



Original Research

Randomized controlled trial on the effect of a 12-month telemedicine program in patients with obstructive sleep apnea on continuous positive airway pressure treatment



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ABSTRACT

Background: telemedicine is an essential tool to follow patients with obstructive sleep apnea (OSA) on CPAP.

Objective: to establish whether in patients with OSA a 12-month follow-up program by a remote medical centre (RMC), functioning as an intermediary between patients and OSA Unit (OU), affects CPAP use compared to patients on usual care (UC).

Methods: in a randomized controlled trial we enrolled 91 patients initiating CPAP in the RMC group and 101 in the UC group. The RMC performed all interventions remotely. Primary outcomes were nightly hours of CPAP use and adherence.

Results: in patients with initial adaptation difficulties (<4h night) mean nightly use of CPAP increased (1st to 12th month) from 2.5 ± 0.8 to 4.3 ± 1.6 h ($P < 0.0001$) in the RMC but not in the UC group. Nights with >4h CPAP use also significantly increased from 9.4 ± 7.7 to 17.7 ± 8.9 ($P < 0.0001$) in the RMC group but not in the UC group. The percentage of patients with an improvement in adherence after 12 months was 34.2 % RMC vs 16.4 % UC, $P < 0.05$. Patients whose adherence worsened were 11.8 % RMC and 19.3 % UC ($P < 0.05$). None of the patients followed at a distance required face-to-face visit for the duration of the study.

Conclusion: long-term telemedicine follow-up compared to standard care is effective in improving adherence to CPAP in patients with initial CPAP adaptation difficulties. The follow-up by a RMC outside the OU can be considered a safe and effective option to reduce the workload of the staff in the OU.

1. Introduction

Obstructive sleep apnea (OSA) is a chronic condition characterized by repetitive collapsing of upper airways during sleep, causing intermittent hypoxia, sleep fragmentation and daytime somnolence [1]. OSA affects almost one billion people worldwide and is associated with relevant morbidity and mortality [1,2]. Particularly if left untreated OSA represents a major public health issue and a heavy burden for the health system [3,4].

Continuous positive airway pressure (CPAP) is a highly effective

treatment, considered the gold standard for treating OSA, improving symptoms, cardiovascular morbidity and mortality in regular users [5]. However, maintaining a good adherence to this mechanical device is challenging for sleep specialists. Although the implementation of educational programs and the adoption of multiple strategies to maximize adherence, this has remained invariably low over the last decades [5,6].

Remote monitoring of patients on CPAP treatment, also known as tele-monitoring, has been explored for long time and its use has increased during the last years also driven by the COVID-19 pandemic

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[7]. Tele-monitoring is nowadays facilitated by the fact that most of the new generation CPAP devices, through built-in modules for wireless transmission, can transmit nightly treatment data to cloud-based platforms accessible to health professionals [8]. The possibility of checking treatment remotely to timely detect problems and rapidly intervene at has been considered as a unique opportunity to maintain adherence, while avoiding continuous patient's visits to the OSA Unit (OU) [9].

One of the putative advantages of implementing telemedicine services is to reduce waiting lists for access to treatment and to diminish the burden of work for the staff of the OU [7]. However, the follow-up of patients transmitting nightly CPAP data and necessitating proactive interventions may be time-consuming for the staff in the OU, where the workforce is often insufficient to meet the demand of a large population of patients. Therefore, it has been suggested that the logistic organization, more than the technology behind telemedicine, is fundamental for its successful implementation [8,10].

Traditional centre-to-home models have expanded to include not only the patient and the OU, but also external home care providers that are often commercial companies specialized in home respiratory devices [9,11,12]. The role of these companies may not be limited to technical support but could be extended to active monitoring, data integration and interaction with patients, functioning as an intermediary between the patient and the OU. This telemedicine model, already widespread in some western countries, could theoretically reduce the workload of the OU offering strict monitoring of CPAP treatment and timely assistance to patients. In a recent pilot study we have shown that in a small group of patients who had already initiated CPAP in our OU a successive 6-month follow-up program through a Remote Medical Centre (RMC) significantly improved adherence while reducing the work of the OU [13].

This randomized controlled trial was designed in order to establish whether patients with OSA undergoing a 12 months follow-up through a RMC nightly CPAP use and adherence were different compared to patients followed by Usual Care (UC) in our OSA Unit.

2. Methods

This is a randomized controlled single centre trial, conducted in the OSA Unit, Respiratory Unit, "Policlinico-S. Marco" University Hospital, Catania, Italy. The study has been approved by the local Ethical Committee and signed consent has been obtained for all participants.

2.1. Study participants

Between December 2022 and December 2023, we enrolled patients >18 years with a diagnosis of OSA and an apnea-hypopnea index (AHI) > 15 to whom CPAP was prescribed. Exclusion criteria were: 1) presence of other respiratory diseases associated with OSA (e.g. chronic obstructive pulmonary disease, chronic respiratory failure); 2) requirement of oxygen supplementation during the night; 3) presence of known psychiatric disorders or history of alcohol or drug addiction; 4) pregnancy; 5) presence of any behavioral or social difficulty that could hamper understanding or cooperation.

2.2. Study design

After the diagnosis of OSA was obtained and indication for CPAP treatment established the study protocol consisted of the following consecutive steps.

- 1) CPAP first approach. In brief, according to our standard protocol a daytime session is performed in-lab by our qualified staff to allow patients to become confident with the device, to fit and choose masks, and to give indications and instructions for the correct use of the device. This step was identical for all patients screened.
- 2) Randomization 1:1 to UC follow-up or to distance follow-up by the RMC of those patients accepting the treatment.

- 3) CPAP adaptation/titration. In our standard practice the adaptation period lasts one month. During this period, we set an auto-CPAP mode (5–15 cm H₂O) and after one month we choose a fixed pressure. During the study, adaptation occurred with different follow-up timing in the UC group and RMC group (see below). However, for all patients both in the UC or in the RMC group the fixed pressure was established by the sleep specialist in our OU.
- 4) Patients were followed up with UC or RMC protocol until the 12th month from CPAP initiation
- 5) After 12 months all patients were evaluated face-to-face in the OU and data were collected.

