SLEEP
REVOLUTION

Information letter for participants

The Sleep Revolution–Lifestyle study
Long-term study

VSN 22-082

Dear participant

We thank you very much for your interest in participating in the Sleep Revolution project. This project aims at finding new approaches to treat snoring to mild sleep apnea with a lifestyle intervention. The data will be collected at Reykjavik University (RU) using sleep studies, a digital sleep diary, different neurocognitive tasks, questionnaires, a smartwatch, as well as body composition and physical fitness measurements. Below is the information about the research and what is included in the participation. If something is unclear or you have any further questions regarding the research, please feel free to contact the undersigned.

What is the aim of the Sleep Revolution project?

The aim is to revolutionize the diagnosis and treatment of sleep apnea by using state of the art measuring methods available, for sleep studies (self-applied measurements), smartwatch, body composition measurements, neurocognitive tests conducted in different ways (e.g. digital attention and vigilance tests), questionnaires as well as a digital sleep diary. Subsequently, machine learning algorithms will be used to assess the severity of the disease and to predict the consequences (e.g. daytime sleepiness, health problems, and diminished quality of life). Furthermore, the Sleep Revolution aims to find new ways of treating snoring/sleep apnea and preventing it from worsening.

Various health-related consequences are associated with sleep apnea, e.g. increased risk of heart disease, hypertension, and traffic accidents due to daytime sleepiness. It is estimated that almost one billion people worldwide have sleep apnea. Current diagnostic criteria, a simple counting of the apnea episodes per hour of sleep, without taking into account the duration of the events or the effect on different systems of the body, relates poorly to these symptoms and comorbidities. Additionally, current clinical procedures used to diagnose sleep disorders are both outdated and expensive. Therefore, the majority of individuals with sleep apnea remain undiagnosed. It is clear that better diagnostic methods are needed as well as prevention and active patient treatment participation.

Sleep Revolution aims to develop machine learning techniques to evaluate the severity of sleep apnea and treatment needs to improve health outcomes and quality of life. These techniques will be implemented using various methods that will be developed in the project to increase access to diagnostic equipment and reduce the cost of measurements.

HÁSKÓLINN Í REYKJAVÍK
REYKJAVÍK UNIVERSITY

Currently, treatment options for mild sleep apnea are limited. The treatment most often involves general advice (such as losing weight, quitting smoking, etc.), and is not standardized. The Sleep Revolution wants to change that by developing a standardized lifestyle program to improve snoring to mild sleep apnea and therewith health outcomes and quality of life.

Why participate in this study?

This study aims to improve habitual snoring to mild sleep apnea through lifestyle intervention that involves sleep studies, neurocognitive testing, evaluation of body composition and physical fitness, physiological data collected with a smartwatch, questionnaires, and a sleep diary. This study will not only allow for the evaluation of a new lifestyle program for mild sleep apnea but is also helping to validate the used equipment, as well as contribute to the understanding of sleep and its related scientific fields.

Interested individuals are asked to answer an online questionnaire (screening list) to evaluate if they meet the criteria for participation. The link can be found on the Reykjavik University Sleep Institute web page: https://redcap.ru.is/surveys/?s=JDR3LWCKXE

Around 200 individuals aged 18 – 40 will be invited to participate. It is aimed to include at least 40% of participants of each gender. Inclusion criteria are a BMI ≥ 25, physical inactivity, and confirmed habitual snoring to mild sleep apnea. Shift workers can not participate.

Participants will be divided randomly into three intervention groups:

1. Exercises in a group with a coach for 12 weeks (3x week, 60 min)
2. Regular use of instructions from the SideKick Health app for 12 weeks
3. Regular use of the Sleep Revolution App for 12 weeks

<u>The research and preparation for the study</u>

Participants that fulfill the inclusion criteria of the study will be chosen from the people that have answered the screening list (https://svefnsetrid.ru.is/en). Some of them have already participated in sleep studies from previous projects in the Sleep Revolution or have sleep study from collaborators but those that do not have a sleep study needs to undergo a simple sleep study to confirm snoring to mild sleep apnea. All chosen participants will be asked to wear a smartwatch and fill in a sleep diary for 2 weeks prior to the intervention period to get a baseline. Participants will be asked to answer a background questionnaire; a personalized link will be sent via e-mail.

