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Trial Protocol: A Randomised, Controlled Cross-Over Trial Evaluating the Digital Sleep Revolution Diagnostic-Therapeutic Pathway for Obstructive Sleep Apnoea

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ABSTRACT

Obstructive sleep apnoea (OSA) is common, but current diagnostic pathways rely on single-night assessment and the apnoea–hypopnoea index. Both are limited for assessment of variability and linking only weakly to symptoms, comorbidity and treatment response. The current protocol addresses this gap by aiming to validate a diagnostic pathway integrating a digital platform, mobile application, multiple-night sleep testing, semiautomated analysis and a novel sleep health questionnaire, labelled as ‘Sleep Revolution’. Study objectives are to compare staff time required for diagnosis between standard care and Sleep Revolution pathway, and to examine associations between multi-night sleep metrics and Positive Airway Pressure (PAP) treatment outcomes, diagnostic concordance, PAP prescription, patient satisfaction, adherence and feasibility. This multicentre, two-arm cross-over study is conducted at 23 sleep centres in Europe within the European Sleep Apnoea Database (ESADA) network. Adults referred for suspected OSA complete both standard care and the Sleep Revolution pathway in randomised order. Standard care includes single-night polygraphy or polysomnography according to local routines. The Sleep Revolution pathway comprises three nights of self-applied polysomnography (NOX-SAS), digital symptom assessment (mobile app) and the Withings ScanWatch (physical activity, physiological signals). Diagnosis and treatment decisions are based solely on the first pathway. Outcomes include staff time (primary), technical performance, diagnostic yield, patient-reported measures, PAP adherence and symptom change. The sample size is calculated as 1000 randomised participants. Ethical approval is obtained at all participating centres. The trial is registered with ISRCTN (ISRCTN17539031). Data acquisition is performed between Q1 2024 and Q2 2025; data cleaning and analyses are ongoing.

The Sleep Revolution Collaborators listed in the [Supporting Information](#).

For affiliations refer to page 9.

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1 | Introduction

1.1 | Background and Rationale

Obstructive sleep apnoea (OSA) affects up to one billion of the adult population, with less than one third experiencing clinically significant daytime symptoms (Benjafield et al. 2019). Although anatomical factors such as obesity, upper-airway crowding or craniofacial abnormalities contribute to risk, these findings are inconsistent, and the underlying aetiology of OSA remains heterogeneous (Lisik and Zou 2025). Continuous positive airway pressure (CPAP) therapy is the most established treatment; however, long-term adherence remains a major challenge. Up to one-third of patients discontinue CPAP after initial trial, and more than half terminate therapy within the first years (Pepin et al. 2021). Patients with more severe disease and prominent sleepiness are typically more compliant, underscoring the need for diagnostic pathways that better identify individuals likely to adhere and benefit from CPAP (Fridriksson et al. 2023; Palm et al. 2021).

Current clinical routines integrate patient history, physical examination with cardiometabolic markers, and overnight sleep testing evaluated by sleep specialists. Despite this multimodal approach, diagnostic decisions still rely heavily on the apnoea–hypopnoea index (AHI). The AHI, however, has known limitations: high night-to-night variability, weak associations with symptoms and comorbidities and limited predictive value for long-term outcomes (Pevernagie et al. 2020). As a result, current pathways insufficiently capture the complexity of OSA pathophysiology, impair accurate risk stratification and fail to guide personalised treatment planning (Pevernagie et al. 2025).

The *Sleep Revolution* project, a major Pan-European research project funded by the European Union Horizon 2020 programme, aimed to modernise this diagnostic landscape by integrating multi-night home-based sleep testing, digital symptom assessment including a novel sleep health questionnaire, automatic analysis and novel physiological markers that better reflect clinically relevant disease (Arnardottir et al. 2022). This validation study evaluates a comprehensive, patient-centred diagnostic pathway combining: (1) multi-night home measurements with type II polysomnography (PSG) performed by the patient; (2) a digital platform encompassing a web-based interface, a mobile application for subjective assessment of sleep and data inflow (e.g., from wearables) enabling richer symptom profiling and patient-reported outcomes; (3) new, evidence-based sleep metrics linked to treatment outcomes; (4) artificial intelligence (AI)-based analysis of sleep tests for characterisation of sleep, respiratory events, and cardiovascular function with quality control by healthcare professionals (semiautomated process); and (5) objective lifestyle and sleep–wake information via wearable actigraphy. Together, these components aim to overcome the limitations of current AHI-centric diagnosis and support more personalised and effective management of patients with suspected OSA. The current study protocol describes a systematic comparison between standard care procedures using single-night polygraphy or polysomnography versus the novel and more comprehensive Sleep Revolution pathway.

2 | Methods

2.1 | Trial Design

Study SR-001 is a multicentre, two-arm crossover trial evaluating the diagnostic concordance and clinical impact of two pathways in patients referred for suspected OSA.

