link to data uploaded by the PI on a shared Manchester Metropolitan Microsoft OneDrive folder.
- No study documents will be shared outside the research study team. The research study team plan to publish the study in a peer reviewed journal and present their findings at scientific conferences.
- The database will be designed to protect patient information in line with the General Data Protection Regulation. Study staff will ensure that the participants' anonymity is maintained through protective and secure handling and storage of patient information at the study centres (as relevant) in line with the Ethics approval. All documents will be stored securely and only accessible by study staff and authorised personnel. Data will be collected and retained in accordance with the General Data Protection Regulation.
- All documentation will state the IRAS number and version.
- Manchester Metropolitan University (sponsor) requires that data is kept for 10 years, as the PI will not be a student at Manchester Metropolitan University for the entirety of this time, the final dataset from the research study will be collated and sent to the CI (data custodian) who will be responsible for its deletion after 10 years. All collected data will be sent to the sponsor via secure email (NHS email) or shared OneDrive folders from the PI to the CI. All

measures in place are to ensure that this study is fully compliant with UK's Data Protection act 2018.

- If there are any data breaches, firstly it will be determined whether this breach was at the Trust or sponsor. The CI will be informed within 24 hours and will then notify the relevant data protection officer (DPO), either at the Trust or the university. The DPO will then determine if a breech has occurred and if so, what action must be taken.
- For the Sunrise portal:
- Security measures in place to protect the data and information, ISO13485 (Quality Management for Medical Devices).
- No data will be transferred outside of the European Economic Area.
- The manufacturers for Sunrise are based in Belgium which is where the Sunrise data is stored. All data through Sunrise is compliant with EU GDPR and UK GDPR (Data Protection Act 2018). Transfers of data from the UK to the EU are permitted on the basis of UK adequacy regulations. For more information please see: https://ico.org.uk/for-organisations/data-protection-and-the-eu/data-protection-and-the-eu-in-detail/the-uk-gdpr/international-data-transfers/.
- The user can ask to delete their personal data from the app / portal at any point. This can be requested by the patient by either clicking the request for account deletion in the app or emailing Sunrise requesting for account deletion.
- No personal data will be processed for marketing purposes by Sunrise.
- No personal data will be shared by Sunrise.
- Automatic backups of the whole Sunrise portal is performed daily.
- Sunrise has controls in place to reduce the cybersecurity risk including the portal/ cloud is certified ISO 27001, monitoring tools to identify suspicious connection attempts, encryption of patient data with customer managed encryption keys and double authentication process for the clinician and patient accounts.

9.3 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution (Rachel Pickersgill, Laura Buckley, Joshua Butler, Amelia Herbert, Zoe Hamilton) and the regulatory authorities to permit study-related monitoring, audits and inspections.

Personnel who have access to the data will be reviewed internally every 6 months. In the event of a member of staff leaving the Trust, this may be reviewed more regularly if required.

The CI will also have access to the collected data as they are ultimately responsible for the storage and deletion of this at the end of the study. Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit study-related monitoring, audits and inspections.

The Patient Information Sheet has information on the Sunrise app. A Data Protection Impact Assessment has been completed internally within the Trust for the Sunrise software and portal. The Sunrise app is downloaded by the patient onto their smart device and links with the Sunrise device. The sunrise portal and app are compliant with General Data Protection Regulation (compliant to ISO

27001 (A09)) when processing any personal data. The personal data will include last name, first name (for the study participants will be asked to insert their study number in place of their name), date of birth, gender, weight, neck circumference, email address, phone number, location, data related to your sleep (the sleep study results), users face picture (face log in if desired through the smart phone) and password for the app. The data will be available to the Sunrise manufacturer as the data processor and UHBW is the data handler (this is similar to how other diagnostic software manufacturers used in the sleep service works and Data Protection Impact Assessment has been completed for these manufacturers when implemented into the service). Consent will be sought from the patients and this is included in the consent form.

