

# Sleep Revolution - evaluation of a novel diagnostic and therapeutic pathway for patients with obstructive sleep apnea

<b>Submission date</b> 31/08/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/02/2024	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/07/2025	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Obstructive sleep apnea (OSA) is when your breathing stops and starts while you sleep, and is associated with various health complications such as a high risk of heart disease, high blood pressure and daytime sleepiness. Despite its negative impact and various associated illnesses, OSA remains poorly diagnosed and ineffectively treated. The EU-funded SLEEP REVOLUTION project is introducing an approach based on machine learning to assess OSA severity and treatment needs. The current study compares the standard care model of sleep apnea diagnosis with a novel approach to study sleep in the patients' homes for 3 nights instead of one single night. In order to analyse the data faster and more accurately, new computer-based analysis will be used to evaluate the large amount of data. It is one aim of the study to identify markers during sleep that are better at predicting patients symptoms of sleep problems compared to current diagnostic procedures. A novel sleep question will be developed and evaluated for the first time in this study. One important aspect of the current study is that 24 sleep centers in more than 15 European countries are involved in the study. Up to 1000 patients with suspected sleep apnea across Europe are intended to include in this study.

### Who can participate?

Patients aged 18 years and over with suspected sleep apnea referred by their physicians to one of the study centers

### What does the study involve?

The study compares the traditional way of sleep diagnosis with a comprehensive sleep study in the hospital or a simplified sleep study at home with a novel approach to perform a comprehensive sleep study for three nights at home. In the novel setting, the patient will be more participatory in the sleep diagnostic process, both by performing the test at home and by providing more information on actual sleep complaints and lifestyle factors. The outcome of those different diagnostic processes will be compared.

### What are the possible benefits and risks of participating?

Sleep tests do not include any major risk, only skin lesions may occur through the placement of

electrodes on the skin. More comprehensive sleep tests may cause discomfort without medical harm. The benefits include more detailed knowledge about sleep quality and the number of severity of sleep apnea events. Further, the new diagnostic principle has a strong focus on a variety of sleep-related symptoms and consequences, it is more patient-centred.

Where is the study run from?

Sahlgrenska University Hospital (Sweden)

When is the study starting and how long is it expected to run for?

March 2020 to February 2025

Who is funding the study?

European Commission

Who is the main contact?

Ludger Grote, ludger.grote@lungall.gu.se

### **Study website**

<https://sleeprevolution.eu/en/home/>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

Prof Ludger Grote

### **ORCID ID**

<https://orcid.org/0000-0002-7405-1682>

### **Contact details**

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

## Study information

### Scientific Title

A randomized cross over trial exploring the Sleep Revolution diagnostic and therapeutic pathway in patients with obstructive sleep apnea

### Acronym

Sleep Revolution WP 8 study

### Study objectives

The current study is a major work package within the overall Sleep Revolution (SR) project. The study focuses on the evaluation of the new SR pathway for sleep apnea diagnosis and treatment follow-up. The feasibility of the following new technologies including patient-related symptom assessment methodology, and data analysis approaches, will be evaluated:

1. Self-applied polysomnography
2. Diagnostic assessment over long time periods including 3 consecutive nights of advanced sleep testing, at least one week of testing with actigraphy, physical activity, sleep symptom questionnaire, and sleep diary
3. Artificial intelligence-based analysis of sleep tests for characterization of sleep, respiratory events and cardiovascular function with quality control by healthcare professionals (semi-automated process)
4. Digital platform for data transfer from the patient to the health care professional
5. Validation of new sleep parameters like hypoxic burden, sleep disturbance index and pulse wave derived cardiovascular indices against comorbidities, baseline symptoms, and response to treatment
6. To evaluate the novel European Sleep Questionnaire (ESQ)

### Ethics approval required

Ethics approval required

### Ethics approval(s)

Submitted 13/11/2023, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46 (0)10-475 08 00; [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: 2023-03829-01

### Study design

Multi-center two-arm randomized cross-over study

### Primary study design

Interventional

### Secondary study design

Randomised cross over trial

### Study setting(s)

Hospital

### Study type(s)

Diagnostic, Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Sleep apnea

**Interventions**

Study SR-001 is a multi-center, two-arm, cross-over study comparing the diagnostic impact and accuracy of two different diagnostic pathways on the outcome of diagnosis and continuous positive airway pressure (CPAP) treatment in patients with suspected obstructive sleep apnea (OSA). Patients referred to one of 24 sleep centers of the Escuela Superior de Arte y Diseño de Andalucía (ESADA) network participating in the Sleep Revolution project will be studied using both the clinical routine of OSA evaluation (standard care [SC]) and the novel Sleep Revolution-based diagnostic pathway including self-applied polysomnography over 3 nights, digitally based symptom evaluation, and actigraphy-based assessment of sleep-wake rhythm and physical activity (experimental condition).