Participants from 23 sleep centres in the European Sleep Apnoea Database (ESADA) (Hedner et al. 2011) undergo both the current standard diagnostic routine and the novel Sleep Revolution (SR) pathway, the latter integrating three-night self-applied PSG (NOX-SAS), digital symptom profiling and actigraphy-based assessment of sleep–wake patterns and physical activity.

Participants are randomised to the order in which the two pathways are applied. Diagnosis and treatment decisions—including potential initiation of CPAP—are based solely on the first pathway. Results from the second pathway remain blinded to both investigators and patients, enabling an unbiased comparison of diagnostic performance and treatment-relevant outcomes.

2.2 | Study Setting and Interventional Arms

Following diagnostic procedures—including sleep testing, symptom assessment and physical examination—patients receive their diagnosis from a sleep specialist. If clinically relevant OSA is confirmed, treatment recommendations are provided. Only patients starting PAP therapy are invited into the treatment and follow-up phase (up to 3 months after CPAP start).

In the standard care (SC) pathway, sleep studies are manually scored at each centre by trained technicians and/or sleep physicians using predefined criteria. In the SR pathway, sleep studies are prescored using an AI algorithmic approach, shifting from scoring the entire recording to focusing only on uncertain segments in the sleep studies. Manual editing is primarily targeted to epochs flagged as uncertain by the automated system; however, manual editing of the entire recording is also possible (Rusanen et al. 2025).

PAP titration, education and support follows each centre's routine procedures. At follow-up, all PAP-treated patients undergo a single-night SR self-applied PSG on treatment.

Symptom and cognitive evaluations—using standard care questionnaires, a cognitive test battery via App and the new European Sleep Questionnaire (ESQ)—are conducted at baseline, during treatment and at 3-month follow-up. Physical activity is assessed in parallel by means of a wearable.

2.2.1 | Standard Care Pathway

In the SC pathway, sleep testing consists of in-lab PSG (American Academy of Sleep Medicine (AASM) level I), home PSG (AASM level 2) or home sleep apnoea testing (HSAT, level 3) performed according to each ESADA centre's routine practice. In clinical routine, different brands of sleep diagnostic devices are used ranging from a single brand in 12 centres up to multiple brands

(5 or 6) in 4 centres. Recordings are manually scored, with optional support from automated software, and all analyses follow the AASM scoring criteria version 2.6 (hypopnea with 30% flow reduction, 3% desaturation w/wo arousal, no separation in obstructive versus central hypopnea). Symptom evaluation includes established instruments such as the Epworth Sleepiness Scale (ESS) (Johns 1991), Pittsburgh Sleep Quality Index (PSQI) (Buysse et al. 1989), the Depression Anxiety Stress Scales–21 (DASS-21) (Lovibond and Lovibond 1995), Clinical Global Impression (CGI) scale (Guy 1976), the Insomnia Severity Index (ISI) (Morin et al. 2011) and the Fatigue Severity Scale (FSS) (Krupp et al. 1989). Translations of these questionnaires are performed according to gold standard procedures in several but not all languages. The ESQ development methodology is described in detail elsewhere (Pevernagie et al. 2026). For methodological comparison, the ESQ, the Sleep Revolution App and the cognitive tests are also administered during standard care, although their results remain blinded to the sleep physician.

2.2.2 | Sleep Revolution Pathway

Sleep testing is performed with self-applied PSG using the NOX A1S device and the validated NOX-SAS electrode configuration (Ferretti et al. 2025). Symptom evaluation includes the newly developed ESQ and the Sleep Revolution App, which collects data on subjective sleep timing, symptoms and neurocognitive performance (Kristbergdottir et al. 2023).

Continuous physiological monitoring is conducted during the diagnostic phase (4 days to 2 weeks) using a wrist-worn device (ScanWatch from Withings) that captures pulse rate, physical activity and high-resolution data for sleep–wake estimation. Sleep analysis from PSG recordings relies on validated semiautomated algorithms assessing sleep stages, arousals, respiratory events, hypoxia and cardiovascular parameters. Both automated and manual scoring follow AASM criteria v2.6. The NOX-SAS configuration used modified EEG electrode placement requiring previously validated scoring rules which adjust for amplitude criteria, for example, for N3 scoring (Rusanen et al. 2024).

2.2.3 | Procedures Irrespective of the Study Arm

Regardless of study arm, all participants undergo a standard physical examination, including weight, height and office blood pressure, accompanied by a structured medical history and medication review. At the end of the diagnostic process, each patient meets the treating physician to review symptoms, examination findings, the final diagnosis, and—if a sleep disorder is identified—the recommended treatment plan.

Study outcome data are stored locally in accordance with clinical routines. In addition, study data are collected and managed using REDCap (research electronic data capture) tools hosted at Reykjavik University. REDCap is a secure, web-based software platform designed to support data capture for research studies (Harris et al. 2019). Original sleep study files are transferred to the Sleep Revolution data cluster at Reykjavik University. Optional blood samples for metabolic markers and inflammation are collected as part of a predefined sub-study.