There will be 5-8 visits (depending on groups) that will take place at RU.

Primary visit (approx. 30- 45min):

The study will be introduced and informed consent signed. Those that need sleep study will get equipment. Then, relevant apps will be installed on the participant's mobile phone. Smartwatch will be handed out to use for two weeks.

SLEEP
REVOLUTION

Visits after participants have been divided into groups

First visit (approx. 5 min):
Participants come to RU to get equipment for a three-night sleep measurement. The equipment is returned after the last measurement night.
Smartwatches are handed out to participants for use during the intervention period.

Second visit (approx. 1.5 hours):
A neurocognitive test battery will be performed at RU. The battery measures various cognitive domains.

Third visit (approx. 1 hour):
First day of the intervention period. A baseline measurement of physical factors.

1. Anthropometric measurements
2. Body Composition measurements
3. Physical fitness measurements
4. Questionnaires answered at home (a link sent via e-mail)

At home, during the intervention period (12 weeks)

1. Participants are asked to:
2. Wear a smartwatch provided for the entirety of the study
3. Answer daily a sleep diary (evening and morning) within the Sleep Revolution app.
4. Perform cognitive tasks which measure attention, vigilance, and more within the Sleep Revolution app and the Sleep Revolution platform (after week four and eight).
5. Track the menstrual cycle of female participants within the Sleep Revolution app.
6. Fill out questionnaires three times during the intervention period (after the first visit, week 6, and week 12). The questionnaires will assess exercise, mental health (stress, depression, anxiety, trauma), self-reported cognitive functioning, and self-reported quality of life.

Fourth visit (1 hour):
Last day of the intervention period

1. Anthropometric measurements
2. Body Composition measurements
3. Physical fitness measurements
4. Questionnaires answered at home (a link sent via e-mail)

Fifth visit (10 min)

The three-night sleep measurement will be repeated at the end of the intervention period, participants will come to RU's reception and pick up the equipment. The equipment is returned after the last measurement night.

Sixth visit (1.5 hours)
The cognitive battery is repeated and smartwatches returned.

Summary of the collected data:

Sleep studies: Sleep stages, sleep quality, breathing, snoring (audio), oxygen desaturation, electrocardiogram, leg movements, body movements, sleep position.

Cognitive battery and brain games: Cognitive functioning is measured through a variety of domains such as memory, attention, processing speed, emotional recognition, working memory, etc.

Anthropometry, body composition, physical fitness: Height, weight, body mass index (BMI), waist-hip ratio, neck circumference, bioelectrical impedance analysis (BIA), grip strength, and 6-minute walking test.

Withings smartwatch: Heart rate, movement, sleep, oxygen saturation.

Sleep Revolution app: Daily sleep diary, lifestyle (caffeine intake, naps, etc.), brain games, menstrual cycle in women.

Sleep Revolution digital platform: Overview of collected data, brain games.

Questionnaires: Mental health (stress, depression, anxiety, trauma), self-reported cognitive functioning, self-reported quality of life, and end-user experience of sleep equipment.

Where and how is the data stored?
Full confidentiality will be maintained regarding all personal and medical information about the participant and in compliance with the Icelandic law regarding the storage of personal data.

All the data gathered in Sleep Revolution will be stored in a secured, access-controlled data storage, which is only intended for this project, within RU. Only the data that is necessary for the project will be stored.

All the data will be pseudonymized. The name and other identifying information as well as the research number will be stored in a separate secure location, independent of the research results. This identification key will only be accessible to the Principal Investigator of this study as well as other relevant research staff.

