ISRCTN16974764 https://doi.org/10.1186/ISRCTN16974764

Effects of a 12-week exercise program and a lifestyle app on sleep-disordered breathing in adults

Submission date
16/01/2023

Recruitment status
No longer recruiting

Registration date
09/02/2023

Overall study status
Completed

Last Edited
27/08/2025

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sleep-disordered breathing (SDB) is a term that covers breathing problems during sleep, such as snoring and obstructive sleep apnea (OSA). OSA is a serious condition that affects one billion people between 30 and 69 years old and can lead to decreased sleep quality and quantity, weight gain, and other health problems such as cardiovascular disease, metabolic syndrome, and decreased daily functioning. Obesity is the main risk factor for SDB, with over 70% of people with OSA being considered obese. Exercise is a well-known treatment for obesity and has been shown to have positive effects on sleep disorders like OSA, by improving sleep quality, exercise capacity, mood and quality of life, and decreasing OSA symptoms. Studies have shown that exercise interventions of up to 12 weeks have significant improvements in OSA symptoms. Regular exercise alone, without significant weight loss, can also reduce the severity of symptoms in OSA patients.

Who can participate?
Patients aged 18 - 50 years with mild to moderate sleep-disordered breathing

What does the study involve?
Participants are randomly allocated to one of three groups.
Experimental group I undergoes an exercise program. The intervention will last 12 weeks with an exercise program of three 60-minute sessions per week. The exercise program consists of multiple stations (circuit training) with a fixed Work/Rest time, and brisk intensity walking for 8-14 minutes. All the sessions start with a ten-minute dynamic warm-up and end with a 10-minute cool-down and static stretches. The practice equipment used in the interventions consists of resistance bands, free weights, aerobic steppers, medicine balls, Bosu balls, and exercise mats. The exercise program follows the general recommendation for exercise programs in SDB patients. The trainer coach will follow these recommendations under the supervision of a Sports Science and Exercise specialist. This trainer coach will monitor the intensity using the Borg scale of perceived exertion, which will be between 13 and 15 in the main part (circuit training and brisk walking) and between 7 and 11 in the warm-up and cool-down.
Experimental group II uses a lifestyle app from SideKick Health (SKH) developed specifically for

this group of subjects. The lifestyle app consists of daily missions with four main pillars: physical activity, relaxation, nutrition and sleep, which are made attractive through gamification and rewards. The daily tasks keep the patients focused on their goal of improving their health through diet and exercise, and the gamification of the intervention will help keep participants motivated and engaged. The Sidekick intervention for lifestyle modification provides a combination of a complete, individualized intervention with feedback (through the platform) from a live coach.
The control group receives treatment as usual.

What are the possible benefits and risks of participating?
The potential benefit would be to reduce the severity of sleep-disordered breathing. The participants in the experimental groups will benefit from an intervention led by researchers in the field of exercise programs and the use of apps with the intention of improving sleep-disordered breathing. Participants in the control group will benefit from knowing their baseline of the parameters studied. There are no special risks.

Where is the study run from?
Reykjavik University (Iceland)

When is the study starting and how long is it expected to run for?
January 2021 to December 2023

Who is funding the study?
European Union Horizon 2020 research and innovation programme under grant agreement no. 965417

Who is the main contact?
Dr Erna Sif Arnardóttir, ernasifa@ru.is

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
European Union’s Horizon 2020 research and innovation programme under grant agreement no. 965417

Study information

Scientific Title
Effects of an exercise program and a lifestyle app on sleep parameters, body composition, physical fitness and neurocognitive function in overweight and obese patients (aged 18-50 years) diagnostic of mild sleep disorders of breathing

Study objectives
An exercise program and lifestyle app achieve improvements in sleep-disordered breathing symptoms in overweight and obese patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/05/2022, Icelandic national bioethics committee (Vísindasiðanefnd, Borgartúni 21 – 4 floor, 105 Reykjavik, Iceland; +354 551-7100; vsn@vsn.is), ref: VSN-22-082

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improvement of sleep-disordered breathing in patients with sleep apnea

Interventions
The participants were randomly assigned to a group using a randomization algorithm. Using a hierarchical structure, the algorithm prioritized balancing the female and male count across the three groups (control, exercise, app). The algorithm then calculated a "score" for each group. The "score" reflected the difference between the average value and standard deviation of key variables in each group to the total sample, total female sample, and total male sample. When gender distribution was not a determining factor, the algorithm used the "score" to balance each group with regard to the overall sample characteristics (total, females, males). The

variables used included the apnoea-hypopnea index, body mass index, and age. These variables were chosen due to their potential confounding effects on the study outcomes. The algorithm was built and run using Python version 3.10.6.

Experimental group I
Exercise program. The intervention will last 12 weeks with an exercise program of three 60-minute sessions per week. The exercise program consists of multiple stations (circuit training) with a fixed Work/Rest time, and brisk intensity walking for 8-14 minutes. All the sessions start with a ten-minute dynamic warm-up and end with a 10-minute cool-down and static stretches. The practice equipment used in the interventions consists of resistance bands, free weights, aerobic steppers, medicine balls, Bosu balls, and exercise mats. The exercise program follows the general recommendation for exercise programs in SDB patients. The trainer coach will follow these recommendations under the supervision of a Sports Science and Exercise specialist. This trainer coach will monitor the intensity using the Borg scale of perceived exertion, which will be between 13 and 15 in the main part (circuit training and brisk walking) and between 7 and 11 in the warm-up and cool-down.