2.2.4 | PAP Treatment Procedures

For patients initiating PAP therapy, standard clinical routines for treatment initiation, training and follow-up are applied, with scheduled visits according to the study protocol. After 3 months, treatment follow-up incorporates both standard care assessments and the experimental methodology used at baseline, including a single-night self-applied PSG study. Patients are encouraged to wear the activity watch and to continue providing data in the Sleep Revolution App (sleep diary, cognitive testing, morning/evening questionnaire and lifestyle) throughout the entire follow-up period. The study concludes with a final interview between the patient and the healthcare provider at the end of the follow-up. Adverse events are monitored continuously throughout the study. A detailed schedule of study activities is provided in Table S1.

2.3 | Eligibility Criteria

Eligible participants are adults aged 18 years or older who have been referred to a participating sleep centre for evaluation of suspected OSA as their primary diagnostic concern. Individuals must be willing and able to provide written informed consent and to adhere to the study schedule and procedural requirements, including the absence of extended travel plans that would impede study participation.

Participants are excluded if they are currently receiving treatment for obstructive or central sleep apnoea, or if they have known significant hypercapnic respiratory failure due to chronic obstructive pulmonary disease or another respiratory disorder. Additional exclusion criteria include any clinically determined contraindication to PAP therapy, participation in a structured weight-loss programme, unstable congestive heart failure or angina pectoris, or any other condition that, in the judgement of the investigator, could compromise adherence to the study protocol or completion of study procedures. Individuals with a history of alcohol or drug abuse within the past year, or with evidence of a substance use disorder at screening, are also excluded.

2.4 | Outcomes

The primary endpoint is staff time spent for the sleep apnoea diagnostic pathway—comparing between SC and the SR pathways at first exposition (two independent groups). Staff time is a critical determinant of the clinical feasibility and scalability of any diagnostic pathway. Current diagnostic practice for OSA varies widely across Europe, with considerable differences in staff resources required for in-laboratory PSG versus HSAT. The SR pathway introduces several innovations—three nights of self-applied PSG, semiautomated analysis using machine-learning tools and digitally supported subjective symptom assessment through a digital platform, both available via a web-based interface and a mobile application—which are expected to improve diagnostic precision and provide a more comprehensive clinical phenotype, including lifestyle, neurocognitive function and patient-reported symptoms. However, the net impact of this modernised approach on staff workload remains unknown. A staff time protocol has been developed and disseminated for the

standardised assessment (Table 1). The time log is completed by personnel in the respective sleep centre, including nurses, sleep scorers and technicians, sleep physicians and/or administrative personnel, performing the different tasks throughout the diagnostic process. Actual staff time spent in each study patient is logged in 5-min blocks according to the protocol. Feasibility of the reporting is checked by the central data management.

Secondary outcomes compare the SR pathway with SC across several dimensions. These include patient satisfaction with the overall

diagnostic work-up, as well as satisfaction with how effectively the diagnostic and therapeutic process addressed their initial clinical concerns. Further comparisons will examine the number of OSA diagnoses, the frequency of PAP and non-PAP treatment prescriptions, and the proportion of patients experiencing PAP failure, defined by lack of acceptance or insufficient adherence, within each pathway. The study will also evaluate the ability of novel diagnostic parameters to predict PAP treatment response, both in terms of adherence and symptom improvement. Associations between, on the one hand, sleep test outputs derived from several diagnostic

TABLE 1 | Recorded staff time for performing the different clinical/analytical activities during Standard Care or Sleep Revolution Care pending on randomisation.

Procedure	Time count (5-min intervals only, like 5, 10, 15, etc.)	Staff initials
Sleep Revolution pathway—Date of start		
Preparation of the sleep study and digital methodology, initiation of the Sleep Revolution app, and the platform		
Patient instruction and handing over of A1S to the patient		
Troubleshooting and monitoring of the patient during home sleep studies		
Patient contact at the return of equipment		
Upload of data and transfer of data to the medical records		
Final scoring of the sleep recordings		
Compiling all data together for the patient-doctor consultation		
Additional activities not listed above		
Sum of activities in the SR pathway		
Standard care pathway—Date of start		
Preparation of the sleep study		
Ambulatory sleep study (if applicable): All procedures from the first clinical appointment prior to the sleep test to the discharge after a successful sleep test procedure (see also explanation text)		
In-house sleep study (if applicable): All procedures from arriving at the sleep lab in the evening to discharge in the morning		
Upload and transfer of data to the medical records (see also explanation text)		
Scoring of the sleep recordings		
Assemble all data for the patient consultation with the sleep doctor		
Additional activities not listed above		
Sum of activities in the routine pathway		
Communication between the sleep doctor and the patient		
Patient consultation with the sleep doctor, including final diagnosis and treatment decision if applicable, and documentation in the medical record		
Any activity not listed above		
Sum of all activities in the study		

routines (in-lab PSG, multiple nights of self-applied PSG, HSAT and wearables) and, on the other hand, symptoms/comorbidities will be analysed for each diagnostic pathway.