2.3. Diagnosis of OSA and CPAP prescription

Procedures for the diagnosis of OSA have been described in detail elsewhere [14]. In brief, the diagnosis was obtained through home cardiorespiratory polygraphy using a Vital Night Plus device (Vitalair, Italy). An auto-CPAP (ResMed Airsense 10 Autoset) with wireless transmission was prescribed to all patients and data treatment for the UC group were available directly by the dedicated AirView platform (© ResMed 2019).

2.4. Interventions

2.4.1. Follow-up with usual care

According to our UC protocol after CPAP is prescribed and the best fitting mask chosen, face-to face visits are scheduled after the first week and after the first month of CPAP use. At each visit we assess symptoms, adherence to treatment and problems occurred and set a fixed CPAP pressure after one month. Patients who initiate CPAP in our OU are usually provided with telephone numbers/e-mails and strongly advised to contact us in case of problems.

After the first month, patients continue the treatment without active control from the OU. After 3 months from initiation, patients are re-evaluated in the OU to assess symptoms and adherence.

Successively, routine controls occur yearly after CPAP initiation, unless unscheduled visits are required by the patients. The Epworth Sleepiness Scale to assess sleepiness is acquired routinely after 1,3 and 12 months (Fig. 1)

2.4.2. Follow-up through the remote medical centre

The Remote Medical Centre is a health facility specialized in home care for patients with respiratory disease operating at a distance, owned by the Vivisol Home Care Services® (Italy) and based in Milano (Italy). All services from the RMC were offered to our Institution free of charge for the entire duration of the study. Details on services and organization of the RMC have been previously described [13]. In brief, the RMC was provided with its own staff including nurses, doctors operating remotely and technicians operating both at a distance or locally if devices presented technical problems. Remote monitoring of patients in the study was carried out using the ViviCheck® platform (Vivisol, S.r.l Italy). This is a digital platform for the comprehensive management of patients in home treatment, through which healthcare professionals can run a number of functions including patient's clinical history, questionnaires, treatment progress in order to acquire information on patients' condition. The platform allows acquisition and storage of data on nightly CPAP allowing distance adjustment of parameters. For this study data on CPAP use were acquired nightly and included: hours of CPAP use, residual AHI, pressures and leaks. Patients were also provided with an app (Vivisol My Care), containing general advices, instruction manual, scheduled replacements of disposals and RMC contact.

2.4.3. Follow-up protocol by the RMC

In brief, according to a protocol established for this study the RMC operated as follows.

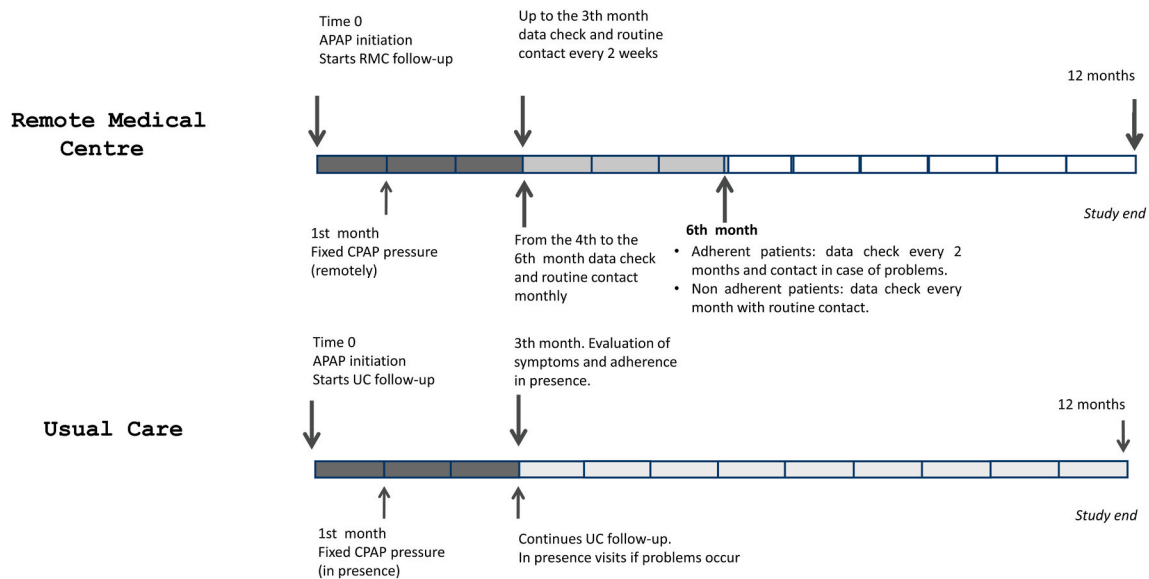


Fig. 1. Study protocol. RMC: remote medical centre; UC: usual care.

- 1st to 3rd month: data check and routine patients' contact occurred every 2 weeks
- 4th to 6th month data check and routine patients' contact occurred monthly

After six months patients followed by the RMC were divided in two groups, adherent and non adherent. Adherence was defined as the use of CPAP for >4 h/night for >70 % of nights.

- Adherent patients: data check every 2 months and patient's contact in case of problems.
- Non adherent patients: data check every month with routine patient's contact.

The ESS was collected after 1 and 3 months by the RMC and after 12 months in the OU for the study conclusion visit. Interventions and routine contacts by the RMC were carried out remotely (phone calls or tele-visits) with the exception of technical interventions made in presence when required. The patient was instructed to contact the RMC for any need. If a problem required an intervention from the specialist an alert would be sent to the OU in order to schedule a face-to-face visit. Routinely the RMC sent to the OU a monthly report for each patient containing the following information: 1) summary of adherence to CPAP and efficacy of the treatment; 2) problems detected and interventions made. Specialists in the OU were allowed to direct login into the Viv-iCheck platform to get details on the treatment of their patients at any study stage. The follow-up by the RMC lasted 12 months (Fig. 1).

2.5. Data collection

At study initiation data collected included demographics, clinical history, symptoms and ESS.

