

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/11/2020	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English Summary

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 strengthen 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 significant 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
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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 hypothesis

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 available in web format pleas use contact details to request a participant information sheet

Condition

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

Overall study end date

01/10/2020

Eligibility

Participant 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

Participant 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

Recruitment start date

01/02/2019

Recruitment end date

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

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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