Exploratory outcomes include the technical failure rates of each diagnostic pathway and the number and nature of adverse or serious adverse events related to diagnostic procedures or PAP treatment. Additional analyses will investigate associations between novel sleep parameters (e.g., hypoxic, ventilatory, arousal burden and pulse wave parameters) and metabolic or inflammatory biomarkers obtained in a subset of participating centres.

2.5 | Sleep Scoring and Standardisation

All sleep scorings (in-lab PSG, self-applied PSG and HSAT) are performed by experienced sleep technicians and/or sleep physicians at each study site, preferably by one scorer for all sleep studies at each study site. If this is not possible, the site had to ensure that interscorer agreement between scores reaches at least 85% and that all recordings from one patient are scored by one technician. Sleep scoring is based on the current AASM manual version 2.6 (Troester et al. 2023). Hypopnoeas are scored with an at least 30% flow reduction, 3% desaturation w/wo arousal, without separation in obstructive versus central hypopnea. At least 4 h of total sleep time is necessary for the valid AHI classification.

From the sleep recording, standard diagnostic variables are transferred to the electronic Case Report Form (eCRF), for example $AHI_{PSG/HSAT}$ (events/h), $ODI_{PSG/HSAT}$, 3% and 4% (events/h), mean and minimum overnight SpO_2 (%), percentages of non-rapid eye movement stages 1 to 3 (N1–N3) and rapid eye movement (REM) sleep (%). The entire PSG report, including more than 100 parameters, is checked for the validity of data and thereafter transferred to the central SR study-specific database for detailed analysis together with the raw data of all sleep tests (SC and SR).

2.6 | Sample Size and Power

Because innovation in clinical pathways must be justified by a feasible balance of costs and benefits, staff time for the diagnostic pathway at first exposure is selected as the primary endpoint. The working hypothesis is that total staff time for the SR pathway will be comparable to that of current standard care; statistics for two independent group comparisons are applied. While automated scoring and patient-driven data collection may reduce staff involvement, additional time may be required to train patients in the use of new devices and to evaluate the expanded diagnostic information. Accordingly, a *non-inferiority design* is chosen, with a predefined margin of 30 min as the threshold for equivalence in staff time across 23 European sleep centres. In the absence of a predefined outcome for staff time, the ≥ 30 min criteria were chosen by consensus as a clinically meaningful time difference between the two diagnostic pathways as it corresponds to a standard patient visit for physicians or nurses.

Power calculations are informed by existing literature (Fischer et al. 2012) and estimates generated through a Delphi process

among participating centres of the ESADA network. A small pilot study within the Sleep Revolution project provided preliminary feasibility data, but detailed staff-time measurements were not available (Ferretti et al. 2025). Thus, the sample size reflects realistic operational assumptions consistent with the expected variability across centres. Key variables used for the non-inferiority study power calculation include the range for SC PSG (220–720, STD 180 min), for SC HSAT (40–95, STD 30 min) and SR PSG (140–240, STD 60). Based on these data, the power calculation suggests 417 patients in each group. The expected dropout rate of patients during the diagnostic phase of the study is 20% (results from the SR pilot study), resulting in 500 patients per group. Therefore, inclusion of 42 patients is allocated to each participating sleep centre at the start of the study.

For the patients receiving PAP treatment in the follow-up part of the study, a study termination rate exceeding 50% is expected at three different points: (A) No clinically relevant sleep apnoea, (B) clinically relevant sleep apnoea but other treatment than PAP and (C) PAP nonacceptance or low adherence (Figure 1).

2.7 | Randomisation and Blinding

At screening, participants are entered into the study's randomisation system, which assigns each individual a unique study ID used throughout the trial. Eligible patients are then randomised in a 1:1 ratio to enter the crossover part of the study beginning with either standard care or the Sleep Revolution diagnostic pathway (Figure 1). Randomisation is performed in blocks of 4; the same scheme is applied at all centres. The randomisation list is handled by personnel at each centre otherwise not involved in the study. Centres are asked to apply their usual testing routine (polysomnography or HSAT) consistently across all study participants. No additional stratification by age, body mass index (BMI), sex or comorbidity is performed.

This is an open-label, crossover trial, and blinding of participants and clinicians to the diagnostic procedures is not feasible. However, the results of the second diagnostic pathway remain fully blinded at the time when the final diagnosis and treatment decision is made. Thereafter, PAP treatment initiation and PAP follow-up procedures are identical across both study arms (Figure 1).