For the group in UC all data on CPAP adherence were retrieved from the i-cloud platform AirView. For the RMC group data were obtained from each monthly report sent to our OU or directly accessing the Viv-iCheck platform in case of uncertainty. Data on CPAP use included: 1) mean hours/night; 2) mean nights/month; 3) mean of the nights/month using CPAP for >4 h, 4) mean residual AHI; 5) mean pressure leaks. Data on CPAP treatment were collected at 1, 6 and 12 months.

2.6. Outcomes

The main outcomes were the nightly hours of CPAP use and adherence in patients followed by RMC or UC after 12 months from CPAP initiation. Secondary outcomes were the rate of abandon in one year and the number of needed interventions.

2.7. Statistical analysis

The primary endpoint of the study was the mean nightly hours of CPAP use. We calculated that assuming an α risk of 0.05 and β risk of 0.2 (2-sided test) the sample size needed to detect a difference of 0.5 h/night highlighted as a margin for a clinically significant difference by the American Academy of Sleep Medicine (AASM) [15] was 72 patients in each group. From our previous studies we calculated a maximum abandon rate of 20 % drop out rate, so to randomize at least 90 patients in each group. Data were analyzed using the SPSS 20 software (Stata-Corp, College Station Tex, USA). Continuous data are presented as mean \pm standard deviation (SD), categorical data as frequency and percentage. Comparison between groups was performed using an appropriate Student's *t*-test or ANOVA. To compare categorical variables, we used the chi-square test (χ^2). Spearman's correlation was used to measure associations between variables. A P value < 0.05 was considered to indicate statistical significance. Data were analyzed as intention-to-treat (ITT), including all patients randomized, and per-protocol (PP) including patients who effectively terminated the study, excluding dropouts.

3. Results

3.1. Study population

We screened a total of 222 consecutive patients to whom CPAP was prescribed who met inclusion criteria (Fig. 2). Of these, 20 patients refused treatment after initial CPAP adaptation during the in-lab daytime session. A total of 101 patients were randomized to the RMC group, however 10 patients withdrew their consent to be followed by the RMC so that the final randomized groups included 91 patients in the RMC and 101 in the UC group. During the 12-month study period follow-up was lost in 2 patients in the RMC group, while 2 patients in the RMC and 3 patients in the UC group no more needed CPAP due to effective weight lost. Patients were mostly middle-aged, predominantly males, obese with a mean AHI of 46 events/h (Table 1). The two groups were similar

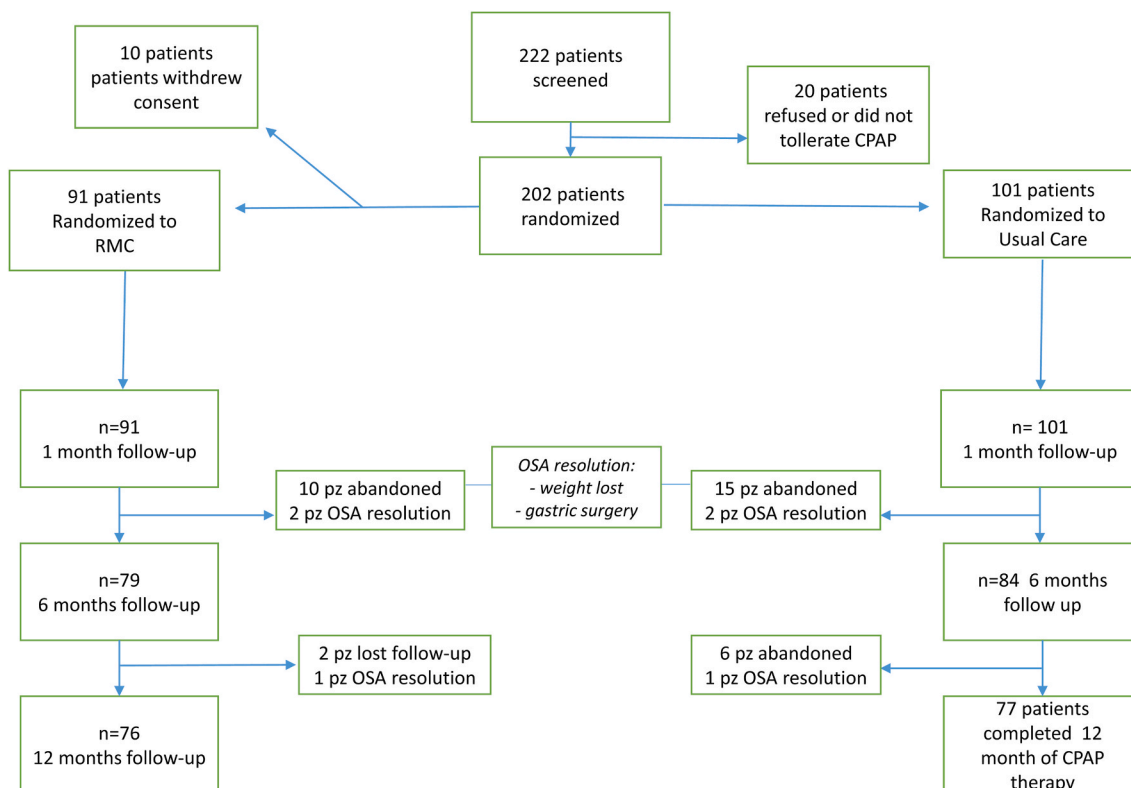


Fig. 2. Study flow-chart.

Table 1
Demographic and clinical data of the study population.

	Remote Medical Centre (n = 91)	Usual Care (n = 101)
Males, %	75.8	75.2
Age, yrs	65.3 ± 12.5	65.4 ± 10.9
BMI, kg/m ²	31.73 ± 5.12	31.15 ± 5.97
AHI events/hour	45.6 ± 21.3	46.4 ± 22.7
ESS	11.5 ± 4.2	11.1 ± 4.9
Mean CPAP pressure	11.3 ± 1.9	11.9 ± 2.1
Residual AHI during CPAP	3.5 ± 4.5	3.7 ± 4.5

Values expressed as mean ± SD AHI: apnea-hypopnea index; ESS: Epworth Sleepiness Scale. Mean CPAP pressure, residual AHI obtained after the first month of adaptation. P value not significant for all variables.

for age, BMI and severity of the disease (Table 1).