9.4 Archiving

- Archiving of study documentation will be authorised by the Sponsor following submission of the end of study report
- A data management plan has been created to review the process of data storage.
- The CI will be responsible for archiving the Sunrise report and patient feedback questionnaire and the anonymised study database. Oximetry and WatchPAT 300 results and new patient questionnaires are saved as part of the EPR as per standard care at UHBW.
- A time limit to store the study data at UHBW will be 1 year from consenting. This period of time it within the PI HSST doctorate study period.
- Within UHBW, the location will be CareFlow EPR and duration of record retention will be eight years as part of the Trust standard pathway of care.
- Raw data for oximetry, WatchPAT and Sunrise will be stored in line with Trust policies covered by document number 5299 'Record-Keeping Standards in Health Records Policy' and 19302 'Records Management and Retention Policy'.
- Essential documents will include patient results from WatchPAT 300 and oximetry, sleep history questionnaire and Epworth Sleepiness Score as part of existing patient care pathway.
- All essential documents will be archived for a minimum of 10 years after completion of study at MMU and 8 years at UHBW.
- Destruction of essential documents as part of the study will require authorisation from the Sponsor
- Hard copies of the patient feedback questionnaires, consent forms and CRF will be destroyed via the Trusts confidential waste. Electronic copies will be saved for 8 years in line with NHS regulations.
- All data will be collected and stored by the CI, who is the data custodian at the University, for a period of 10 years following the end of the study in the Research Data Storage Drive (RDS) at MMU. This is compliant with the retention and disposal schedule at MMU.
- The study information will be transferred within MMU from the OneDrive folder to the RDS. The CI will be responsible to ensure the OneDrive storage will be deleted at the end of the study. The OneDrive folder is compliant with GDPR.
- The CI will have access to the identification log, with the participants study numbers. This information cannot be used to identify individual patients, as only Trust staff who are part of the patient's clinical care have access to the patients' medical records. The CI will be responsible for safe destruction of the data. Once all the study data has been transferred by the PI to the CI, the PI will delete the identification log from the Trust's IT files, and any remaining data will be anonymised. The Trust will not retain any data after the study, except a copy of the consent forms, which will be uploaded to the patients' electronic notes.

- All archived data will be in electronic format
- Archived data will include: blank consent forms, PIS, ethical approval, research protocol, study supporting documents, starting certificates, approval forms and communications.

10 MONITORING, AUDIT & INSPECTION

- The study will be the subject to the audit and monitoring regime of Manchester Metropolitan University in line with applicable MMU SOPs and policies.
- The sponsors are independent from the study and the monitoring personnel.
- All study related documents will be made available on request for monitoring and audit by MMU ethics team, the relevant Research Ethics Committee and for any other regulatory authorities.
- Monitoring can be done by exploring the study dataset or performing site visits
- To assist the sponsor with monitoring the study, the PI and co-investigator can facilitate site visits. The co-investigator will have overall view of the dataset and will be able to communicate any concerns to the sponsor

11 REGULATORY ISSUES

11.1 Ethics Approval

The Chief Investigator has obtained approval from the xxx Research Ethics Committee. The Chief Investigator will require a copy of the HRA approval letter and confirmation of completion of Trust Cost, Capability and Capacity checks before accepting participants into the study. All correspondence with the REC will be retained in the study master file. Substantial amendments that require review by the REC will not be implemented until they have been reviewed and approved by the sponsor and submitted to the REC and HRA and granted a favourable opinion.

The Chief Investigator will notify the REC of the end of the study, and if the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

11.2 Peer review

The protocol has been written by the co-investigator and PI who are the Lead Clinical Sleep Physician (medical consultant) and the Lead Sleep Clinical Scientist of the sleep service at UHBW. The protocol has been reviewed by the CI and academic supervisor at Manchester Metropolitan University and a subject specialist supervisor based at University West of England who will be supervising the PI

through the Higher Specialist Scientific Training (HSST) doctorate process but not involved directly in the daily running of the study.

11.3 Public and Patient involvement

Patient feedback and complaints within the department have been reviewed and have contributed to the study idea and design. The patient feedback and recent NICE guidance on novel diagnostic devices published in December 2024, have been combined to design this study.