Additional permission will be requested for long-term data storage and data access by other researchers in the future. This will be performed according to the guidelines from the Data Protection Authority and the Bioethics Committee. We plan to set up an open-source Sleep Revolution database which will be located in Iceland. Similar databases already exist abroad (e.g., https://eosc-portal.eu).

We intend to publish the results of this project both domestically and in international scientific journals and at conferences. All results published will be anonymous.

What are the risks involved in participating in the study?

There is low to no risk in participating in the study itself. However, individuals may experience some discomfort related to the sleep study and experience some difficulties with sleeping as well as usual.

Participation in a training program can increase the risk of minor injuries or accidents related to the exercise program. However, risks will be minimized, and all training will be performed under the supervision of an experienced coach.

Do I have to participate?

Your participation is voluntary and will only be with your written permission.

You can withdraw your approval and stop your participation at any time without giving any reason. This means all the information collected from you in the study will be deleted if you withdraw your consent and the researchers will not be able to trace the identification key to you. After the study finishes in 2025, the personally identifiable key referred to above will be deleted. The data will, however, be stored in the long-term database if you have given permission for such storage. You will receive a copy of your signed informed consent listing all parts of the study.

What are the benefits of participating in this study?

Participation in this research helps scientists to develop better diagnostic tools to evaluate snoring and sleep apnea and their health effects in addition of evaluating new ways of treatment. In that way, patients, doctors, and researchers can benefit from this knowledge.

All participants who request it will receive a letter with the results of their sleep and whether the measurement indicates sleep apnea or other sleep disorder. The benefit for participants is that they get a clear knowledge of their sleep, and the results will be sent by e-mail to participants if such consent is obtained. Participants will be advised to contact primary health care if the results indicate that further assessment is needed. The doctor will in continuation send a reference to the Landspitali – University Hospital if needed. If results indicate sleep apnea or other sleep disorders in need of treatment, the data from the sleep studies will be sent to Landspitali if such consent was obtained from the participant. The data will therefore be useful for clinical purposes for the participant. The study is free of charge for participants.

Additionally, participants can request the results from the anthropometric, body composition, and physical fitness measurements, as well as a basic summary of their performance in the cognitive battery. Measurements and entries from the Withings smartwatch, the Sleep Revolution app, and the digital platform can be obtained by the participants themselves at any time.

SLEEP
REVOLUTION

In the end of the intervention period – participants from relevant groups can get an exercise program from a certified trainer to use on their own.

What happens to my answers to questionnaires and the medical data?

Personal information about the participant (name, social security number, e-mail, telephone number) will be registered on the declaration of approval and stored in locked storage under the guarantor of the study. Only the responsible person and the relevant staff will have access to this file, which will be kept separate from the data in the study. This file will be deleted by the end of 2026. The measurement results and other data will be de-identified and stored as such in the database.

If the results of the sleep studies indicate sleep apnea or other sleep-related diseases, the results can be sent to Landspítali (at given consent) for further evaluation. The data from the sleep study will be uploaded to a safe data storage at Landspitali along with a report of clinically relevant results.

Who is responsible for this research?
Reykjavik University is the responsible party for this research and the Principal Investigator is Dr. Erna Sif Arnardóttir. The project is funded by the European Union - Horizon fund of 2020 (project number 965417).

We are grateful for your participation in this research study.
We hope that we have answered most of your questions about the research. Please take the time you need to consider participation and if you have any questions, please contact The Reykjavik University Sleep Institute via email: sleeprevolution@ru.is or by phone at 617-9552.

Best regards

On behalf of the Sleep Revolution research group

Erna Sif Arnardóttir

Dr. Erna Sif Arnardóttir
Assistant Professor, Reykjavik University

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement no. 965417

HÁSKÓLINN Í REYKJAVÍK
REYKJAVÍK UNIVERSITY