3.2. Abandon rate

In the ITT analysis the overall abandon rate was 13.1 % in the RMC vs 20.7 % in the UC group, $P = 0.18$. All drop outs occurred within the first 6 months for RMC, while for the UC group 14.8 % within the first 6 months and 5.9 % between the 6th and 12th month (Fig. 3).

3.3. Nightly hours of CPAP use

CPAP use during the 1st (baseline) and 12th month in patients completing the study is shown in Table 2 (PP analysis). In the RMC group the mean nightly CPAP use increased from 4.7 ± 2.1 h (h) in the 1st month to 5.2 ± 1.7 h in the 12th month ($P = 0.01$). In the UC group the mean hours of CPAP use were slightly higher at baseline compared to RMC, 5.0 ± 1.9 , $P < 0.01$, and remained unchanged after 12 months (4.8 ± 2.1 , $P = \text{NS}$). Overall, considering all patients in the study, no

differences were observed between the two groups at baseline and after 12 months in mean nights/month and nights/months of CPAP use for >4 h (Table 2). In our previous pilot study we showed that patients with the lowest number of hours of CPAP use where those who had more benefits from distance follow-up through the RMC. We therefore analyzed subsets of patients with <4 or ≥ 4 h/night CPAP use.

In the RMC group patients with a mean nightly CPAP use <4 h were 25 (32.4 %) at baseline and 14 (18.1 %) at the 12th month ($P = 0.06$), while in the UC group were 31.5 % at baseline and 32.5 % at the 12th month ($P = 0.7$). In the subset of patients followed by the RMC the mean nightly CPAP use increased from 2.5 ± 0.8 to 4.3 ± 1.6 h ($P < 0.0001$), remaining unchanged in UC group (Table 3). Numbers of nights with >4 h CPAP use also significantly increased in the RMC group from 9.4 ± 7.7 to 17.7 ± 8.9 ($P < 0.0001$) but not in the UC group (Table 3).

In the subset of patients with a use ≥ 4 h/night the mean nightly CPAP use remained unchanged from baseline to the 12th month of treatment follow-up in the RMC group, whereas in the UC group significantly decreased by about 1 h (Table 3). Numbers of nights with >4 h CPAP use decreased in both groups by three days on average, although statistical significance was reached only for the RMC group (Table 3).

Fig. 4 shows the percentage of patients who used CPAP from 1 to >6 h per night at baseline and after 12 months in RMC and UC.

3.4. Adherence to CPAP treatment

According to a widely acknowledged definition a patient is considered “adherent” to the treatment when using CPAP for >4 h/night for more than 70 % of nights. In our study non adherent patients were 50 % at baseline and 39 % after 12 months ($P = 0.2$) in the RMC group and 43.4 % baseline vs 42.1 % after 12 months ($P = 0.3$) in the UC group (Fig. 4a). In non adherent patients the mean nightly hours of CPAP use and the number of days with >4 h/night use significantly increased in the RMC group from the first to the 12th month remaining unchanged in

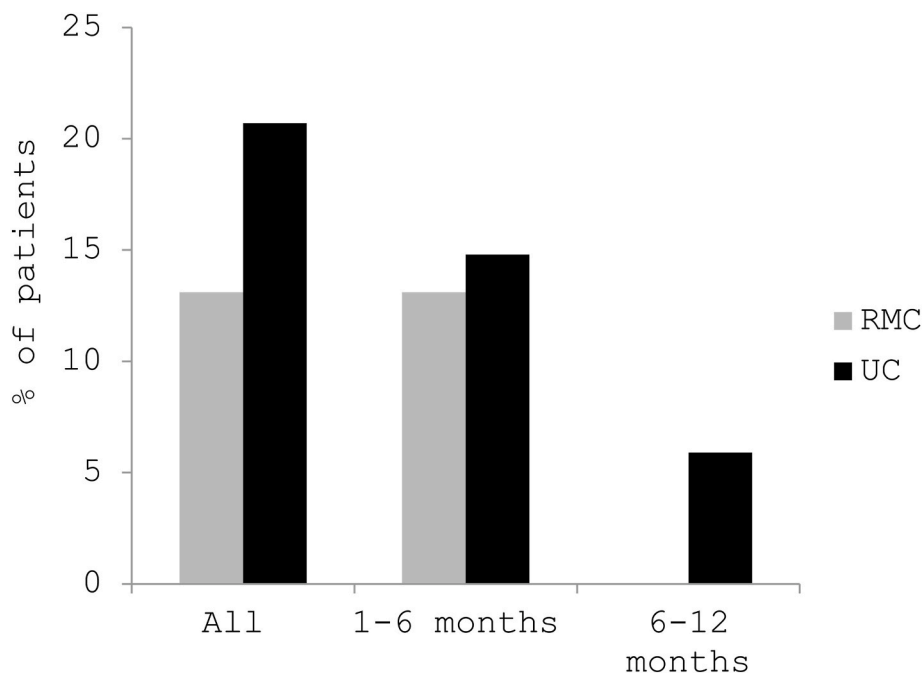


Fig. 3. Percentage of patients abandoning CPAP during the study period. ITT analysis.

Table 2

CPAP use in the study population at baseline (1st month) and after one year follow-up.