A selection of five patients referred into UHBW sleep service, who have already undergone oximetry or WatchPAT studies have been given the PIS to read and give their feedback on the study. Patients were also asked if they understood the PIS and the concept of the study. Feedback was reviewed and necessary amendments made.

Patients who are referred into Bristol Royal Infirmary sleep unit will be recruited into this study. Patient feedback questionnaires for the Sunrise device will be given to participants.

Patient feedback from the questionnaires will be used by the clinical service to review our existing pathway and consider whether Sunrise could be used within our service after the study if the quantitative and qualitative data are supportive of its utility.

11.4 Regulatory Compliance

- Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator must, as part of their Cost, capability and Capacity checks must provide confirmation that the research can start at the site and have the sponsors approval that the research can begin.
- For any amendment that will potentially affect a site's NHS permission, the Chief Investigator/ Principal Investigator will confirm with that site's R&D department that NHS permission is ongoing (note that both substantial amendments, and amendments considered to be non-substantial for the purposes of REC may still need to be notified to NHS R&D)

11.5 Protocol compliance

- Protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.
- Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

11.6 Data protection and patient confidentiality

All investigators and study site staff must comply with the requirements of UK's Data Protection act 2018 (Parlimentary Act, 2018) and EU's General Data Protection Regulation 2016 (European Parliment and of the Council of the European Union, 2016) with regards to the collection, storage, transfer, processing and disclosure of personal information and will uphold the law's core principles.

- Personal information will be collected, kept secure and maintained on the UHBW Trust computer network, which is compliant with GDPR and Information Governance.
- Patients will be recruited into the study and will be assigned numbers e.g. 001, 002, 003 up to 100. Numbers will be added on the CRF and within the database spreadsheet alongside patient information. Research documentation such as the participants questionnaires and sunrise reports will be labelled with this ID number and not a personal identifier.
- Participant information will be saved on the UHBW department shared drive within a secure folder where the PI, co-investigator, Clinical fellow, Administrator lead and database manager will have access. This will be set up through the Trust IT service. Having restricted access will limit the number of people able to access the data.
- No identifying information will need to be transferred. The additional data from the study will be the Sunrise report and patient feedback questionnaire. This will be stored on the MMU Research Data Storage system (RDS) at the end of the study and will be transferred in anonymised format. Reports will be saved by patient number e.g. 001, 002, 003 etc. The anonymised patient feedback questionnaire, oximetry, WatchPAT 300 and Sunrise data will be transferred by the PI using a secure link to data on a shared Manchester Met Microsoft OneDrive folder which the CI will access and transfer the data to the RDS.
- The retention period of study documentation will be 10 years with MMU.
- Patient referral letters and results of oximetry or WatchPAT 300 will be stored on the electronic patient record as part of their clinical care. Data specific to the study will be deleted from the Trust IT folders once the study has been completed and data has been transferred to the CI to archive the study data as described in section 9.4.
- The data custodian is the CI

11.7 Conflicts of Interest

Study costs will be covered by the Higher Specialist Scientific Training (HSST) bursary and Sunrise devices will be purchased via the distributer Sefam Medical Ltd, Lincoln, England.

The distributor or manufacturer does not have any involvement in the study design or outcome. The study has been designed independently by the CI, PI, co-investigator and academic supervisors who have no conflicts of interest with Sunrise.

The Bristol Royal Infirmary sleep unit currently work with Sefam as their CPAP provider. Sefam were awarded as a supplier through a CPAP tender process via NHS Supply Chain.

The study group do not have any personal conflicts of interest with the study.

11.8 Indemnity

Manchester Metropolitan University holds insurance that provides cover for harm arising from the design, conduct and management of the research.

11.9 Amendments

If any amendments are required, the following process will be followed:

- Any substantial amendments will require a submission of valid notice to an amendment to the REC for consideration. As well as being shared with the sponsor for review and approval.
- Any non-substantial amendments will be notified to the NHS R & D office, Manchester Metropolitan R & D team, the local research team and submitted to the authorising REC.
- If amendments are required, this will be discussed with the study team and protocol will be reviewed. The study team includes clinical and non-clinical academics.
- The CI will have overall responsibility for the final decision if the protocol requires amendments.
- Substantive changes will be communicated to relevant stakeholders in writing.
- The amendment history will be tracked in protocol version history within the protocol document. The most recent version will be used as part of the study.

