The effectiveness of remote monitoring in improving CPAP compliance: a randomised, controlled study.

Published: 03-07-2015
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This study emphasizes on the effect of telemonitoring and the effect on compliance in the first period after starting the treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41977

Source
ToetsingOnline

Brief title
AREMOC= Airview Remote Monitoring CPAP.

Condition

- Other condition
- Respiratory disorders NEC

Synonym
obstructive sleep apnea, OSAS

Health condition

slaapgeneeskunde/OSAS

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: De leverancier van CPAP apparatuur. Deze stelt het gebruik van de airview-service ter beschikking (maar geen geld) voor dit onderzoek. De onderzoekers en behandelaars zijn verder financieel onafhankelijk van de leverancier. Alle betrokken personen werken hier op vrijwillige basis aan mee.

Intervention

Keyword: Compliance, CPAP, OSAS, Remote monitoring CPAP

Outcome measures

Primary outcome

mean hours/night CPAP use after 10 weeks, compared between the two groups.

Secondary outcome

a. Number of patients who stop their therapie after 10 weeks and after 1 year

b. Increased efficiency of treatment, regarding check-up's and hospital visits

c. CPAP related complaints/symptoms

Study description

Background summary

Obstructive sleep apnea (OSA) is the most common sleep-related breathing disorder.
Continuous positive airway pressure is the treatment of choice, with adherence of 60-70%.
Because short-term adherence and early perceived benefits are the best predictors of long-term adherence, efforts to optimise adherence are best done before or shortly after starting treatment. Intensive support can be beneficial according to some studies.
Telemonitoring is enabling clinicians and patients to continuously obtain specific parameters
of disease processes, thereby permitting prompt and timely adjustments to therapy if
needed. Regarding telemonitoring in patients with OSAS, there have been several studies, but not yet

in OSAS patients in the Netherlands. Studies of Sparrow et al and Fox et al showed that an
intervention (by telemonitoring) resulted in improved CPAP adherence. Of course there are
several limitations within these studies and there is need for more research.
This study emphasizes on the effect of telemonitoring and the effect on compliance in the first period after starting the treatment in the dutch population. Adoption of this type of system could result in substantially improved care of patients with OSAS.

Study objective

This study emphasizes on the effect of telemonitoring and the effect on compliance in the first period after starting the treatment.

Study design

Randomized Controlled trial, single blind.
250 patients

Intervention

Telemonitoring of the CPAP machine

Study burden and risks

none

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- newly diagnosed OSAS patient
- apnea hypopnea index > 29/hour
- CPAP therapy
- Age between 18-75 years

Exclusion criteria

- anxiety disorder
- mental disorder/retardation
- significant central sleep apnea component
- expected other changes in physical well being cause of comorbidity/other diseases and expected weight loss or gain such as pregnancy, bariatric surgery.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2015
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	03-07-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL52339.015.15