2.8 | Data Collection and Management (eCRF, EDC, QC; Privacy)

Clinical study data are captured using an eCRF within a validated electronic data-capture (EDC) system (REDCap), ensuring standardised documentation across sites and facilitating real-time monitoring (Harris et al. 2019). Data entry follows predefined quality-control procedures, including automated range checks, query management, and regular consistency reviews by the coordinating centres (Reykjavik and Gothenburg Universities). Sleep study files, wearable outputs and app-based patient-reported data are transferred securely to the Sleep Revolution data cluster at Reykjavik University, where they undergo structured quality assurance and storage on protected servers. All procedures comply with the General Data Protection

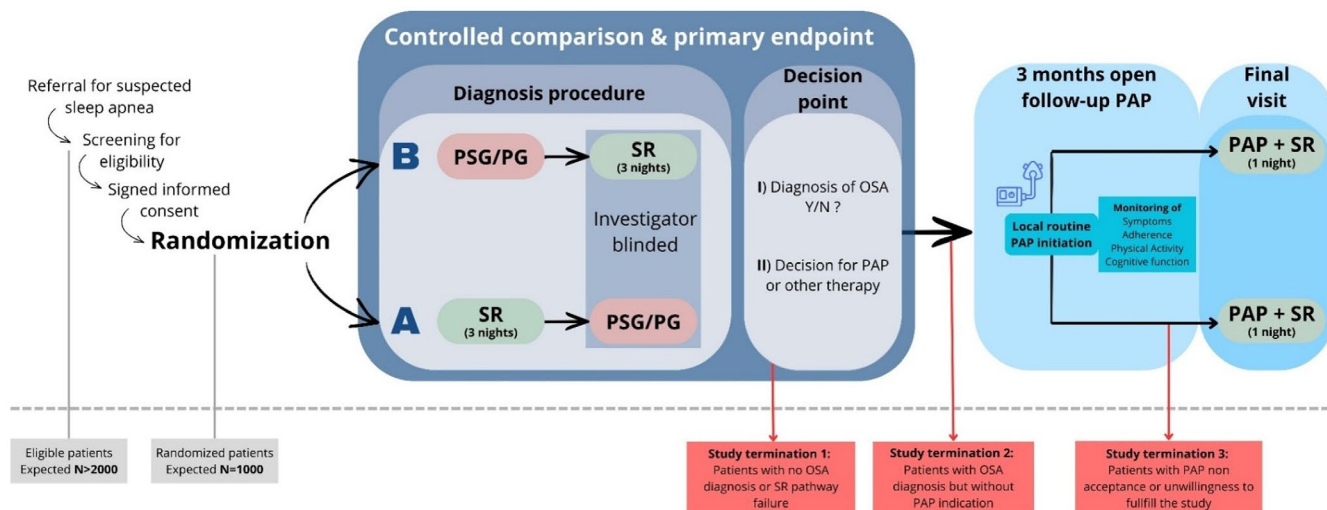


FIGURE 1 | SR 001 study flow chart. Data from eligible patients not included in the study were not further stored or analysed. PAP, positive airway pressure treatment; PG, polygraphy; PSG, polysomnography; SR, Sleep Revolution pathway; PSG/PG, Standard Care pathway; OSA, Obstructive Sleep Apnea; PAP, Positive Airway Pressure therapy.

Regulation (GDPR), with pseudonymisation applied before central transfer. Strict access control is maintained throughout the study. Together, this data-management framework ensures robust data integrity, traceability and privacy protection across the multicentre study. Table 2 illustrates the data available for analysis in this study.

Data from the wearable (Withings Scanwatch) are sampled during diagnosis, CPAP treatment initiation and follow-up, and stored on the study data cluster at Reykjavik University. A specific analysis plan for this extensive data package will be published at the trial registry. All analyses of these data are considered as tertiary study outcomes.

2.9 | Statistical Analysis

The primary outcome is the comparison of staff time required to complete the SR or SC diagnostic pathway, from the initial visit through the diagnostic conclusion. Each patient is included in the analysis with one staff time measure required for the randomised diagnostic pathway—SR or SC. The primary analysis will be conducted on the intention-to-treat (ITT) population, including all randomised patients according to their assigned group. Descriptive statistics will be presented for staff time by group, including means (standard deviation), medians (interquartile range) and range (minimum/maximum). In the primary analysis, staff time between the two groups is compared while adjusting for centre effects in a linear mixed-effects model (LMM): Fixed effect is group (SC vs. SR), random effect is centre. Among others, a predefined sensitivity analysis will compare staff time for centres using PSG or PG as standard care.

Secondary analyses are focused on the diagnostic outcome in the respective diagnostic arm (SC or SR, e.g., single night vs. multiple night assessments). In addition, the relationship between diagnostic metrics and treatment response will be analysed. For example, a planned analysis will examine the association

between overnight hypoxic load, averaged across multiple nights in the SR pathway, and the change in clinical symptoms including the ESS score after 3 months of PAP therapy. Those associations will be compared with the relationship between the AHI, derived from a single-night assessment in standard care, and ESS improvement, with both models adjusted for relevant confounders. Further analyses evaluate the predictive capacity of additional novel severity markers (e.g., hypoxic-, ventilatory- and arousal burden) derived from multiple nights of testing in comparison with traditional indices such as the AHI, oxygen-desaturation index (ODI) and mean oxygen saturation. Their value in predicting PAP treatment associated changes in the patient's initial help request after 3 months of PAP will be assessed using parallel modelling approaches. Additional analyses will explore content validity of the ESQ.

