ISRCTN12865936 https://doi.org/10.1186/ISRCTN12865936

# The effect of telemonitoring on adherence to continuous positive airway pressure in sleep apnea hypopnea syndrome

**Submission date**
18/01/2017

**Recruitment status**
No longer recruiting

**Registration date**
26/01/2017

**Overall study status**
Completed

**Last Edited**
10/05/2021

**Condition category**
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Sleep apnea-hypopnea syndrome (SAHS) is a common condition that makes it difficult to breathe due to narrowing of the throat while sleeping. Some of the symptoms include trouble sleeping, snoring, and difficulty in breathing. SAHS can increase the risk of high blood pressure, heart attacks, diabetes and stroke. Continuous positive airway pressure (CPAP) treatment is one of the main treatments for SAHS. CPAP is a facemask connected to a pump that provides an airflow that stops the throat from closing while sleeping. This treatment is a key reason in improving health issues associated with SAHS. However, it is found that many people do not always use their CPAP machine as it can be uncomfortable and can cause headaches, runny nose, ear pain, and difficulty breathing through the nose. The CPAP can be changed to be more comfortable for the patient through follow up appointments and discussions with treatment staff. In order to help patients continue with their CPAP usage, multiple ways of following up with patients are can be used, such as telemonitoring (monitoring through the usage of technology to get in contact with treatment staff). The aim of this study is to assess whether telemonitoring-based CPAP follow-up can improve the amount of people who continue to use the CPAP compared to the standard face-to-face follow-up.

Who can participate?
Adults diagnosed with SAHS that are starting CPAP therapy.

What does the study involve?
Participants are allocated randomly to one of two groups. The first group has three face to face appointments with a respiratory therapist. During the first appointment the CPAP is set up. During the following two appointments the CPAP usage is monitored, the settings are checked and side effects are discussed. The telemonitoring group has only one face to face appointment with a respiratory therapist to set up the CPAP. The following two appointments are done remotely. The respiratory therapist is able to remotely access the CPAP to check the settings, monitor the usage and then will discuss how to manage side effects with the patients over the phone. All participants have follow up appointments with a pneumologist 3 and 12 months after beginning CPAP treatment.

What are the possible benefits and risks of participating?
Participants may benefit from being able to have their CPAP appointments done remotely as they will not have to travel to the respiratory center. There are no notable risks of taking part of the study

Where is the study run from?
1. Centre de Médecine du Sommeil et de l'Eveil (Switzerland)
2. Centre Médical de la Servette (Switzerland)

When is the study starting and how long is it expected to run for?
September 2016 to December 2018.

Who is funding the study?
Ligue Pulmonaire Genevoise (Switzerland)

Who is the main contact?
Olivier Contal
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
CCER2016-01601

# Study information

### Scientific Title

The effect of Telemonitoring on adherence at one year to Continuous Positive Airway Pressure in sleep apnea hypopnea syndrom: A randomised controlled trial

## Acronym
TeleCPAP

## Study objectives
The aim of this study is to evaluate if telemonitoring follow-up enhances the adherence to CPAP treatment compared to standard care to face telemonitoring management.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Commission cantonale d'éthique de la recherche scientifique de Genève (CCER), 12/12/2016, ref: 2016-01601

## Study design
Single-center prospective randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
GP practice

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Sleep Apnea Hypopnea Syndrome

## Interventions
Participants are referred to the trial through the diagnosis of sleep apnea-hypopnea syndrome (SAHS) and prescription for continuous positive airway pressure (CPAP) by a pneumologist.
Participants will be allocated to groups through the usage of a randomisation program. Envelopes numbered from 1 to 120, prepared by independent member of our staff, allocate the participants to one of two groups:

Standard group: Participants receive three face-to-face appointments in order to initiate and setting/monitoring of the CPAP with a respiratory therapist.
The first appointment includes explanations about SAHS and CPAP, identification of the adequate interface, how to set the CPAP for titration with autoadjusting (APAP) and a band of pressure in accordance with pneumologist prescription, and will review symptoms of depression.
The second appointment (1 or 2 weeks later) includes checking the CPAP objectives by

downloading the memory card from the CPAP in order to evaluate how well the CPAP is working (reviewing leaks, adherence, AHI), discussing management of the side effects of the CPAP and fixating the treatment pressure at the 95th percentile pressure during the titration phrase. The third appointment (1 or 2 weeks after the second appointment) includes checking the CPAP objectives by downloading the memory card from the CPAP in order to evaluate how well the CPAP is working (reviewing leaks, adherence, AHI) and discussing management of the side effects of the CPAP.

Following the three respiratory appointments, participants have two follow up appointments with the pneumologist 3 and 12 months after beginning the CPAP treatment. This includes a clinical evaluation, checking the CPAP objectives by downloading the memory card, reviewing depression symptoms and oxymetry.

Telemonitoring group: Participants only receive 1 face-to-face appointment for the initiation of the CPAP and then the monitoring and the settings are proceeded through the usage of telemonitoring.
The first appointment includes explanations about SAHS and CPAP, identification of the adequate interface, how to set the CPAP for titration with autoadjusting (APAP) and a band of pressure in accordance with pneumologist prescription, and will review symptoms of depression. The second appointment with the respiratory therapist takes place over the phone. The respiratory therapist receives the information regarding CPAP objectives remotely through the airview program and they review this with the participant. They also review the management of side effects and they remotely fix the treatment pressure at the 95th percentile pressure during titration phase by the airview program. The third appointment again takes place over the phone and the respiratory therapist reviews the CPAP objectives and discusses the management of side effects.

Following the three respiratory appointments, participants have two follow up appointments with the pneumologist 3 and 12 months after beginning the CPAP treatment. This includes a clinical evaluation, checking the CPAP objectives by downloading the memory card, reviewing depression symptoms and oxymetry.

## Intervention Type
Device

## Primary outcome measure
Mean CPAP use (hours/day) is measured by reviewing the downloaded data of the CPAP machine at 3 months and 12 months.

## Secondary outcome measures
1. Percentage of adherent patients (>4h/day) is measured by reviewing the downloaded data of the CPAP machine at 3 months and 12 months
2. Percentage of treatment discontinuation is measured by reviewing the downloaded data of the CPAP machine at 3 months and 12 months
3. Time of nursing work in minutes measured using a chronometer. The time of nursing work is recorded at the end of each appointment on a specific sheet

## Overall study start date
01/09/2016

## Completion date

31/12/2018

# Eligibility

### Key inclusion criteria
1. Diagnosis of Sleep apnea hypopnea syndrome
2. The Apnea Hypopnea Index (AHI) recorded as greater than 15 per hour
3. Patient starting CPAP therapy
4. Over the age of 18

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
120

### Total final enrolment
120

### Key exclusion criteria
1. Previously treated for SAHS
2. Pregnant or nursing

### Date of first enrolment
16/01/2017

### Date of final enrolment
30/08/2017

# Locations

### Countries of recruitment
Switzerland

### Study participating centre
**Centre de Médecine du Sommeil et de l'Eveil**
Rue de Chantepoulet 21

Geneva
Switzerland
1201

**Study participating centre**
**Centre médical de la Servette**
Avenue De-Luserna 17
Geneva
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1203

## Sponsor information

**Organisation**
Ligue Pulmonaire Genevoise

**Sponsor details**
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**Sponsor type**
Other

**ROR**
https://ror.org/02ra2yn55

## Funder(s)

**Funder type**
Not defined

**Funder Name**
Ligue Pulmonaire Genevoise

## Results and Publications

## Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

## Intention to publish date
31/12/2019

## Individual participant data (IPD) sharing plan
Data will be avaialble upon request from Stéphanie Vaudan
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## IPD sharing plan summary
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 20/04/2021 | 10/05/2021 | Yes | No |