ISRCTN90694424 https://doi.org/10.1186/ISRCTN90694424

The effects of an m-health application for exercising the mouth and facial muscles in patients with sleep obstructive syndrome

Submission date
16/05/2020

Recruitment status
No longer recruiting

Registration date
19/05/2020

Overall study status
Completed

Last Edited
03/11/2020

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Obstructive sleep apnea is a potentially serious sleep disorder. It causes breathing to repeatedly stop and start during sleep.
There are several types of sleep apnea, but the most common is obstructive sleep apnea. This type of apnea occurs when your throat muscles intermittently relax and block your airway during sleep.
The classic treatment of this disease is based on dietary measures, losing weight, and exercise, and the use of a continuous positive airway pressure (CPAP) machine (a device that reduces collapsibility of the upper airway by emitting a flow of air). Other options are upper airway surgery treating the obstacle of the airway or correcting the muscles that do not perform their function properly, and mandibular advancement devices (MAD), which push the tongue forward to avoid it falling backward and collapsing the airway.

Myofunctional therapy (MT) has become one of the newest treatments for sleep-disordered breathing. MT is based on daily exercises of the throat muscles in an attempt to strength them and facilitate opening of the airway.

Who can participate?
Patients diagnose with sleep apnea and aged between 18 – 75 years.

What does the study involve?
Participants will be randomly allocated to either use of the 'Airway gym' smartphone app or treatment as usual for three months. The airway gym app provides instructions on how to perform exercises to strengthen the throat muscles and also reminds participants to perform the exercises for 20 minutes per day. Each month participants will be assessed at the clinic.

What are the possible benefits and risks of participating?
Benefits: Curing sleep apnea syndrome.
There are no signficant risks for participants.

Where is the study run from?
Hospital Quironsalud Marbella (Spain)

When is the study starting and how long is it expected to run for?
October 2018 to November 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Carlos O'Connor Reina, coconnor@us.es

Contact information

Type(s)
Scientific

Contact name
Dr Carlos O'Connor Reina

ORCID ID
https://orcid.org/0000-0002-1670-4235

Contact details
Avenida Menendez y Pelayo 44 5c
Sevilla
Spain
41003
+34 658059669
coconnor@us.es

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AWGAPN-2019-01

Study information

Scientific Title
Effects of myofunctional therapy with an m-health application airway gym in severe apnea /hypopnea sleep obstructive syndrome. A randomized multicentre control trial

Acronym
MTASSAOS

Study objectives
The periodical use of the app 'Airway Gym' designed to perform and increase adherence in Myofunctional therapy (MT), improve obstructive sleep apnea/hypopnea syndrome (OSAHS) in patients with severe disease (AHI>30) increasing the tone of the upper airway muscles.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/02/19, Ethical Committee Costa del Sol Hospital (Comité de Ética de Investigación Área Costa del Sol, Hospital Costa del Sol Autovía del Mediterráneo, Km 187, 29603, Marbella (Málaga), Spain; +34 951976620; cto@hcs.es), ref: 81-01-2019

Study design
Interventional prospective multicentre trial with consecutive random assignment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not avalaible in web format pleas use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Severe sleep apnea/hypopnea syndrome

Interventions
Experimental group: Myofunctional exercises based on a mHealth App AirwayGym daily performed during 3 months 20 minutes a day.
Control group: No intervention.

Patients will be randomized consecutively.

Intervention Type
Behavioural

Primary outcome measure
At baseline and 3 months:
1. Severity of apnea measured using The Apnea–Hypopnea Index

2. Saturation O2 and Nadir O2 measured using oximeter
3. Tongue strength measured using the Iowa Oral Performance Instrument (IOPI)

Secondary outcome measures
Measured each month for 3 months:
1. Sleep quality measured using Pittsburgh Sleep Quality Index (PSQI)
2. Sleepiness measured using Epworth sleepiness scale
3. BMI (kg/m²)
4. Neck and waist circumference (cm)

Overall study start date
01/10/2018

Completion date
01/10/2020

Eligibility

Key inclusion criteria
1. Age between 18-75 years
2. Recently diagnosed with severe sleep apnea and do not have any previous experience or information with this pathology
3. Consent signed

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
30

Total final enrolment
40

Key exclusion criteria
1. IMC (BMI) >40 kg/m²
2. Inability to fill up questionnaires
3. Severe drug or alcohol abuse
4. Hypnotic medication

5. Not controlled coronary disease
6. Decompensated Heart failure
7. Stroke
8. Systemic Disease associated with inflammatory diagnosed entity (arthritis, sarcoidosis, vasculitis, lupus…)
9. Neuromuscular disease (like Duchenne)
10. Craniofacial deformities.
11. Active oncologic process.
12. Any antecedents of MT treatment or other treatment for sleep apnea could affect study results of the study (surgery, DAM or CPAP).

Once the patient accepted and signed consent and met inclusion criteria, they will be attended by Ent specialist to rule out:
13. Severe upper airway obstruction (Complete nose obstruction, Tonsills grade IV/IV)
14. Presence of tongue tie (Marchesani Protocole) with limitation of tongue movements
15. Antecedents or presence of temporomandibular joint disorders

Date of first enrolment
01/02/2019

Date of final enrolment
15/09/2020

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Quironsalud Marbella
Avda Severo Ochoa 22
Marbella
Spain
29603

Study participating centre
Hospital Quironsalud Campo de Gibraltar
Edificio Artysur PE Las Marismas de Palmones
Palmones-Los Barrios
Spain
11379

Sponsor information

Organisation
Hospital Quironsalud Marbella

Sponsor details
Avenida Severo Ochoa 22
Marbella
Spain
29603
+34 952774282
carlos.oconnor@quironsalud.es

Sponsor type
Hospital/treatment centre

Website
http://www.quironsalud.es

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 18/09/2020:
We will try to publish in high-impact-factor journals of informatics, sleep and pulmonology research.

Intention to publish date
01/11/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

Previous publication and dissemination plan:
We will try to publish in high impact factor journals of sleep and pulmonology research.

IPD sharing statement:
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		19/05/2020	08/06/2020	No	No
Results article	results	09/11/2020	03/11/2020	Yes	No