Tertiary outcomes include for example a dropout analysis identifying factors associated with missing data in the SR pathway, such as incomplete sleep testing, app use or ESQ submission. Further tertiary assessments encompass biomarker results at baseline and during treatment response, the feasibility and completeness of the three-night home PSG procedure, patient-reported tolerability of the procedure as well as novel sleep parameters (e.g., hypoxic, ventilatory, arousal burden and pulse wave parameters).

Chapter 8.10 in the statistical analysis plan, available on the trial registry, contains detailed information about the analytical strategies to address data missingness in the trial: Mean/Median Imputation, Regression Imputation and/or Multiple Imputation.

2.10 | Monitoring

Study monitoring and data management on the Sleep Revolution data cluster are performed continuously throughout the study by the teams at the Reykjavik and Gothenburg Universities. This process includes systematic analysis of clinical data (anthropometrics, sleep study results, including criteria), questionnaire

TABLE 2 | Data inventory on the SR cluster at Reykjavik University.

Data category	Contents	Source/system	Notes
Main analysis dataset	Clinical data; staff time; diagnostic outcomes; treatment recommendations; questionnaire results (CGI, DASS21, FSS, ISI, PSQI, ESS, PGI); key sleep study parameters (SR and SC); PAP outcomes (symptom change, adherence)	ESADA centres REDCap Sleep studies PAP devices	Serves as the primary analysis file for endpoints and modelling
High-resolution sleep recordings	All original sleep recordings at full data resolution	PSG/HSAT devices SR: NOX A1S SAS SC: centre-specific	Complete raw files retained for reanalysis and quality check
Sleep scoring results	Scoring outputs for SR (three consecutive self-applied PSG nights) and SC (single night); ABOSA hypoxic-load metrics; DEEP RESP outputs (hypoxic, ventilatory, arousal burden; pathophysiological endotypes)	SR semiautomated pipelines (aSAGA) ABOSA DEEP RESP Manual verification	SR uses AI-assisted prescoring with targeted manual edits; AASM v2.6 criteria
REDCap exports	Structured questionnaire results; cognitive function performance data; European Sleep Questionnaire results	REDCap eCRF	Harmonised export format for analysis/traceability
Sleep Revolution App data	Sleep diaries; morning and evening questionnaires; cognitive function results at baseline and during treatment follow-up	Sleep Revolution App	Patient-reported
Activity Watch	Physical activity data, physiological data (pulse rate, pulse wave and saturation) assembled in high-resolution mode	Withings Scan Watch, raw data transferred to the SR Cluster at Reykjavik University	Recorded from patients wearing the device

Abbreviations: AASM, American Academy of Sleep Medicine; ABOSA, automatic blood oxygen saturation analysis software; AI, artificial intelligence; aSAGA, semiautomated sleep EEG scoring algorithm; CGI, clinical global impression; DASS21, Depression, Anxiety and Stress Scale-21; DEEP RESP, automated scoring tool for sleep recordings; eCRF, electronic case report form; ESS, Epworth Sleepiness Scale; ISI, Insomnia Severity Index; PAP, positive airway pressure; PG, polygraphy; PSG, polysomnography; PSQI, Pittsburgh Sleep Quality Index; REDCap, research electronic data-capture system; SC, standard care pathway; SR, Sleep Revolution pathway.

data, randomisation procedures, communication between study centre and patients, completeness of Sleep Revolution App data, and sleep stage scoring (respiration, sleep and motor activity during sleep). Comprehensive and individualised data monitoring reports are sent to each study centre. These reports contain detailed and specific queries for data cleaning and completing data sources. Thereafter, the data files are closed for final analyses according to the statistical analysis plan. Detailed quality control of sleep scoring results for the in-home PSG studies is performed.

2.11 | Ethics and Dissemination

The main ethical application submitted to the Swedish Authority 'Ethix', diary number DNR 2023-03829-01, was approved on the 19th of November 2023. Local ethical approvals at all study sites are obtained and granted prior to patient inclusion. Informed consent (oral and written) is obtained from all study participants by the trial personnel. The risk to benefit assessment summarises that the methods used are well-known and not associated with significant harm. No risk increase is expected with

the SR procedure whereas it is expected that the sleep expert as well as the patient will gain more important insights during the diagnostic process supporting a better-informed diagnostic and treatment decision. The core study results will be published in the trial registry and in international scientific journals.

2.12 | Trial Registration Details

The study has been registered at the ISRCTN trial registry with protocol number 17539031. First submission date is 31 August 2023, and the date for final registration is filed 23 February 2024, accessible via <https://www.isrctn.com/ISRCTN17539031>. The statistical analysis plan, publicly accessible on the registry website, is finalised and archived on the UK Clinical Trial Registry (ISRCTN17539031) on 26 June 2025, with subsequent updates on 4th July (version 2.0) and 2nd November 2025 (Amendment 1). Those amendments are exclusively related to secondary and tertiary study outcomes, mainly related to novel biosignal analyses and PSG analysis software packages.