11.10 Access to the final study dataset

- Individuals with full access to the final data set include: Dr Laura Buckley, Rachel Pickersgill, Zoe Hamilton, Dr Joshua Butler and Amelia Herbert. Rachel Pickersgill and Dr Joshua Butler will not have access to oximetry and WatchPAT 300 results during the study as they will be triaging the Sunrise results. All are employed by UHBW with access to all patient information as part of their NHS roles.
- This is a single site study and there are no expected access restrictions for study investigators.
- The study will allow site investigators to access the full dataset if a formal request describing their plans is approved by the steering group.

12 DISSEMINATION POLICY

- The data is owned by Manchester Metropolitan University as the study sponsor.
- On completion of the study, the data will be analysed and tabulated and a Final Study Report/thesis prepared for informing UHBW clinical practice and for assessment within the HSST degree programme at MMU.
- The end of study report will be sent to the REC that includes a summary of the findings.
- The participating investigators have the rights to publish the study data.
- There are no time limits or review requirements on the publications.
- No funding or supporting body needs to be acknowledged within the publications and will not have review and publication rights of the data from the study
- Study participants will receive a letter thanking them for their participation after returning their oximetry and Sunrise or WatchPAT and Sunrise informing them a summary of the study findings is available upon request.
- Participants will have access to their results of the WatchPAT 300 or oximetry results as part of their diagnostic pathway regardless of the study. If the participants specifically request

access to the Sunrise results, this can be accessed via written request to the PI and be provided after the final study report has been compiled.

- The study protocol, full study report, anonymised participant level dataset, and statistical code for generating the results will not be made publicly available. No personal identifying information will be made available beyond the Trust.
- The study will be registered on www.clinicaltrials.gov.

12.1 Authorship eligibility guidelines and any intended use of professional writers

The authors for the final study will include: Rachel Pickersgill, Dr Laura Buckley, Dr Elizabeth Hill, Dr Virginia Hawkins, Prof Sonia Correra-Muller, Dr Joshua Butler and Zoe Hamilton.

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14 APPENDICES

Appendix 1 - Summary of investigations, treatment and assessments

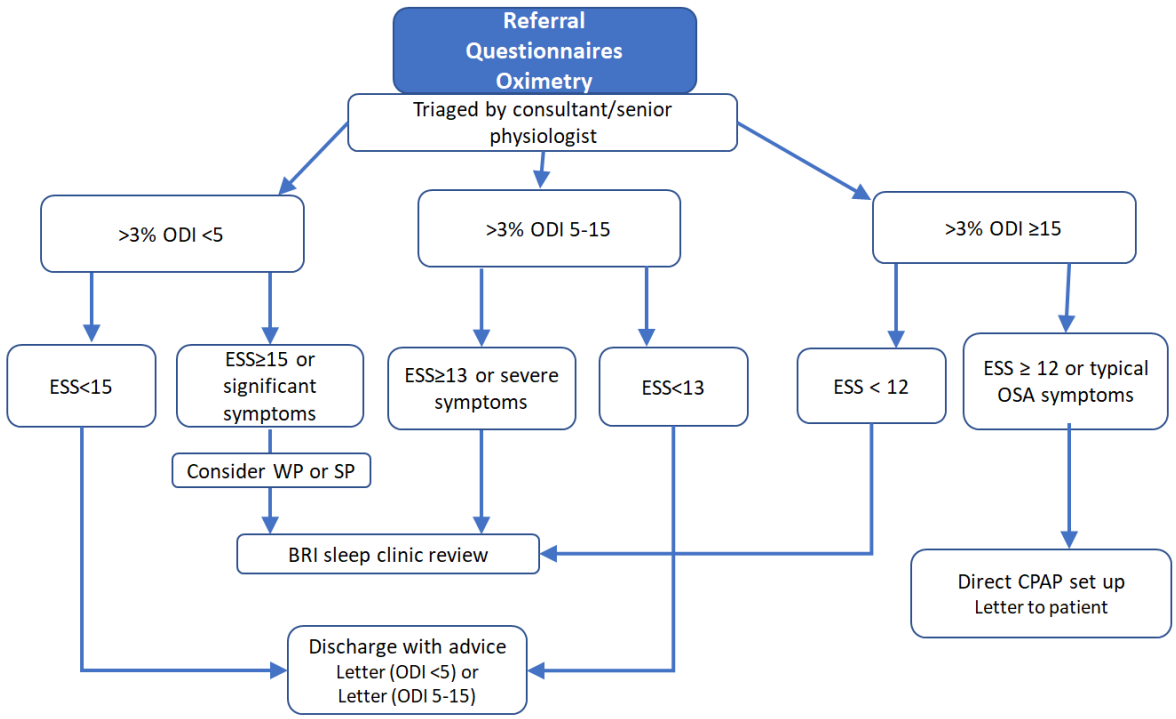
Procedures	Visits			
	Screening (Reviewing referral letter) Completed by PI	Baseline (initial telephone call to the patient) Completed by PI	Diagnostic Phase (collection of diagnostic equipment, Visit 1) Completed by PI and database manager	Follow Up (returning the equipment, Visit 2) Database manager
PI to read referral letter	X			
Demographics reviewed	X			
Eligibility assessment against inclusion / exclusion criteria	X			
Verbal explanation of the study		X		
Informed consent		X		
Sign consent form Clinical Record Form completed for patient			X	
Clinical Record Form completed for patient Height and Weight measured. BMI calculated.			X	
Height and Weight measured. BMI calculated. Issue equipment, new patient questionnaire, Epworth Sleepiness score and equipment (oximetry + Sunrise or WatchPAT 300 + Sunrise), equipment instructions			X	
Issue equipment, new patient questionnaire, Epworth Sleepiness score and equipment (oximetry + Sunrise or WatchPAT 300 +			X	

Sunrise), equipment instructions				
Equipment returned by patient				X
Check sleep history questionnaire and feedback questionnaire are completed				X
Patient exits study and continues on existing clinical pathway				X

Appendix 2 - Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.0	18/02/2025	R. Pickersgill, L. Buckley, V. Hawkins, S. Correra-Muller, L. Hill	First draft of protocol agreed.

Appendix 3 - Post diagnostic flow chart



Manchester Metropolitan University

University Hospitals Bristol and Weston NHS Foundation Trust

Covering Page for document upload

Official Title: Sunrise Consent Form UHNW & MMU

REC Number: 25/NW/0102

IRAS ID: 353743

Document Date: 24/02/2025

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website: www.uhbw.nhs.uk

IRAS ID: 353743

Centre Number: _____

Study Number: _____

Participant Identification Number for this study: _____

CONSENT FORM Version 1.0

Title of Project: Sunrise in Obstructive Sleep Apnoea (SOSA)

Name of Researcher: _____

	Please initial box
1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	☐
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from University Hospitals Bristol and Weston NHS Foundation Trust, and anonymised data relevant to the study may be looked at by named academic supervisors from Manchester Metropolitan University. Where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
4. I agree to my General Practitioner being informed of my participation in the study.	☐
5. The Sunrise app will have access to personal data inputted by myself as part of the study. I understand this is compliant with General Data Protection Regulation (GDPR).	☐

6. I agree to be consented regarding future research opportunities from the Sunrise in Obstructive Sleep Apnoea Study data. I understand that the information collected about me may be used to support other research in the future and may be shared anonymously with other researchers (**Optional**). ☐

7. I would like to receive a summary of the final study results (**Optional**) ☐

8. I understand that the information held and maintained by University Hospitals Bristol and Weston NHS Foundation Trust may be used to help contact me or provide information about my health status. ☐

9. I agree to take part in the above study. ☐

Name of Participant	Date	Signature

Name of Person taking consent	Date	Signature