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Effect of throat exercises in lower jaw advancement to treat sleep apnea

Submission date
14/04/2023

Recruitment status
Recruiting

Registration date
17/04/2023

Overall study status
Ongoing

Last Edited
04/08/2026

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Obstructive sleep apnoea/hypopnoea syndrome (OSAHS) is a condition in which the upper airway is narrowed or closes during sleep when muscles relax, causing under-breathing or stopping breathing. Myofunctional therapy (MT) is a treatment option for OSAHS based on performing regular exercises with the upper airway muscles in order to increase their tone of them and prevent their collapsibility. Mandibular advancement devices (MADs) are used for OSAHS treatment creating a tongue and jaw protrusion and causing changes in the upper airway (UA) widening its dimensions. The aim of this study is to determine the effectiveness of and adherence to upper airway muscle exercises performed with an App (Airway Gym) in patients with moderate OSAHS who use a MAD.

Who can participate?
Patients aged between 18 and 75 years with moderate OSA

What does the study involve?
Participants are randomly allocated to one of four groups. One group will undergo sham therapy. Another group will have to use an app to perform myofunctional exercises and another will do exercises with a MAD and another will have to wear a MAD for OSA treatment for 3 months. Patients will be examined and the tone of the upper airway muscles is measured with a tongue digital spoon device. Polysomnography (sleep study) will be repeated after 3 months in all the groups. A sleep diary will be provided to patients to measure adherence.

What are the possible benefits and risks of participating?
The benefits will come from improvements in OSAHS symptoms. The researchers hope no risks will be involved.

Where is the study run from?
Grupo Quironsalud (Spain)

When is the study starting and how long is it expected to run for?
January 2023 to December 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Carlos O'Connor-Reina, carlos.oconnor@quironsalud.es

Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Protocol serial number
AWAGAP-2023-1

Study information

Scientific Title
Influence of oropharyngeal exercises in the adherence and efficacy of mandibular advancement device therapy in patients with moderate obstructive sleep apnea: a multicentre randomized clinical trial pilot study

Acronym
MADOMTCOMPLIANCE

Study objectives
The main objective will be to evaluate the changes in apnea-hypopnea index (AHI), oxygen desaturation index (ODI) and minimal O2 desaturation (min sat o2) after 3 months of myofunctional therapy (MT) with an App in moderate sleep apnoea patients that use a mandibular advancement device (MAD) (Noa® from Orthopnoea®).

The secondary objectives will be:
1. If the use of MAD modifies the strength of the genioglossus muscle measured by TDS and IOPI
2. If oropharyngeal exercises increase subjective parameters measured with Epworth, VAS and Pittsburgh questionnaires

3. If oropharyngeal exercises increase adherence to the use of MAD
4. If prior score obtained with TDS and IOPI can influence adherence or efficacy of MAD
5. If oropharyngeal exercises increase objective measures obtained with TDS and IOPI
6. If oropharyngeal exercises create any morbidity in patients with MAD (adverse effects)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2023, Comite de Ética de Investigación de Malaga Hospital Regional Universitario (7ª planta Pabellón A, Avda. –Carlos Haya s/n, 29010, Málaga, Spain; +34 (0)951 29 1447 / +34 (0)951 29 1977; portaldeetica.csalud@juntadeandalucia.es), ref: 0324-N-23

Primary study design
Interventional

Study design
Prospective controlled randomized clinical trial pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Sleep apnea

Interventions
A myofunctional and anatomical evaluation of the patient diagnosed with obstructive sleep apnea/hypopnea syndrome (OSAHS) will be conducted in the same week as the polysomnography is performed. During this evaluation, patients are blindly examined by an otorhinolaryngologist and blindly allocated to each group.

Randomization will be simple randomization depending on the order the patient attends the Ear, Nose and Throat (ENT) consultation. The total duration of therapy will be 3 months. There will be four arms:
1. Sham therapy: expiratory exercises daily performed and written in a diary.
2. Myofunctional therapy: oropharyngeal exercises performed by an APP Airway Gym followed by telemedicine
3. Mandibular advancement device therapy: use of a titratable mandibular advancement device (NOA device)
4. Mandibular advancement device and oropharyngeal exercises: a combination of both

Subsequently, the muscle tone of the genioglossus muscle and the buccinator muscle are evaluated with IOPI, taking three measurements of each one and using the highest value. The tone of the tongue muscles is measured with the digital spoon, taking three measurements and using the highest one. Then is referred to the dentist to adapt MAD at the maximum distance allowed.

DISTRIBUTION OF HOSPITAL VISITS:
Visits during the study are distributed as follows:
SELECTION VISIT: The patient diagnosed with OSAHS at a pulmonology laboratory by means of an initial sleep study (with measurement of baseline AHI, night-time oxygen desaturation index

and the lowest night-time oxygen saturation figures) is evaluated vis-à-vis the inclusion and exclusion criteria and then informed about the study. After reading the information and having any doubts solved, the patient accepts and signs the informed consent form in duplicate, taking one copy home.
ONE-OFF VISIT: The patient is evaluated by the otolaryngologist and fills in the sleepiness questionnaires, the TDS and IOPI. Exercises are explained and the group with MAD is referred to the dentist to provide the MAD.
FINAL VISIT: After 3 months there is another sleep study with anatomical measurements and questionnaires.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Apnea-hypopnea index (AHI) measured by polysomnography/polygraphy measured on the first day and after 3 months

Key secondary outcome(s)
Measured on the first day and after 3 months (except for sleep diary):
1. Oxygen desaturation index (ODI) measured by polygraphy/polysomnography
2. Minimal O2 desaturation (min sat o2) measured by polygraphy/polysomnography
3. Strength of the genioglossus muscle measured by Tongue Digital Spoon (TDS) and Iowa Oral Performance Instrument (IOPI)
4. Adherence to the use of MAD measured by sleep diary daily
5. Sleepiness measured with the Epworth sleepiness scale subjective scale
6. Subjective measure of snoring by partner using Visual Analogue Scale (VAS)
7. Quality of sleep measured with Pittsburgh questionnaires
8. Oropharynx dimensions measured with Friedman anatomical scales

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. Aged between 18 and 75 years
2. Diagnosis of moderate OSAHS (AHI between 15-30) without having had previous experience of said condition and not undergoing treatment due to different circumstances
3. Not having undergone any previous treatment for OSAHS
4. Signed informed consent (IC) form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Cognitive or neurological deficit
2. Inability to answer questionnaires
3. Severe alcoholism
4. Presence of craniofacial malformations
5. Active neoplastic disease
6. History of prior orofacial muscle rehabilitation therapy and any prior apnoea treatment which may modify the study results (surgery, MAD, continuous positive airway pressure [CPAP])
7. Not having a smartphone
8. Temporomandibular joint dysfunction
9. Absence of dentition to wear a MAD

Date of first enrolment
03/05/2023

Date of final enrolment
01/12/2026

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Quironsalud Marbella
Avda Severo Ochoa 20
Marbella
Spain
29603

Study participating centre
Hospital Quironsalud Campo de Gibraltar
Edificio Arttysur.Avda de los Empresarios s/n 11379

Palmones, Cadiz
Spain
11370

Sponsor information

Organisation
Quirons salud investigacion

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Carlos O'Connor (carlos.oconnor@quironsalud.es). Data will be available on 01/01/2026. The type of data that will be shared: raw data. Consent will be obtained from all participants. Data will be collected anonymously.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			17/04/2023	No	Yes