3 | Patient and Public Involvement

A central feature of the SR pathway is the active involvement of patients in the data-collection process. The protocol is designed to empower individuals to take an active role in documenting their sleep patterns, symptoms and daily functioning, thereby generating richer, more ecologically valid information than can typically be obtained during clinical single-night evaluations. Patient participation is embedded throughout the SR procedures: participants conduct self-applied PSG across up to three consecutive nights in their home environment, they complete structured morning and evening reports as well as a daily sleep diary delivered through a mobile application over several days, engage in continuous physiological monitoring using a wrist-worn wearable device, and are encouraged to perform a neurocognitive performance assessment in the same mobile application. The APP function, the questionnaire and the sleep test technology are developed using codesign principles for patient participation (Arnardottir et al. 2021; Ferretti et al. 2025).

4 | Discussion

4.1 | Expected Contributions

The Sleep Revolution validation study is expected to provide a substantial contribution to the modernisation of sleep apnoea diagnosis by demonstrating the feasibility and clinical value of a patient-centred, multi-night home-based assessment (Korkalainen et al. 2024). By combining self-applied PSG, digital symptom tracking and profiling, wearable actigraphy, and novel physiological markers, the study aims to overcome well-known limitations of single-night, AHI-driven clinical routines.

Multi-night assessment of sleep apnoea has been shown to improve diagnostic reliability and precision. Most clinical trials have compared HSAT or wearable devices against in-laboratory PSG as the gold standard methodology. There is no data available from large scale studies evaluating multi-night PSG versus

single night in-lab PSG or HSAT. Further, there is significant uncertainty about what type of diagnostic equipment should be used for multi-night assessments in patients with suspected OSA. This is actually an important area, as no clinical guidelines have been suggested so far. Thereby, the additive diagnostic value of variability assessment in PSG variables on top of today's gold standard can be assessed in our controlled study setting.

The enhanced patient participation integrated into the Sleep Revolution pathway—through repeated home measurements, daily symptom reporting, and continuous wearable-based monitoring—provides a richer and more representative characterisation of individual sleep–wake patterns, symptom burden and physiological variability. By integrating repeated, real-life measurements with ongoing patient-reported data, the Sleep Revolution pathway aims to capture individual variability in sleep–wake behaviour, symptom expression and lifestyle factors that influence OSA. The SR approach thus moves beyond the traditional, largely technician-driven single-night assessment towards a diagnostic model in which patients become active contributors to their own diagnostic evaluation. Further, diagnostic metrics that are more closely aligned with clinically relevant outcomes, including treatment adherence and symptomatic improvement on PAP therapy, will be evaluated.

The study is conducted within the pan-European ESADA network, which provides a well-characterised clinical cohort reflecting the diversity of European healthcare systems, socio-cultural contexts and established OSA management practices (Hedner et al. 2011). This broad setting enhances the validity of the findings and strengthens the applicability and generalisability of the expected results across different clinical environments.

Beyond establishing diagnostic concordance between pathways, the study may clarify which novel markers and patient-reported elements contribute most to predicting meaningful treatment response. The findings are expected to support a more personalised, scalable and resource-efficient diagnostic pathway that strengthens patient engagement and may ultimately improve both clinical decision-making and long-term outcomes for individuals with suspected OSA.

4.2 | Strengths and Limitations

A major strength of this protocol is its comprehensive, patient-centred diagnostic approach. The study integrates several novel and recent aspects in sleep apnoea diagnostic procedures, including multi-night self-applied PSG testing, strong patient participation with longitudinal subjective digital symptom assessment twice per day over the course of 3 months, and continuous objective physiological monitoring by wearables also encompassing 3 months. Thereby, this study captures a broad representation of sleep–wake behaviour compared to single-night, technician-driven assessments (Timmis et al. 2026). The research network includes expertise in the development and evaluation of AI-assisted scoring, combined with manual verification, to test diagnostic precision and staff time savings from automated analysis. The inclusion of actigraphy and patient-reported outcomes over extended time periods supports a multidimensional characterisation of OSA beyond the AHI. Conducting the study

within the pan-European ESADA network provides a diverse clinical population that reflects variations in healthcare systems and OSA management practices, strengthening the generalisability and applicability of the expected findings.

However, the protocol also has limitations. The high level of participant engagement—including multiple nights of home PSG, daily diaries, and continuous wearable use—may introduce variability in data quality and poses a risk for nonadherence. Complex new technologies may place a considerable burden on patients as well as on clinical and research personnel, thereby increasing the risk of data loss or patient inclusion bias toward younger and/or technology-interested individuals. Indeed, it has been shown that complex digital solutions in health care may exclude the more vulnerable patients. Differences in clinical routines and expertise across centres may contribute to heterogeneity in standard care diagnostics. Assessment of the study primary endpoint cannot be blinded and relies on the reporting of the individual staff members in 5 min windows. This procedure may be viewed as rather imprecise and less objective. However, as gold standard procedures for staff time assessments in sleep medicine are lacking, we judged this procedure as the most practical and appropriate one for this large trial. We also defined a rigorous staff time protocol and compliance with these procedures was monitored by the central data management. Furthermore, the optional biomarker sub-study and reliance on local infrastructure may limit the completeness or comparability of certain exploratory outcomes. More detailed information about patients not included in the study cannot be collected due to the lack of ethical permit. However, there is substantial historic data on patients with suspected OSA included historically to the ESADA providing excellent reference material to the study population finally included in the current trial. Despite these constraints, the study is well-positioned to provide robust evidence for a more scalable and personalised diagnostic pathway for OSA.