	1st month	12th month	P value
<i>CPAP hours/night</i>			
Remote Medical Center	4.7 ± 2.1	5.2 ± 1.7	<0.01
Usual Care	5.0 ± 1.9	4.8 ± 2.1	0.3
<i>CPAP nights >4 h/month</i>			
Remote Medical Center	19.5 ± 10	20.0 ± 1.7	0.5
Usual Care	20.9 ± 8.7	20.8 ± 9.0	0.3
<i>CPAP nights/month</i>			
Remote Medical Center	26.4 ± 4.7	26.4 ± 5.5	0.08
Usual Care	26.8 ± 4.8	25.2 ± 6.5	0.7
<i>Residual AHI</i>			
Remote Medical Center	2.6 ± 3.5	2.4 ± 3.0	0.4
Usual Care	3.2 ± 2.4	2.7 ± 2.0	0.09

Mean values ± SD calculated in the PP sample; AHI = apnea-hypopnea index.

the UC group (Fig. 5). The percentage of patients with an improvement in adherence after 12 months was significantly higher in the RMC group compared to UC, 34.2 % vs 16.4 %, $P < 0.05$. Patients whose adherence worsened were 11.8 % in the RMC and 19.3 % in the UC group ($P < 0.05$). All other patients had unchanged adherence (Fig. 6)

The time course of the changes in mean nightly hours of CPAP use and number of nights with >4h use in non adherent patients is shown in Fig. 7.

3.5. Interventions

The mean number of interventions per patient during the 12-month study period were 5.1 ± 5.0 at in the RMC group and 2.13 ± 0.4 in presence in the UC group ($P < 0.0001$). Most of the interventions were necessary within the first 6 months (Fig. 8). In the RMC group there was a small but significant inverse correlation between the number of interventions and hours of CPAP use ($r = -0.35$, $P < 0.01$), total number

Table 3

CPAP use at baseline (1st month) and after one year follow-up in users for <4 h/night and users for ≥4 h/night.

	1st month	12th month	P value
Patients using CPAP for <4 h night at baseline			
<i>Hours/night</i>			
Remote Medical Center	2.5 ± 0.8	4.3 ± 1.6	<0.0001
Usual Care	2.6 ± 0.7	3.1 ± 2.3	0.3
<i>CPAP nights >4 h/month</i>			
Remote Medical Center	9.4 ± 17.7	17.7 ± 8.9	<0.0001
Usual Care	14.3 ± 4.4	12.1 ± 2.3	0.4
Patients using CPAP for ≥4 h night at baseline			
<i>Hours/night</i>			
Remote Medical Center	6.0 ± 1.6	5.6 ± 1.6	0.3
Usual Care	6.6 ± 1.3	5.5 ± 1.2	<0.01
<i>CPAP nights >4 h/month</i>			
Remote Medical Center	25.6 ± 4.8	21.9 ± 6.5	<0.05
Usual Care	26.0 ± 4.2	23.1 ± 6.0	0.6

Mean values ± SD calculated in the PP sample.

of nights of CPAP use ($r = -0.30$, $P < 0.05$) and number of nights with CPAP use >4h ($r = -0.31$, $P < 0.01$). Most common problems requiring interventions are shown in Fig. 9. During the 12-month study period none of the patients in the RMC required in presence visit in the OU.

4. Discussion

In this randomized controlled study we have shown that a 12-month follow-up program at a distance through a remote medical centre functioning as an intermediary between the patient and the OU, increases nightly CPAP use in patients with OSA. Compared to usual care we observed that the follow-up through the remote medical centre was more effective in those patients who showed low adherence after treatment initiation. Although several studies have been published of TM follow-up of patients treated with CPAP as far as we know this is the study with the longest TM intervention, lasting 12 months and

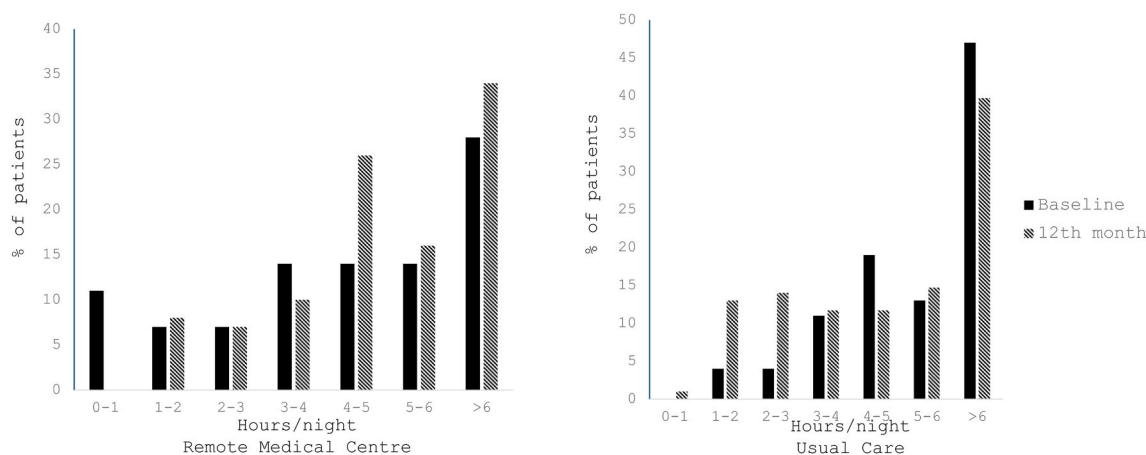


Fig. 4. Percentage of patients with CPAP night/use from 0 to >6 h at baseline (1^o month) and at the end of the study (12^o month).

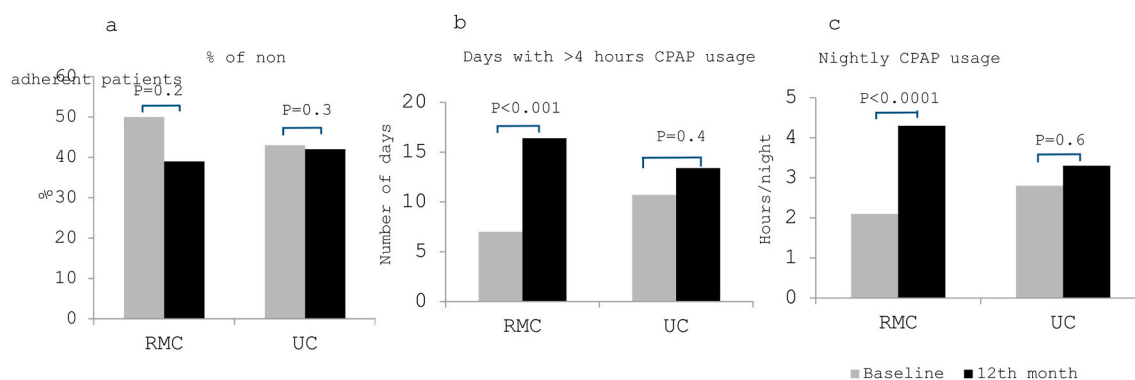


Fig. 5. a) Percent on non adherent patients in the Remote Medical Centre and Usual Care at baseline (1st month) and after 12 months; b) mean number of days with CPAP use >4h/night in non adherent patients in the Remote Medical Centre and Usual Care at baseline (1st month) and after 12 months; c) mean number of nightly hours of CPAP use in non adherent patients in the Remote Medical Centre and Usual Care at baseline (1st month) and after 12 months.

conducted via a centre outside the OSA unit.

