Feasibility of a program consisting of exercise training and dietary advice in mild obstructive sleep apnea syndrome.

Published: 15-12-2009
Last updated: 04-05-2024

the primary objective of this study is to investigate whether a structured program including exercise training and dietary advice is feasible in mild OSAS patients in a primary care setting.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON33318

Source
ToetsingOnline

Brief title
OSAS

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
'OSAS' and 'sleep apnea'

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: UMCG

Intervention

Keyword: dietary advice, exercise training, obstructive sleep apnea syndrome, OSAS

Outcome measures

Primary outcome

Feasibility assessed by patient compliance to the treatment: number of patients dropping out of the program; percentage training sessions attended by each patient; usage of the pedometer; amount of times patient fills in the diary.

Secondary outcome

Fat-free mass, weight, subjective daytime sleepiness, health related quality of life, the influence of excessive sleep on physical-, mental- and social functioning in daily life, symptoms of current depression and anxiety, activities of daily living, compliance with treatment, intima-media thickness (IMT) of the carotid arteries, Advanced Glycation Endproducts (AGEs).

Study description

Background summary

Obstructive sleep apnea-hypopnea syndrome (OSAS) is a common sleep-related breathing disorder characterized by repetitive upper airway collapse during sleep, disruptive snoring and excessive daytime sleepiness. Many OSAS patients are characterized by obesity. As obesity is probably the most important risk factor for OSAS and the number of people with obesity is increasing, the prevalence as well as the incidence of OSAS will probably increase even further. Specific lifestyle patterns often play a predominant role in developing obesity and helping obese OSAS patients in changing their lifestyle patterns is probably of great importance. Recently an evidence based guideline on diagnostics and treatment of OSAS in adults was presented. This guideline recommends that in all OSAS patients conservative measures (i.e. weight reduction, avoidance of stimulants in the evening, avoidance of sedative medication and alteration of sleeping position) should be considered first. Conservative measures may be effective in mild OSAS. However, studies that

investigated the effectiveness of the conservative measures were of evidence level 3. Therefore, within the mild spectrum of OSAS further research is needed to investigate the effects of conservative measures on OSAS symptoms. This pilot study will increase our knowledge in the specific area of lifestyle intervention and will provide information on the feasibility of the study.

Study objective

the primary objective of this study is to investigate whether a structured program including exercise training and dietary advice is feasible in mild OSAS patients in a primary care setting.

Study design

the protocol concerns a longitudinal study without a control group.

Intervention

patients with mild OSAS will receive a structered program, consisting of exercise training and dietary advice for 24 weeks, with follow-up measurements after 12 and 24 weeks.

Study burden and risks

on three moments (baseline, 12 weeks, 24 weeks) fat-free mass will be assessed, cardiovascular risk will be assessed, 4 questionnaires have to be filled in, and a walking test has to be performed. After 12 and 24 weeks the number of apneas and/or hypopneas will be assessed during ambulant polysomnography. Benefits of the treatments could be a reduction of the number of apneas and/or hypopneas per hour, reduction of subjective daytime sleepiness, improvement in quality of life, and on the long term reduction in cardiovascular risk.

Contacts

Public
Universitair Medisch Centrum Groningen

Postbus 30001
9700 RB Groningen
Nederland
Scientific
Universitair Medisch Centrum Groningen

Postbus 30001

9700 RB Groningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Individuals who have been subjected to polysomnography and are diagnosed as having mild (5<=AHI<15) OSAS
2. Aged > 20 years
3. Body mass index (BMI) > 25

Exclusion criteria

1. Patients with previous treatment for OSAS (continuous positive airway pressure (CPAP), oral-appliance therapy, uvulopalatopharyngoplasty (UPPP))
2. Morphologic abnormalities of the upper airway (e.g., a compromised nasal passage, enlarged tonsils or adenoids, or upper airway soft-tissue or craniofacial abnormality)
3. Endocrine dysfunction (hypothyroidism, acromegaly, or pituitary adenoma)
4. Reported or documented severe cardiac- or pulmonary co-morbidity (daytime respiratory insufficiency, severe chronic obstructive pulmonary disease (COPD), heart failure, coronary disease, or severe cardiac arrhythmias)
5. Psychiatric disorders (e.g., depression or schizophrenia)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2009
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL27839.042.09