SLEEP REVOLUTION

HÁSKÓLINN Í REYKJAVÍK REYKJAVÍK UNIVERSITY

Funded by the European Union

Information letter for participants

The Sleep Revolution– testing of new equipment
Long-term study

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 diagnose sleep apnea. The data will be collected at Reykjavik University (RU) using neurocognitive testing, a sleep study, digital sleep diary, attention- and vigilance tests, questionnaires, smartwatches, and body 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.

Due to Covid-19 it should be noted that extreme caution will be kept during the research procedures. All the necessary precautions will always be taken.

What is the aim of Sleep Revolution project?

Aim: The aim is to revolutionize the diagnosis and treatment of sleep apnea by using state of the art measuring methods available, both for sleep studies (self-applied measurements) smartwatches, neurocognitive testing, questionnaires, digital attention- and vigilance tests 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, stroke, death).

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 a billion of people worldwide have sleep apnea. Current diagnostic criteria, a simple counting of the apnea episodes per hour of sleep, without taking into the 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 Additionally, current clinical procedures used to diagnose sleep disorders are both outdated and expensive.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 the sleep apnea remain undiagnosed. It is clear that better diagnostic methods are needed as well as preventions 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.

Why to participate in this study?
This part of Sleep Revolution aims to examine neurocognitive tests, evaluate body composition and data from smartwatches as well as test the influence of three nights sleep studies instead of one with new equipment that will be used in the research and to validate end user experience of the equipment as well as the measurement quality of self-applied sleep studies. Also, to try a new mobile application (SleepRevolution app) that contains a sleep diary, attention- and vigilance tests.

Interested individuals are asked to answer an online questionnaire to evaluate if they meet the criteria for participation. The link can be found on the Reykjavik University Sleep Institute´s web page: https://svefnsetrid.ru.is/en

Around 130 individuals will be invited to participate, both men and woman, in the age range of 18-99 years. Both healthy individuals, snoring individuals, and those with suspected or confirmed sleep apnea will be invited. We plan to include individuals with a wide range of body mass index, age, and gender. The participants will be selected based on these criteria. At the same time as the participant gets the first appointment, an online questionnaire will be sent that needs to be answered before first visit to RU.

The research and preparation for the study

There will be 2-3 visits that will take place at RU (one of the visits can be done in electronic chat i.e. Teams) .

First visit (approx. 3 hours):

It will start with an explanation of the study and following that the signing of an informed consent form. Next, your height and weight will be measured as well as body composition where the ratio of muscles and fat will be estimated. The SleepRevolution app, Empatica Care app, and Withings Health Mate app will be installed in your mobile phone. You will be asked to wear smartwatches, fill in the digital sleep diary and do the attention- and vigilance tests for 90 days. Access will be given to the website SleepWell (hosted by RU) where participants have access to their own data collected in the SleepRevolution. Next, the participants will have Nox Medical A1 equipment put on that evaluates sweating and heart rate and perform neurocognitive tests, measuring cognitive abilities such as memory, attention, and processing speed. The neurocognitive tests will take about 90 minutes to complete. Next, a questionnaire about the experience of cognitive skills will be answered. At the end of the visit, the sleep study will be introduced. The Sleep equipment measures sleep stages, sleep quality, breathing, snoring, oxygen saturation, electrocardiogram, leg movements, body movements and position. Sleep equipment will be delivered. The participant goes home with the equipment, applies itself and sleeps at home. Study is repeated for three nights in a row and the participant takes it off in the morning and applies again in the evening. After three nights the equipment is returned to the RU reception.

At home:

The participant is asked to fill in the sleep diary daily (evening and morning) and perform attention and vigilance tests weekly. The participant will be asked to fill out questionnaires 3 times during the 12 weeks period (after the first visit, week 6, and week 12). The questionnaires will assess exercise, social functioning, and mental health (anxiety, stress, depression, and trauma).

Second visit in RU or interview on Teams (approx. 1 hour):

An interview about the experience that the participant has had of the study and also if he/she has had Covid-19. Audio recording will be done in the interview and will be deleted after registration of it.

Third visit (approx. 2,5 hours):

The Withings and Empatica watches with accessories returned. Body composition measurements and neurocognitive tests will be repeated.

Additional study:
Participants are offered to perform additionally a one-night sleep study with the Nukute sleep collar, during the first night of the 3-night sleep study. The Nukute sleep collar measures breathing sound, pulse and oxygen saturation.

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 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 and encrypted. The name and other identifiable information as well as the research number will be stored in a completely separated 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 the long-term data storage. It will enable data access for 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 the results 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.

Do I have to participate?

Your participation is voluntary and will only be with your written permission. It is possible to deny participation in certain aspects of the study without affecting your participation in the study in any way. You can withdraw your approval and stop your participation at any time within five years without giving any reason. After that time, the personally identifiable key referred to above will be deleted. The pseudonymized data will be stored in the long-term database if you have given permission for such storage. 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. You will receive a copy of your signed informed consent.

What are the benefits from 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 that way, you and others will benefit from this knowledge. All the participants will receive a letter with their results regarding sleep and whether the measurement indicates sleep apnea or another sleep disorder, upon request. Additionally, participants will receive information about their body composition if requested. The participants will benefit from this study by getting a detailed information about their sleep. If the results of sleep study are considered to require further examination due to a possible sleeping disorder, it will be advised to consult a doctor and seek appropriate treatment within the healthcare system. The results will be sent by e-mail or letter to participants if such consent is obtained.

Participants will be advised to contact the primary health care if the results indicate that further assessment is needed regarding a possible sleep disorder. The doctor will in continuation send reference to the Landspitali – University Hospital if needed. In cases where results indicate sleep apnea or other sleep disorders, the data from the sleep studies will be sent to Landspitali if such consent was obtained from the participant. The data will then be useful for clinical purposes. The study is free of charge for participants.

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 a 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 separated 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.

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).

The additional study with the Nukute sleep collar is funded by Nordforsk (Nordsleep project nr. 90458-06111)

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: rusi@ru.is or by phone 617-9552.

Best regards

On behalf of the Sleep Revolution research group

Erna Sif Arnardóttir

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