Randomisation is carried out in blocks of four patients, and a randomisation list will be distributed to each participating centre in the study. The randomisation list was generated by a publicly available service at <https://www.sealedenvelope.com/simple-randomiser/v1/lists> on 17 August 2023 with the seed for the randomization list of 275031337567920. Actual randomization will be performed at each study site by personnel otherwise not involved in the study.

Standard sleep diagnostic procedure (standard care pathway): Single night polygraphy or polysomnography both at baseline. Limited numbers of questionnaire data.

The experimental setting (Sleep Revolution pathway) includes three nights of self-applied polysomnography, app-based assessment of symptoms, sleep diary, cognitive function and physical activity. Actigraphy-based assessment of sleep-wake cycle and objective physical activity. In case of clinically relevant sleep apnea according to the results of the diagnostic assessment, patients will be offered treatment for sleep apnea with CPAP.

**Intervention Type**

Device

**Pharmaceutical study type(s)**

Not Applicable

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Not applicable

**Primary outcome measure**

Staff time spent for the sleep apnea diagnostic pathway – comparison between Standard Care (SC) and the Sleep Revolution (SR) model in patients with suspected obstructive sleep apnea (OSA) from patient inclusion to final consultation with the sleep physician (units: minutes)

## Secondary outcome measures

1. Patient satisfaction and preference with the diagnostic work-up (score of the patient global impression scale and the patient preference question) at visit 1c: end of diagnostic procedure
2. Patient satisfaction with the resolution of the initial help request through diagnosis and treatment (only in patients with CPAP therapy, specific question in the European Sleep Questionnaire) at V3b: end of study follow-up visit
3. Number of OSA diagnoses, Positive Airway Pressure (PAP) treatment prescriptions, and non-PAP prescriptions by either pathway (number of patients in each group) at V1c and V3b
4. Number of patients with PAP failure (no acceptance/low adherence) by either pathway (number of patients in each group) at V3b
5. Prediction of PAP treatment responders in terms of adherence and symptom improvement by novel diagnostic parameters (SR versus SC) (predictor analysis of adherence with PAP treatment in h/night, conventional diagnostic markers versus novel diagnostic markers) at V3b
6. Association between sleep test output variables (polysomnography [PSG] and home sleep apnea test [HSAT]) (respiration, hypoxia, cardiovascular function, sleep) and symptoms /comorbidities obtained in SC and SR at V1c

## Overall study start date

01/03/2020

## Completion date

28/02/2025

# Eligibility

## Key inclusion criteria

Main Inclusion Criteria:

1. Referral to the sleep center due to suspected obstructive sleep apnea as the main question for evaluation
2. Male or female aged 18 years and above
3. Willing and able to provide written informed consent
4. Willing and able to comply with the study design schedule and other requirements (e.g. no long-term travel conflicting with the planned visits throughout the study)

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

1000, according to power analysis (non-inferiority design) based on time estimates in SC and SR care models, 1000 patients need to be randomized (500 patients in each of the 2 diagnostic pathways) corresponding to 42 patients per ESADA study centre. An interim analysis will be performed after 500 patients to determine the final number of patients to be included.

**Total final enrolment**

1037

**Key exclusion criteria**

Main Exclusion Criteria:

1. Any ongoing treatment for OSA or central sleep apnea (CSA)
2. Known significant hypercapnic respiratory failure due to chronic obstructive pulmonary disease or other respiratory condition
3. Any other clinically determined contraindication for PAP treatment
4. Patients participating in any type of weight loss treatment program
5. Unstable congestive heart failure or angina pectoris
6. Any other condition – to the judgement of the investigator – which potentially may jeopardize the completion of the study according to protocol
7. History of alcohol or drug abuse during the last year, substance use disorder at screening

**Date of first enrolment**

20/12/2023

**Date of final enrolment**

28/02/2025

**Locations****Countries of recruitment**

Belgium

Croatia

Cyprus

Czech Republic

Denmark

Finland

France

Germany

Greece

Ireland

Italy

Poland

Portugal

Romania

Sweden

Türkiye

**Study participating centre**

**Center for Sleep and Wake Disorders**

Sahlgrenska Academy  
Gothenburg University  
Medicinaregatan 8B  
Gothenburg  
Sweden  
41346

**Study participating centre**

**Sleep Unit**

Department of Pneumonology  
Democritus University of Thrace  
Alexandroupolis  
Greece  
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**Study participating centre**

**Multidisciplinary Sleep Disorders Centre**

Antwerp University Hospital and University of Antwerp  
Antwerp  
Belgium  
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**Study participating centre**

