The effects of video consultation on patients* self-efficacy regarding CPAP treatment in patients with sleep apnea, a randomized controlled trial

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We will evaluate the effects of video consultation versus face-to-face and consultations by telephone for patients with sleep apnea in terms of patients* CPAP treatment self-efficacy (primary outcome). Also the effects on risk perception, outcome...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disturbances (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON46188

Source
ToetsingOnline

Brief title
Video consultation for sleep apnea patients treated with CPAP

Condition

- Sleep disturbances (incl subtypes)

Synonym
obstructive sleep apnea, Sleep apnea

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: interne projectgelden

Intervention

Keyword: randomized controlled trial, self-efficacy, sleep apnea, video consult

Outcome measures

Primary outcome

The primary study parameter is treatment self-efficacy, which is a subscale of the Self-Efficacy Measure for Sleep Apnea (SEMSA).The SEMSA is a 26-item scale and indicated good psychometric properties with reported internal consistency (Cronbach*s alpha = 0.92) and test-retest reliability (0.68). The subscale self-efficacy consists of 9 questions including *I would use CPAP*if have to wear a tight mask* and *I would use CPA*if it disturbed my partner*. These items will be rated on a 4-point scale ranging from not at all try - very true. A sum score for this subscale will be calculated by taking the mean score of the nine items.

(See protocol - methods - main study parameter)

Secondary outcome

- Risk perception (SEMSA subscale)

Risk perception is a subscale of the Self-Efficacy Measure for Sleep Apnea [22], and consists of 8 questions, for example *having OSA, my chances of falling asleep driving* and *having OSA my chances of difficulty concentrating*. These items will be rated on a 4-point scale ranging from *very low to very high*. A sum score for this subscale will be calculated by taking the mean score of the eight items.

- Outcome expectancies (SEMSA subscale)

Outcome expectancies will be measured, which is a subscale of the Self-Efficacy Measure for Sleep Apnea [22], and consists of 9 items for example *If I use CPAP*I will be more active*. These items will be rated by a 4-point scale ranging from *not at all true - very true.* A sum score for this subscale will be calculated by taking the mean score of the eight items.

- Adherence

Adherence will be measured with Encore anywhere (Philips) and information will be obtained from the Electronic Medical Record. Adherence for CPAP use is defined as using CPAP at least seven nights a week for at least six hours a night, according to the protocol in Rijnstate hospital.

- Expectations and experiences - according to constructs of the UTAUT model

Questions covering constructs of the Unified Theory of Acceptance and Use of Technology (UTAUT) model will be used to measure expectations and experiences of use of the video consult system. The UTAUT consist of four constructs that influence behavioral intention and behavior: (1) performance expectancy, (2) effort expectancy, (3) social influence, (4) facilitating conditions [23].
Eight items will be rated on a seven point scale. Results will be presented as mean and standard deviation (SD).

- Satisfaction

All patients will be asked to fill in a questionnaire assessing effects on

satisfaction with the video consultation system (for the intervention group only) and patient-professional communication.

Healthcare professionals will also be asked to fill in a questionnaire, after patients* treatment, measuring effects on:

• experiences with the system;

• satisfaction

• organizational benefits (e.g. time, efficiency of work processes)

(See protocol)

Study description

Background summary

Obstructive Sleep Apnea (OSA) is a sleep disorder that affects at least 2% - 4% of the adult population and is characterized by repeated episodes of full or partial occlusion of the upper airway during sleep. OSA can be considered a chronic disease and can have multiple effects on patients* health such as cognitive dysfunction, a decrease in health-related quality of life, an increase in cardiovascular disease risk and sleepiness during daytime. Treatment of OSA is dependent on the severity, which can be expressed as the apnea-hypopnea index (AHI), the oxygen desaturation index (ODI) and symptoms. The AHI represents the number of apneas and hypopneas per hour and is classified as mild (5-15 per hour), moderate (15-30 per hour) or severe (>30 per hour). Continuous Positive Airway Pressure (CPAP) is the treatment of choice, especially for moderate to severe OSA. However, treatment adherence is often problematic especially due to the discomfort of the mask and the machine. As the effectiveness of CPAP is dependent on the use good adherence is essential.

Participation of patients in their own treatment and support during treatment can positively affect adherence. Patients often decide at an early stage of the treatment process whether or not to use the CPAP machine, and this start can be predictive of further use. Behavior change is considered a relevant factor for

CPAP use and treatment self-efficacy is an important predictor for behavior change.

Video consultation is a useful way of supporting OSA patients during their treatment and is a technology used to realize a real-time visual and audio connection at a distance. Isetta et al. found that patients* knowledge after receiving training about OSA and CPAP via video consult was comparable to the knowledge of patients that received the same training face-to-face. They also found patients to be positive about the use of video consultations. While studies have evaluated the use of video consult for OSA patients and the relation between patients* self-efficacy and CPAP adherence, few have examined the effect of the use of video consultation on patients* self-efficacy during CPAP treatment using a controlled design.

(See protocol - Introduction)

Study objective

We will evaluate the effects of video consultation versus face-to-face and consultations by telephone for patients with sleep apnea in terms of patients* CPAP treatment self-efficacy (primary outcome). Also the effects on risk perception, outcome expectancy, CPAP adherence, video consult use (expectations and experiences), and patients* and professionals* satisfaction will be assessed (secondary outcomes).

(See protocol - objective)

Study design

The study will be a randomized controlled trial with an intervention group (video consult) and a usual care control group (1:1 allocation), with assessments at baseline and after four weeks. The intervention group, receiving video consultation combined with face-to-face consultations during their treatment with CPAP, will be compared to a control group receiving face-to-face and consultations by telephone.

(See protocol - study design)

Intervention

Patients are informed about the video consult study by their physician during their first face-to-face consult in the hospital. After this consult the researcher will provide patients with additional information and, if asked for, answer questions. Because of clinical necessity patients have to start treatment the same day and therefore the researcher will ask patients for their informed consent and to fill in the baseline questionnaire (approximately 20

minutes) in the hospital. After that, patients will be randomized. Participants in the intervention group are also provided with information about how to install the video consult system at home. Two days after the start all participants will have a consultation by telephone and approximately 1 week after start with CPAP the participants in the intervention group will have a video consultation planned and the controlled group a face-to-face consult. Three focus points will be discussed during the consults: (1) adherence (> 6 hours per night); (2) rest AHI <5 (or <10 if age >70); and (3) improvements or complaints. As long as these objectives are not achieved a video consult will be planned weekly for the intervention group and face-to-face consults in the control group. If the objectives are achieved one week after start with CPAP, a video consult will be planned four weeks later.

(See protocol - study procedures)

Study burden and risks

We used the risk analysis provided by Rijnstate. The use of this checklist resulted of the classification of this study as *little*. Because the estimated change for damage is *little*, the level of severity of the damage is *light* and there is no vulnerable population include in the study.

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

• diagnosed with moderate or severe sleep apnea AHI > 15
• patients will be treated with CPAP
• no history of CPAP treatment
• having (access to) a functional tablet or smartphone
o with a (integrated) webcam, speakers, microphone
o working internet connection
o access to the browsers Chrome, Firefox, Internet Explorer or Safari.
• able to use a tablet or smartphone (including a web-cam)
• ability to read and understand the Dutch language
• signed informed consent

Exclusion criteria

having a severe cognitive or psychiatric disorder

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-01-2019

Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	05-12-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL66192.091.18