The AASM has stated in a recent document that telehealth is an essential tool for the provision of high quality, patient-centered care for patients with sleep disorders. In the document the AASM encourages legislators, policymakers and clinicians, to work together to ensure that telehealth services are permanently available and accessible for all patients seeking sleep medicine care [16]. Although telemedicine is being implemented in all stages of OSA management [11], telemonitoring of CPAP treatment is one of the best established practice used in more than 70 % of European countries [17]. However, although the popularity of this practice, due to the wide availability of i-cloud platforms, still important issues need to be addressed and confirmed. These include the non-inferiority of the distance follow-up compared to standard care in term of adherence, the ideal duration of TM follow-up programs and the best logistic organization to release pressure on the OUs' staff.

This study provides new information not only on the usefulness of a CPAP treatment remote monitoring program in the long-term but only on the possibility to carry out the program through a home care provider via a remote clinical centre, rather than within the OU, in order to reduce the workload of the staff.

4.1. CPAP use and adherence

It is acquired that a dose-response relationship exists between hours of CPAP use and improvement in health outcomes, such that increasing nightly hours of CPAP use is considered fundamental to control complications related to OSA [18]. In our patients who used CPAP for less than 4 h, considered the minimum for clinical benefit, we found that

during the RMC follow-up on average the nightly use increased from 2.5 to 4.3 h after 12 months, well above the minimum increase of 0.5h defined as significant by the AASM [15]. We also found in the study group a significant increase in the number of patients who were fully adherent after one year compared to the first period of treatment. A number of RCTs have been published so far on CPAP treatment follow-up through TM programs, mainly performed during the first 3–6 months of treatment [19–22]. Latest meta-analyses suggest a trend toward a greater adherence in patients followed with TM compared to standard care [19–21]. One of these showed that TM programs on average improved CPAP use by 29.2 min/night, with better results obtained by those studies looking at devices with a built-in software for wireless transmission [19]. However, it is noteworthy that studies included in these meta-analyses are extremely heterogeneous, particularly for intervention techniques, clinical outcomes, duration and intensity of the TM program and telemonitoring systems. In addition, as adherence during the first 3-month period predicts long-term adherence most of the TM programs are limited to this short period of time [23]. Indeed, with some exceptions, studies have shown that during this period of time TM improves compliance compared to usual care, also due to the possibility to an early intervention in case of technical problems [24–28].

In one of the most authoritative early RCT Pepin and colleagues showed that a 6-month multimodal TM program was associated with better nightly CPAP use compared to UC (5.28 h vs 4.75h) in patients with OSA and high cardiovascular risk [29]. In another study including patients with stroke and OSA after a 6-month TM program daily CPAP use time was 4.4 h and 2.1 h in the TM and standard care group,

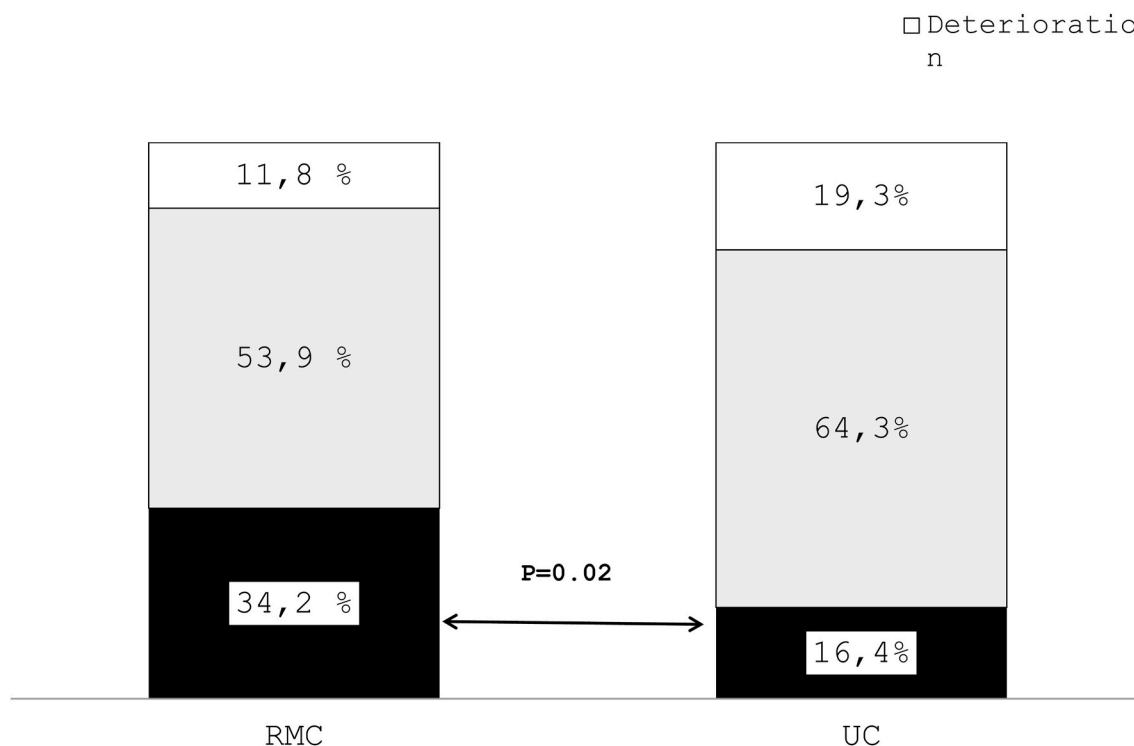


Fig. 6. Percentage of patients completed the study and changed their adherence to CPAP from baseline (1^o month) to the end of the study (12^o month). Adherence was defined as the number of nights with CPAP use ≥ 4h for 70 % of the month. Improvement was defined as change ≥5 %, deterioration < -5 %, no change changes ≥ -5 % to <5 %. Number in the blocks within the bars represent the percentage of patients with improvement, deterioration or no change. RMC: remote medical Centre. UC: usual care.