5 | Trial Status

The first patient recruitments were done in late 2023; however, most centres started the recruitment after April 2024. The data collection ended in late July 2025. At that stage, 1036 patients were randomised, and data management and data cleaning were partially performed in parallel throughout the study. Initially, 24 centres participated in the study, but 1 centre dropped out due to lack of staff. Remaining patients were redistributed to six centres with good recruitment potential.

A primary endpoint analysis on staff time was performed in August 2025 in a subset of 715 patients for reporting preliminary results to the EU Commission. Data cleaning, in particular completion of sleep scoring, is still ongoing in the second quarter of 2026. Thereafter, the master data analysis file will be closed, and the final analysis of primary and secondary endpoints will take place.

Author Contributions

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Ethics Statement

All patients signed an informed consent prior to study participation. The study was approved at the Swedish Ethix authority with Dnr 2023-03829-01. All study centres received approval from the local ethics committee (list of DNR available at sleepsupport@ru.is).

Conflicts of Interest

Potential COI related to the content of the current manuscript: Nox Medical is an industry partner of the Sleep Revolution Horizon 2020 grant. Withings supported the project with discounted devices and technical support. A representative from Nox Medical is a member of the Sleep Revolution Executive Board. L.G. does not report any further COI with Nox Medical or Withings. E.S.A. has received honoraria for conference lectures from Nox Medical. Outside the topic of the manuscript, L.G. has lectured for Resmed, Philips Lundbeck, and Astra Zeneca. L.G. was member of the advisory board for Onera BV. L.G. owns shares in a company with a patent for OSA drug treatment licensed to Desitin GMBH. Outside the topic of the manuscript, D.T. has lectured for Philips Respironics and

was member of the advisory board for Bioprojet and Coloplast. J.V. sits on the advisory board of Bioprojet. J.V. reports grants and fees from Aescubrand, AirLiquide, AuroBindo, Azelis, Bioprojet, Epilog, Inspire Medical Systems, Löwenstein Medical, Mediq, Micromed OSG, Nyxoah, Philips, ProSomnus, ResMed, Sefam, SD Worx, SomnoMed, SOS Oxygène, Tilman, Total Care, Vivisol, Vlaamse Gemeenschap, Westfalen Medical, Withings and Zoll Respicardia, and consultancy for Bioprojet, Brussels Gewest, Epilog, KBC, and Procter & Gamble. S.M. has lectured for Astra Zeneca and Chiesi; R.S. has lectured for Resmed, Philips and Somnomedics; M.R.B. reports Advisory Board activity with Takeda and Bioprojet, and preparing educational material for ResMed; T.S. has lectured for the Finnish Medical Society Duodecim, Boehringer Ingelheim, Chiesi, the Organisation for Respiratory Health in Finland and the Finnish Dental Association Apollonia. T.S. is the President of the Task Force for the Finnish Current Care Guidelines of Adult Sleep Apnoea. P.S. has received honoraria for lecturing from AstraZeneca, Boehringer Ingelheim, Chiesi, ELPEN, GSK, Guidotti, Menarini, Pfizer, and ResMed. P.S. has also received consulting fees from AstraZeneca, Boehringer Ingelheim, Chiesi, ELPEN, GSK, Guidotti, Menarini, and Pfizer. C.L. has lectured for ResMed, Philips, Idorsia, Neopharmed Gentili, and Fidia. C.L. was a member of the advisory board for Eli Lilly. W.R. reports honoraria from Löwenstein Medical, Bioprojet, Philips, Westfalen Medical, Novamed and Resmed, travel support from Löwenstein Medical, Philips and Bioprojet, participation in advisory boards from Lilly, Bioprojet. J.H. has received lecture fees from Idorsia and SomnoMed. J.H. has earlier served on external advisory boards for SomnoMed and Shionogi. J.H. is a share holder of a company developing pharmacological therapies to treat OSA. Outside the topic of the manuscript, E.S.A. reports honoraria from ResMed, Philips, research collaboration with Empatica and SideKick Health via the Sleep Revolution, a research grant from Samsung, previous Medical Advisory Board member for Philips and Lille as well as a current Data Monitoring Committee membership for SleepCycle. The remaining coauthors do not report a COI.

Data Availability Statement

This study protocol description does not contain specific data. Data from the study have been collected at the cluster at Reykjavik University (RU). Data are made available upon reasonable request. Requirements as well as limitations in data sharing based on the ethical study approval at different study sites need to be considered. Formal data request can be forwarded to RU through the following contact: sleepsupport@ru.is.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Appendix S1:** Scheme for data assessment in the study.