**Multidisciplinary Sleep Disorders Centre**

Antwerp University Hospital and University of Antwerp  
Antwerp  
Belgium  
-

**Study participating centre**

**Pulmonary Medicine**

National and Kapodistrian University of Athens  
Athens  
Greece

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**Study participating centre****Charité – Universitätsmedizin Berlin**

Berlin  
Germany

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**Study participating centre****Sleep Disorders Unit**

Department of Respiratory Medicine  
Medical School  
University of Crete  
Crete  
Greece

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**Study participating centre****Department of Respiratory Medicine**

St Vincent's University Hospital  
Dublin  
Ireland

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**Study participating centre****Pulmonary and Sleep Disorders Unit**

St. Vincent's University Hospital  
Dublin  
Ireland

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**Study participating centre****Sleep Disorders Center**

Pulmonary Department  
Sahlgrenska University Hospital



Göteborg  
Sweden

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**Study participating centre**  
**Université Grenoble Alpes**  
INSERM HP2 (U1042)  
Grenoble University Hospital  
Grenoble  
France

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**Study participating centre**  
**Department of Chest Diseases**  
Ege University  
Izmir  
Türkiye

-

**Study participating centre**  
**Department of Sleep Medicine**  
National Institute of Mental Health  
Klecany  
Czech Republic

-

**Study participating centre**  
**Department of Respiratory Medicine**  
Hospital de Santa Maria  
Lisbon  
Portugal

-

**Study participating centre**  
**Dries Testelmans**  
Sleep Disorders Centre  
University Hospital Gasthuisberg  
Leuven  
Belgium

-

**Study participating centre**

**Department of Respiratory Diseases**

Louvain University Center for Sleep and Wake Disorders (LUCS)

University Hospitals Leuven

KU Leuven

Leuven

Belgium

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**Study participating centre**

**ENT department**

Mainz University Hospital

Mainz

Germany

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**Study participating centre**

**Istituto Auxologico Italiano**

IRCCS

Department of Cardiovascular, Neural and Metabolic Sciences

St Luke Hospital

Milan

Italy

-

**Study participating centre**

**Department of Medicine and Surgery**

University of Milano-Bicocca

Milan

Italy

-

**Study participating centre**

**PROMISE Dept.**

University of Palermo

Palermo

Italy

-

**Study participating centre**  
**Unità Operativa di Medicina del Sonno**  
Istituto Scientifico di Pavia IRCCS  
Pavia  
Italy

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**Study participating centre**  
**Pulmonology Department Hospital São João**  
Medicine Faculty of Porto University  
Porto  
Portugal

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**Study participating centre**  
**Sleep Disorders Centre**  
Pulmonary Clinic  
Solingen  
Germany

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**Study participating centre**  
**Sleep Medicine Center**  
Department of Neuroscience  
University of Split School of Medicine  
Split  
Croatia

-

**Study participating centre**  
**Respiratory Failure Unit**  
G. Papanikolaou Hospital  
Thessalonika  
Greece

-

**Study participating centre**  
**Pulmonary Department**  
Victor Babes University of Medicine and Pharmacy  
Victor Babes Hospital  
Timisoara

Romania

-

**Study participating centre**

**Division of Medicine**

Department of Pulmonary Diseases

Turku University Hospital and Sleep Research Centre

Department of Pulmonary Diseases and Clinical Allergology

University of Turku

Turku

Finland

-

**Study participating centre**

**2nd Department of Respiratory Medicine**

Institute of Tuberculosis and Lung Diseases

Warsaw

Poland

-

## **Sponsor information**

**Organisation**

Directorate-General for Research and Innovation

**Sponsor details**

SDME 2/2

Brussels

Belgium

B-1049

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daniellek@ru.is

**Sponsor type**

Government

**Website**

<http://ec.europa.eu/research/index.cfm?pg=dg>

**ROR**

<https://ror.org/01ef4as46>

# Funder(s)

## Funder type

Government

## Funder Name

European Commission

## Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκή Επιτροπή, Европейская комиссия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiripas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

# Results and Publications

## Publication and dissemination plan

It is planned to publish the results of this major study on approximately 1000 patients in several papers submitted to high-ranking medical peer-reviewed journals after the finalization of the study in 2025.

## Intention to publish date

31/12/2025

## Individual participant data (IPD) sharing plan

The datasets generated during the current study may be available upon reasonable request from Danielle Knieriem (daniellek@ru.is). Further details will be published at a later stage.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 1.3	29/05/2023	26/06/2025	No	No
<a href="#">Statistical Analysis Plan</a>	version 2.0	26/06/2025	26/06/2025	No	No
<a href="#">Statistical Analysis Plan</a>	version 2.1	04/07/2025	04/07/2025	No	No