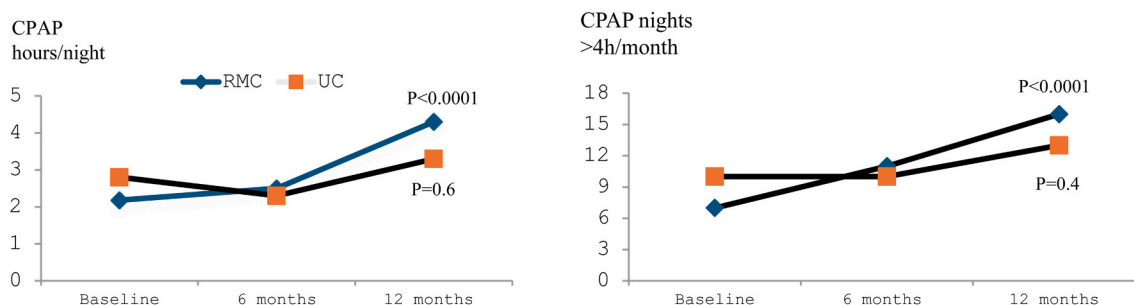


Fig. 7. Time course of the changes in mean nightly hours of CPAP use and number of nights with >4h/night use in non adherent patients. RMC: remote medical Centre. UC: usual care.

respectively [30]. It has to be mentioned that some programs lasting 3–6 months failed to show benefits of TM compared to standard care [31, 32].

In our study we found that the drop-out rate over 12 months was double in the UC group compared to the RMC, however statistical significance was not reached. This is not surprising as the study was not powered to assess drop-outs and this is an important aspect that needs further investigation, with well powered studies.

4.2. Timing of TM programs

Maintaining adherence to CPAP over the long term should be the final aim of TM programs, therefore, establishing the proper duration of a TM intervention is an important issue to address for long-lasting results. Currently, data are still few and inconclusive.

The few studies looking at long term adherence suggest that although early TM programs improved adherence in the first 3–4 months beneficial effects were not maintained over the long term and ceased after

termination of the program [28,33,34]. In one study, TM monitoring was initiated after the habituation phase and terminated after achievement of optimal adherence, however the adherence after 1 year was similar to standard care [33].

Another study showed that a 3-month TM program during the habituation phase failed to affect nightly CPAP use after one year [28]. In the HOPS study TM produced a better adherence during the first 3-months compared to standard care, but results at one year were inconclusive due to high rate of abandon [34]. Conversely, we have previously shown that a 6-month TM program through a RMC the benefits observed in adherence were maintained after 12 months from the program termination [13]. However, in that study the follow-up initiated after 3 months of standard care, while in the current study patients were CPAP-naïve and initiated TM follow-up immediately after CPAP initiation. Noteworthy, in the present study the first 6 months of follow-up were not sufficient to reach full adherence in non adherent patients. Although most of remote interventions occurred during the first 6 months it is likely that checking after the first semester of

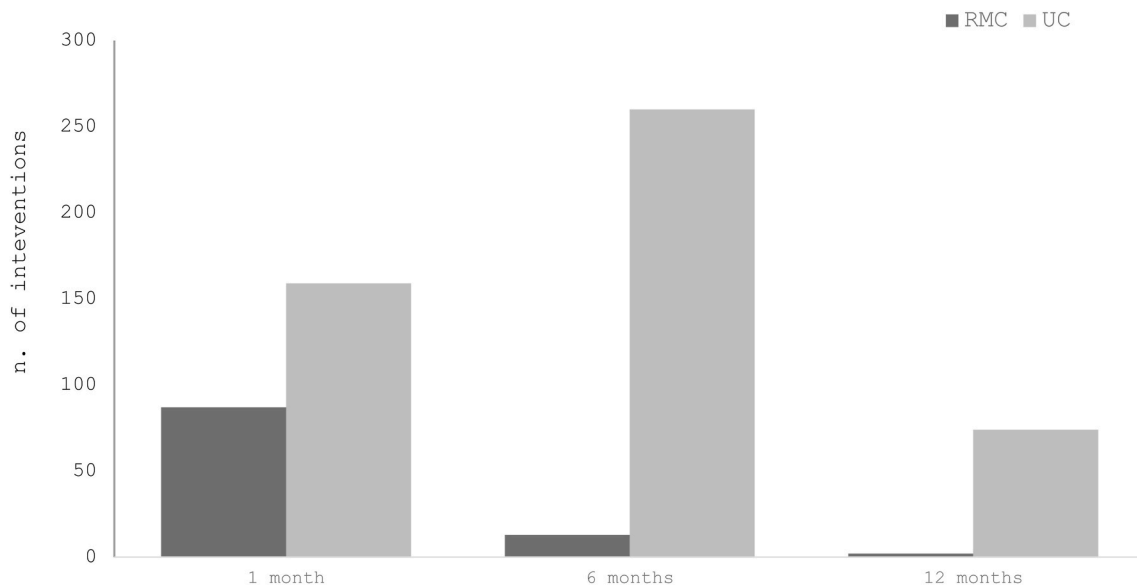


Fig. 8. Total number of interventions through the follow-up period. RMC: remote clinical centre; UC: usual care.

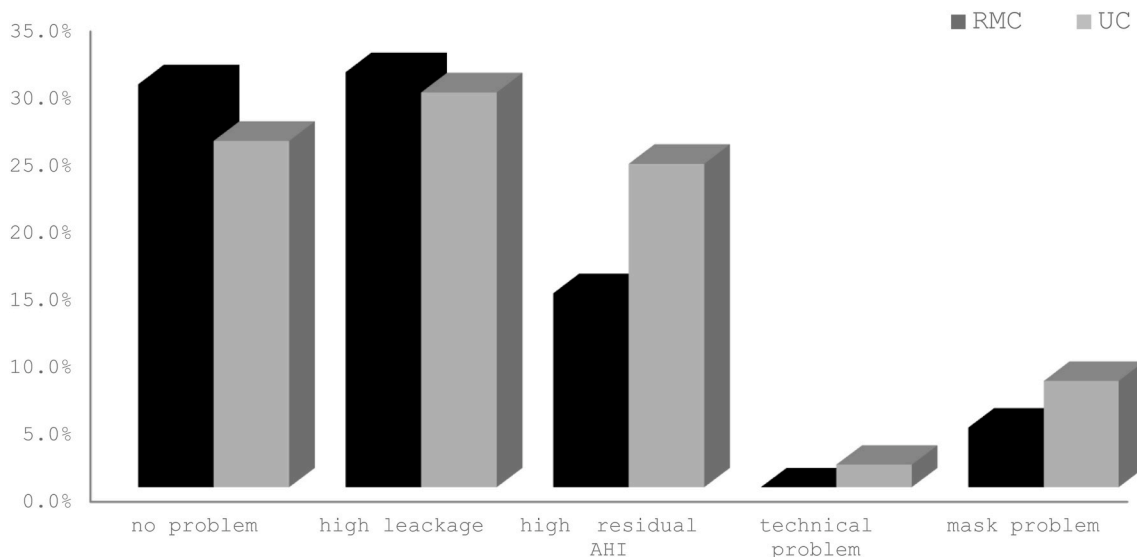


Fig. 9. Most common problems requiring intervention during the first month of CPAP use. RMC: remote medical centre. UC: usual care.

follow-up was useful to further improve adherence.

4.3. Patients' selection

Another important issue when implementing TM programs is the selection of those patients who may benefit more from intensive remote interventions for a patient-focused approach and to avoid waste of health services. According to our results, these could be those patients with <4 h use during the first month, in which we observed the maximal benefit of TM intervention. Our previous study showed that patients using CPAP for about 5 h/night did not significantly further improve meantime of CPAP use [13]. This was in accordance with a RCT showing no effect of TM in patients using CPAP for 5–6 h/night [35]. In the current study we found that good users had an average of 6 h night use in the first month that tended to slightly decrease in both groups after 1 year remaining, however, well above 5 h. Taken together these data indicate that initial good users might, after initial follow-up, be left out of intensive TM programs, thus saving resources and time for those patients who present adaptation problems.

4.4. The role of RMC

Another novel aspect of this study is that we delegated a commercial home care provider, to take full charge of our patients for those aspects not necessitating sleep medicine professionals. In addition to technical issues, these included educational issues, contact with patients and non-specialist medical evaluation. It has been suggested that the integration of these services in a remote facility could release the pressure on OU, allowing a limited number of specialists to serve a broader patients population [9,36]. However, while in many countries where health system is based on *private insurance reimbursement* this model has been implemented, in Italy, as well as in other countries where costs are covered by the National Health System, these models of care are still under evaluation, so that studies are essential to establish benefits and limitations (Spicuzza 2024). It is noteworthy that throughout the entire follow-up period patients in the RMC follow-up never required an in-presence visit in our OU. Thus, a reduction in the workload for the staff in the OU can be included among benefits of this follow-up program, in accordance with a previous report [39].

4.5. Strengths and limitations

The main strength of this study is that it is a well powered randomized trial. In addition, we believe that evaluating the role of a long-term follow-up is important at this point to establish the real value of TM programs in real life. In fact, from the studies evaluating short-term TM interventions it seems that the positive effect ceases after termination of the program [28,33,34].

The main limitation of this study is the cost of a TM model entirely managed by a home care provider. While we showed benefits for the workload of our OU, as none of the RMC-followed patients required in presence visits at the OU, we did not evaluate the costs of this program. This will be our next step for the design of future trials. It is noteworthy that since investments in telemedicine are rapidly growing, digital health companies are providing outcomes and cost validation to clarify this aspect [36].

Several studies have already shown that TM in OSA is cost-effective, particularly if global costs are calculated and not only those related to procedures in the OU and to the technology needed. As an example, patients' travel expenses or days off-work should be considered in this analysis [36–39]. In addition, it should be considered that this kind of approach, reducing the workload for the OU, will allow a quicker access to treatment to patients with OSA, thus reducing the burden and costs of OSA-associated co-morbidities while patients are untreated [39].

5. Conclusion

This randomized controlled study shows that a long-term telemedicine program, compared to standard in presence care, is effective in improving adherence to CPAP over a 12-month period in those patients with initial adaptation difficulties and low initial CPAP nightly use. The study confirms our prior observation that a TM program can be safely and effectively carried out by a remote clinical centre, outside the OSA Unit, managed by a home care provider specialized in respiratory care. In this study the follow-up in the remote medical centre has been associated with a reduction in the workload of the staff in the OU as none of the patients followed through the TM program required in presence assistance in the OU for the entire duration of the study. Furthermore, the study highlights the need for a long-term duration of TM programs for non adherent patients, while this kind of intervention seems unnecessary for CPAP good user at treatment initiation. This study therefore contributes to better define a patient-focused strategy for the management of OSA. Further studies to validate cost-effectiveness of this TM approach are granted.

CRediT authorship contribution statement

Salvatore Mancuso: Writing – original draft. **Domenico Caratozzolo:** Investigation. **Alessandro Libra:** Formal analysis. **Chiara Pasquali:** Investigation. **Giuseppe Muscato:** Methodology. **Antonella Ficili:** Methodology. **Davide Campagna:** Methodology. **Chiaramonte Rita:** Methodology. **Francesco Leonforte:** Data curation. **Carlo Vancheri:** Conceptualization. **Lucia Spicuzza:** Conceptualization.

Ethics

The study has been approved by the local committee and has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All persons gave their informed consent prior to their inclusion to collect data and to publish.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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