Electronic sleep diary with standardized feedback through the Sleep Revolution mobile application and continuous monitoring of heart rate, activity monitoring, and SpO2 with Withings ScanWatch for 12 weeks.

Experimental group II
Sidekick health group
The lifestyle app used is from SideKick Health (SKH) and was developed specifically for this group of subjects. The lifestyle app consists of daily missions with four main pillars: physical activity, relaxation, nutrition and sleep, which are made attractive through gamification and rewards. The daily tasks keep the patients focused on their goal of improving their health through diet and exercise, and the gamification of the intervention will help keep participants motivated and engaged.
The Sidekick intervention for lifestyle modification provides a combination of a complete, individualized intervention with feedback (through the platform) from a live coach.

Control group
Treatment as usual.

Electronic sleep diary with standardized feedback through the Sleep Revolution mobile application and continuous monitoring of heart rate, activity monitoring, and SpO2 with Withings ScanWatch for 12 weeks.

Intervention Type
Behavioural

Primary outcome(s)
SDB severity is measured with a three-night sleep study, using self-applied somnography (SAS) from NOX Medical (Reykjavik, Iceland) at baseline and follow-up (12 weeks).

Key secondary outcome(s))
1. Sleep quality measured objectively with SAS and subjectively with a sleep diary. Objective measures of sleep quality at baseline and 12-week follow-up. Subjective measures of sleep quality daily for the 12-week intervention.
2. Body composition at baseline and 12-week follow-up:

2.1. Body mass index. BMI is a person's weight in kilograms divided by the square of height in meters.
2.2. Body fat percentage. Bioelectrical impedance analysis (BIA) will be used to estimate body composition. In BIA, a weak electric current flows through the body and the voltage is measured in order to calculate the impedance (resistance) of the body. The equipment used will be the Bodystat 500 (Isle of Man, UK). It uses 4 electrodes (ankle and wrist) to measure raw data at any segment of the body. Waist-hip ratio. The waist-to-hip ratio is the ratio of waist circumference to hip circumference, a simple calculation of the measurements of the waist girth divided by the hip girth.
3. Physical fitness at baseline and 12-week follow up:
3.1. Strength. Hand dynamometry of the dominant hand will be was evaluated with a Vernier hand dynamometer (Vernier, Orlando, FL, USA), with the subject seated and the elbow at 90°.
3.2. Cardiorespiratory endurance. The 6-Minute Walking Test is a sub-maximal self-paced test that measures the individual´s sub-maximal capacity to perform activities. The 6-Minute Walking Test measures how far an individual can walk when walking as fast as he/she possibly can in a period of six minutes on a hard and flat surface. The 6-Minute Walking Test is performed indoors on a walking course of 30 meters (60-meter lap).
4. Physiological parameters measured via Withing smartwatch (including SaO2 measurements for SDB severity estimation, movements and pulse) continuously for the 12-week intervention.
5. Neurocognitive function measured using the Rey Auditory Verbal Learning Test (RAVL-T) wordlists, the Wechsler Memory Scale, the Verbal Fluency Test, Digit span, Trail making test, at baseline and 12-week follow-up.

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Signed, informed, written consent
2. Age 18 - 50 years
3. Verified mild to moderate sleep-disordered-breathing according to the current American Academy of Sleep Medicine and International Classification of Sleep Disorders criteria
4. The SDB level may range from habitual snoring to positional and mild obstructive sleep apnea, not fulfilling the criteria for continuous positive airway pressure therapy treatment
5. BMI ≥25 kg/m2 (overweight or obese)
6. Inactive person (no participation in exercise programs at baseline)
7. Subjects willing to try lifestyle change, including an exercise program
8. Willingness to perform the study-specific testing both at baseline and during follow-up
9. Ability to read, follow the lifestyle program and answer the questionnaires in DMP, electronic sleep diary and objective daytime testing (via DMP and physical visits)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
200

Key exclusion criteria
1. Severe OSA
2. Inability to perform an exercise
3. Regular use of hypnotic medications
4. Clinically verified dominant central sleep apnea
5. Known history of active malignant disease
6. Blindness or hearing loss
7. Unstable cardiometabolic disease
8. Unstable psychiatric disease
9. Ongoing alcohol or drug abuse
10. Other medical conditions which may interfere with the study protocol in the opinion of the investigator

Date of first enrolment
01/08/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Iceland

Study participating centre
Reykjavik University
Menntavegur 1
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102

Sponsor information

Organisation
Horizon 2020 - European Union

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
There will be no possibility of sharing individual participants' data

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/06/2025	27/08/2025	Yes	No
Other publications	follow-on study	12/08/2025	27/08/2025	Yes	No
Participant information sheet			09/02/2023	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes