Can the use of telemedicine in the management of CPAP for the treatment of obstructive sleep apnoea reduce clinical time and additional appointments: A randomised controlled trial.

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Abstract

Introduction: Obstructive sleep apnoea (OSA) is a common sleep breathing disorder and is associated with increased cardiovascular risk and daytime sleepiness. Continuous positive airway pressure (CPAP) is a treatment for OSA, which splints the airway open. The introduction of telemedicine in CPAP devices offers clinical staff an alternative method of reviewing patients, monitoring treatment and reducing clinical time.

Materials and Methods: A randomised control trial was conducted with patients randomised to one of three arms. Arm 1 (standard care), Arm 2 (modem and a virtual appointment) and Arm 3 (modem, smart device application DreamMapper™ and a virtual appointment). Ninety participants requiring treatment with CPAP following a diagnosis of OSA were recruited and data collected at baseline, 14 days and 180 days. Additional contacts or appointments were also recorded.

Results: Ninety participants were recruited (68% males and 32% females) with an average age of 52.0 ±13.13 years and apnoea/hypopnoea index (AHI) 43.5 ±21.92 (events per hours). There was a statistically significant difference between the three arms in the average clinical time taken for the first follow up appointment (p=0.001). There was a statistically significant difference between the three arms in the number of additional appointments or contacts required (p=0.03).

Discussion and Conclusion: Telemedicine reduced clinical time at first follow up and in patients who received standard care or a smart device application to monitor their own CPAP treatment there was significantly less additional appointments required when compared to telemedicine support in the form of a modem alone.

Introduction

Obstructive sleep apnoea (OSA) is a common sleep breathing disorder affecting up to 50% of middle-aged men and 26% of women[1,2] and is associated with excessive daytime sleepiness[1] and increased cardiovascular risk.[3-5] Risk factors include increased age, being male, menopause in women[1] and increased weight, with up to 70% of patients diagnosed with moderate to severe sleep apnoea (apnoea/hyopnoea index [AHI] ≥ 15) being defined as obese[6] (body mass index [BMI] >30).

Continuous positive airway pressure (CPAP) is considered the first line treatment in moderate-severe sleep apnoea and is considered for the treatment of mild sleep apnoea when all conservative treatments have failed such as weight loss and improved sleep hygiene techniques.[7] Compliance with CPAP treatment has been shown to improve reported daytime sleepiness, cognitive function, quality of life and mood,[8] with symptoms returning on stopping treatment. Compliance to CPAP treatment is often troublesome and this may be due to the side effects of treatment such as dryness of the mouth and nose, mask leak, facial discomfort and abdominal bloating.[9,10]

The introduction of telemedicine into CPAP devices over the last few years offers the ability to remotely monitor treatment and offer early clinical intervention. Previous studies have focused on patient compliance to CPAP treatment when using telemedicine, with the American Academy of Sleep Medicine calling for further research.[11]

The use of telemedicine worldwide has increased since the pandemic and this is likely to grow in the future.[12] During COVID-19, Cengiz et al.,[13] found 28% of CPAP patients experienced a negative impact on their OSA treatment with 20% of patient stopping CPAP treatment due to reduced access to medical services. Telemedicine may offer the ability to improve compliance by early intervention when problems with CPAP arise, increase the use of virtual appointments, reduce additional clinical appointments and therefore reduce clinical time. Telemedicine also offers the potential to provide a continuous service in the future[13] with NICE recommending the use of telemonitoring in the first 6 months, an annual review of CPAP to optimise treatment and access to sleep services for advice and support.[8]

The study will examine standard care against two different telemedicine technologies.[14] The aim of this study was to assess clinical time taken for follow up CPAP appointments, any additional interventions or contacts and to compare standard care with telemedicine. Patients were randomised to one of three arms: standard care with face-to-face appointments (Arm 1), virtual modem monitoring (Arm 2) and virtual modem monitoring with a smart device application (DreamMapper), which allowed the patient to review their own health data and monitoring their CPAP use (Arm 3).

Materials and Methods

Participants

The study data is part of an overarching single centre randomised controlled trial, of the use of telemedicine in the management of CPAP for the treatment of OSA.[14] The study flowchart is shown in *Figure 1*. Participants were consecutive patients referred to the Respiratory and Sleep Department on the Isle of Wight, UK with suspected OSA. Patients were referred from both primary care (General Practitioner) and secondary care (hospital). Diagnosis of sleep apnoea followed an overnight home cardiorespiratory sleep study (Somnotouch, Somnomedics, UK) with OSA confirmed as AHI ≥ 5.[15] One hundred and sixteen participants were approached (5 patients declined who went on to receive routine clinical care), 10 patients did not meet the inclusion criteria and 11 participants withdrawing from the study early due to stopping CPAP treatment.

NHS Health Research Authority (HRA) ethics approval was granted on 1st July 2020 (Ref No 280212) and study recruitment, data collection and analysis took place between September 2020 and October 2022. The inclusion criteria were patients diagnosed with OSA following a cardiorespiratory sleep study with an AHI ≥ 5[15] and between the age of 18-80 years old. Patients were excluded if their diagnosis included complex sleep apnoea such as Cheyne Stokes Respiration (CSR) or central sleep apnoea. Pregnant women and patients with mental or physical impairment that prevented them from managing their own treatment were also excluded. As the study included the use of technology, patients who did not understand or have access to a smart device with Bluetooth were not recruited.

Protocol

Participants who met the inclusion criteria following their cardiorespiratory sleep study were sent written information concerning the study before they attended their CPAP appointment at the hospital. Patients who wished to take part were consented and randomised to one of 3 arms using a number generator (Excel version 2108). All patients (standard care and telemedicine) started CPAP treatment following a one-to-one session of 1 hour with a qualified Clinical Respiratory and Sleep Physiologist, this included standardised education about their diagnosis, CPAP use and care. Patients also received written information to support their treatment, including telephone and email addresses should they require any further clinical support. They were fitted with either a nasal or oronasal mask and an automatic CPAP device with pressure setting 4cmH2O-20cmH2O (Dreamstation1, Philips). A full clinical history was taken and patient demographics including weight, height, BMI, collar size and Epworth daytime sleepiness score (ESS) were recorded.

Arm 1, standard care patients were reviewed at 14 days and 180 days (± 7 days) in clinic face to face by the sleep physiologist who was able to access the CPAP data via a digital data card (SD) which was downloaded to a cloud-based website (Encore Anywhere, Philips). Patient and clinician had no access to the CPAP data outside of this face-to-face appointment.

Participants randomised to Arm 2 telemedicine had a removable cellular modem installed on the CPAP device, which wirelessly transmitted the therapy data daily, as long as the CPAP had power and a connection to 3G. The modem transmitted the data to a cloud-based website at a bandwidth 1250KHz. This data was then accessible to the clinician but not to the patient. It allowed remote prescription changes and monitoring of CPAP compliance, mask leak and residual AHI. Participants in Arm 2 were reviewed at 14 days and 180 days (± 7 days) virtually via telephone by the sleep physiologist.

Arm 3, telemedicine patients had the same cellular modem installed in their CPAP device as Arm 2 but also had access to their own CPAP data via a mobile smart device application (DreamMapper, Philips). The CPAP device uses built in Bluetooth connectivity to pair with a smart device allowing access via the application or any web browser with the patient private log in details to view the information stored on the device. The information includes compliance data (hours used in every 24 hours), mask leak, average CPAP pressure and AHI. The application also allows the patient to set goals and offers educational videos on mask fitting and CPAP use. Participants in Arm 3 were reviewed at 14 and 180 days (± 7 days) virtually via telephone by the sleep physiologist.

Patients were made aware by the clinician and in the written information supplied at the initial CPAP appointment that they had access to additional support should they require it. During the study any additional appointments or contacts were recorded including who triggered the extra appointment, the clinician or patient. The reason for the extra contact, the time taken for any extra appointments and whether this was a face-to-face appointment or telephone (virtual) appointment. Data was recorded for any addition of humidification or a CPAP mask change.

Patient who did not achieve compliance with CPAP treatment at 14 days (± 7 days) were offered additional appointments with the clinician until compliance was achieved (using CPAP device for ≥ 4 hours in 24 hours 70% of the time).

Sample size calculation
Sample size was determined by the overarching study examining CPAP compliance (hours used in 24 hours), with CPAP patients randomised to one of 3 arms, standard care or one of two different telemedicine technologies.[14]

Statistical analysis
Statistical analysis was performed using IBM SPSS statistics (version 27). Continuous variables with normal distribution patient characteristics were reported as mean and standard deviation (SD), these were reported in group and for each arm. One-way analysis of variance (ANOVA) was used to analyse group differences and two-way ANOVA used to analyse significant difference between arms. A value of $p<0.05$ was considered statistically significant.

Results

Participants
Ninety patients with complete data at 180 days ± 7 days (*Table 1*) were included in the data analysis, which consisted of 61 males (68%) and 29 females (32%). Thirty patients were randomised to standard care (Arm 1), 29 patients to telemedicine with a modem (Arm 2) and 31 patients to telemedicine with modem and mobile smart device application (Arm 3). The mean age of the participants was 52 years ± 13.13 years with an average AHI 43.5 ± 21.92 (events/hours) at baseline.

Patient characteristics
Baseline patient characteristics are shown in *Table 1*. In each characteristic a one-way ANOVA was carried out to test for any significant baseline differences between group. This included age, weight, height, BMI, collar size, Epworth Sleepiness Score (ESS) and AHI. A Pearson Chi-Square was carried out to analyse significant baseline differences between group in gender. Analysis showed a significant statistical difference in baseline ESS (p=0.013) and AHI (p=0.049) between arms in group. A post hoc test of baseline AHI was performed and did show a significant difference in Arm 1 vs Arm 2 (p=0.013*)* and Arm 2 vs Arm 3 (p=0.025). A post hoc test of baseline ESS was performed and did not show any significant statistical between arms. Jones et al found AHI and ESS at baseline had no statistically significant impact on compliance data.[14]

Patient 14 day follow up appointment.
Patients were routinely reviewed at 14 days ± 7 days either face to face (standard care, Arm 1) or via telephone for patients who received a telemedicine intervention (Arm 2 and Arm 3). 14 day data is shown in *Table 2*. Jones et al.,[14] reported full data analysis which included patient compliance to treatment (hours used in 24 hours and percentage of days used), mask leak, residual AHI and ESS with no significant statistical difference in each arm with high compliance to treatment in both hours used and percentage of day used and improvement in ESS and AHI in group.

The average clinical time taken at the first follow up appointment was recorded. Clinical time was considered as the amount of time the sleep physiologist spent with the patient, whether this was face to face or via the telephone. This did not include any administration time such as letter typing or updating clinical records. A one-way ANOVA on appointment time in minutes and seconds showed a significant statistical difference between arms (p=0.001), with a post hoc test showing a significant difference in Arm 1 vs Arm 2 (p<0.001) and Arm 1 vs Arm 3 (p<0.001). There was no significant statistical difference between Arm 2 and Arm 3 which both received telemedicine interventions.

Additional appointments or contacts

During the 180 days ± 7 days of the RCT study[14] any additional appointments or contacts were recorded as shown in *Table 3*. This included the number of additional appointments or contacts, time taken for the appointment, whether this was a face to face or virtual (telephone) appointment and who instigated the appointment and for what reason.

A one-way ANOVA was conducted on additional appointments or contacts and total clinical time required. There was a significant statistical difference between arms in group (p= 0.03) for the number of extra appointments, with post hoc test showing a significant statistical difference in Arm 1 vs Arm 2 (p=0.027) and no difference in Arm 1 vs Arm 3 and Arm 2 vs Arm 3. The additional clinical time required in each arm for an appointment showed no significant difference (p=0.434), with an average appointment time 17.43 ± 10.56.

There was no statistically significant difference (p=0.662) between arms, in the clinician or the patient instigating any additional appointments with 48% initiated by the clinician and 51% by the patient (*Table 3*). Additional appointments were triggered by several factors as shown in *Figure 2*, with the most frequent factor being dryness of the nose and/or mouth and nasal congestion.

Additional appointments were also triggered by patients' poor compliance to treatment. Any patient not using the CPAP device for ≥ 4 hours in 24 hours for 70% of the time were offered additional appointments by the sleep physiologist to support improvement in treatment. In standard care (Arm 1) this additional appointment was face-to-face as the sleep physiologist required the SD card to download the CPAP data to check on usage. The telemedicine groups (Arm 2 and 3) appointment was available virtually as the clinician was able to access the CPAP data via the cloud-based platform (Encore Anywhere, Philips).

A small number of patients in the total group (10%) required a change in the CPAP mask following initiation of CPAP treatment, with no statistically significant difference (p=1.000) between arms in group. Patients who reported dryness of the nose and/or mouth or nasal congestion were fitted with humidification, with no statistically significant difference (p=0.879) between arms in group with 11.1% of the group (N=90) requiring humidification.

Discussion

The analyse of clinical time and additional appointments or contacts was part of the overarching RCT study which investigated patient compliance to CPAP treatment for OSA in standard care and telemedicine.[14] Participants were randomised but not blinded to reduce bias and were allocated to one of three arms. The study was unique as it compared standard care to two types of telemedicine interventions: Arm 2, the addition of a modem to transmit data to a cloud-based platform that can be accessed by the clinician but not the patient with virtual appointments and Arm 3, the addition of a modem and a smart device application (DreamMapper, Philips) allowed the patient to access their own data and health information with virtual appointments. Jones et al.,[14] found that telemedicine was as effective in the treatment of OSA with CPAP as standard care, with patient compliance to treatment high in all arms of the study (average 6.18 ± 2.12).

Previous studies have evaluated the economic cost-effectiveness of telemedicine and CPAP.[16,17] However these studies included the following, clinical time, health benefits, direct and indirect costs (medical and patient travel) within the cost analysis. Lugo et al.,[17] found that there was no difference in the medical costs in the standard care group when compared to the telemedicine group. A small number of studies have compared standard care with a telemedicine intervention and the effect of staff labour.[18,19] Munafo et al., [19] also explored the link between staff labour and patient compliance to treatment in standard care and telemedicine. These studies concluded that the use of telemedicine reduced the amount of

nursing time per patient with effective compliance to treatment, with the greatest impact during the initialisation of CPAP treatment.

In this study the standard care arm who received face to face follow up appointments, clinical time required for the appointment averaged 16.67 ± 7.24 minutes which was statistically significantly greater than Arm 2 and 3 who received the telemedicine intervention and their appointments via telephone. This is possibly due to the instant access for the clinician to the CPAP data in the telemedicine group as this is transmitted daily. In the standard care group during the appointment, time is taken by the clinician to remove the SD card and manually download the data before being able to assess the patient's compliance to treatment. Could there also be some differences in the amount of information a patient may share during a telephone conversation when compared to a face-to-face with the clinician and the one-to-one relationship. Jones et al.,[20] previously explored the patient experience of CPAP and virtual appointments and found that some patients expressed the view that telephone appointments could not replace that clinical relationship formed during face-to-face appointments.

The number of additional appointments were statistically significantly greater in Arm 2, the telemedicine group with a modem and virtual appointment when compared to Arm 1 standard care and Arm 3, modem and smart device application. We could speculate this is due to less support in Arm 2 than the other two arms of the study. Arm 1 received the face-to-face support from the clinician, the longer clinical time taken at their first follow up appointment may have offered greater reassurance with the continuing treatment and reduced the patients need for further intervention or contact. Arm 3 had access to their own CPAP data and support via the smart application with motivational videos and goal setting. The instant access to information such as a mask leak allowed the participants in Arm 3 to make daily adjustments to their treatment and therefore reduce the need to seek further clinical advice.

Limitations

Due to the size of the study and the small number of patients requiring additional appointments in each arm it is difficult to determine effect size. Previous studies exploring clinical labour in CPAP are non-UK based and therefore have different healthcare systems in place (eg private health care). The participants within this study were a white demographic and the study may therefore not be representative of the multiethnic diversity across the UK. The access to technology and social economic differences within the research group may add bias to the study.

Conclusions

The use of telemedicine has been shown by the authors to be as effective as standard care on CPAP compliance[14] with less clinician time required at first follow up. The need for support is evident in the number of additional appointments required in patients with perceived reduced support (Arm 2). Support in the form of CPAP smart device applications have a positive impact on reducing the number of additional appointments and clinical time. Telemedicine has the ability to reduce clinical time and therefore increase activity and to offer virtual continued support to patients due to locality or ill health who can not visit the hospital clinic.

Future research

A larger multi centred longitudinal study of telemedicine and CPAP use would offer the ability to assess clinical time at a variety of points within the treatment pathway, from initialisation of treatment to the yearly review of treatment. Any further research should consider a variety of telemedicine interventions as not all telemedicine applications are the same or offer the same value or outcomes to the patient as the current study has shown.

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Conflict of Interest

This is not an industry supported study. DreamMapper and Encore Anywhere is registered product of Philips Respironics. No financial support was provided, the authors indicate no financial conflicts of interest.

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Figure 1 – Study Flow Chart

Flowchart of randomised controlled trail, including patient selection, inclusion and exclusion. Data collection at follow up appointments and collection of data concerning additional interventions and contacts.

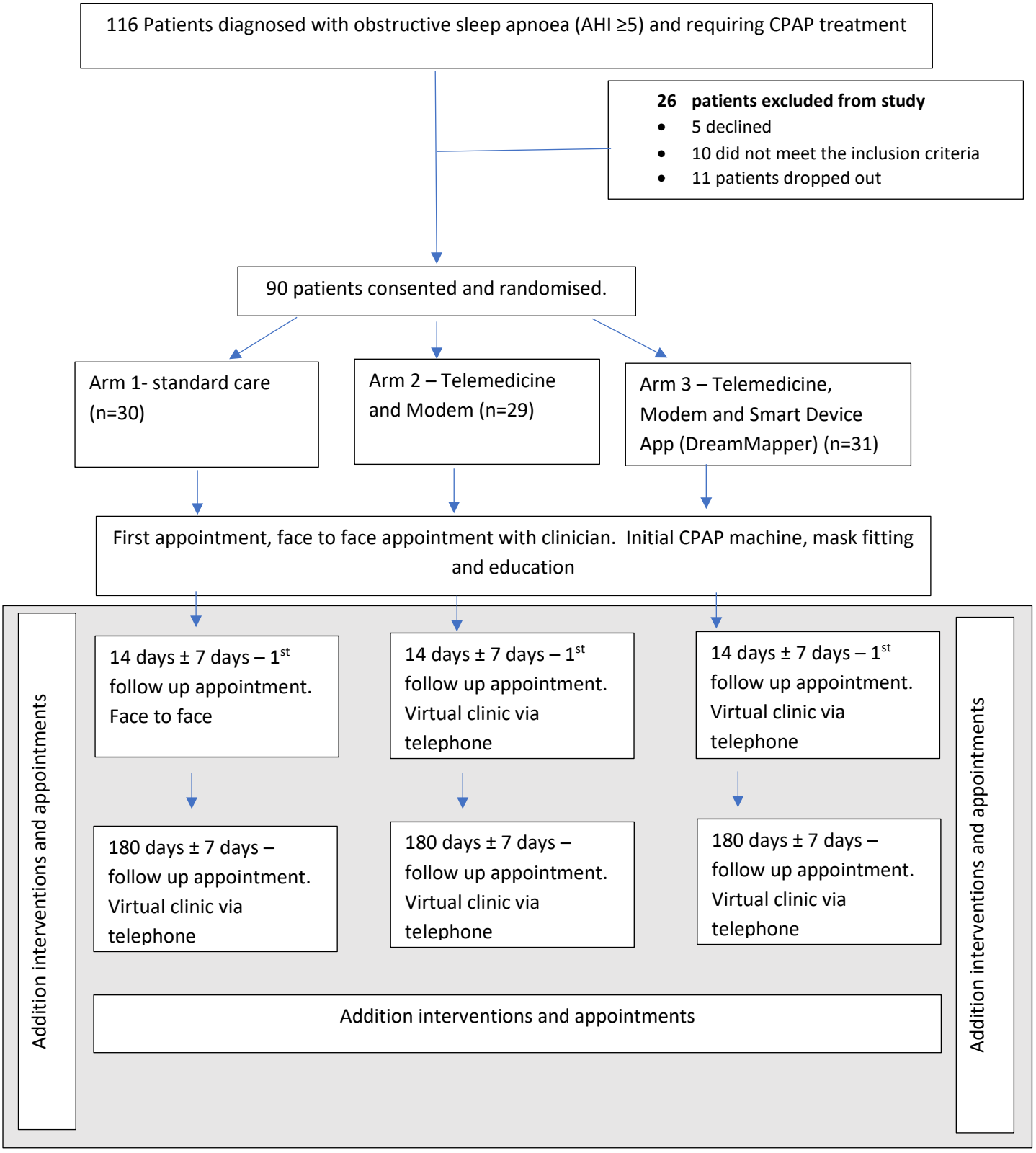

Figure 2 – Factors which triggered additional appointments.

Number of reported and category of CPAP issues that triggered the need for additional follow up appointments in each arm of the study.

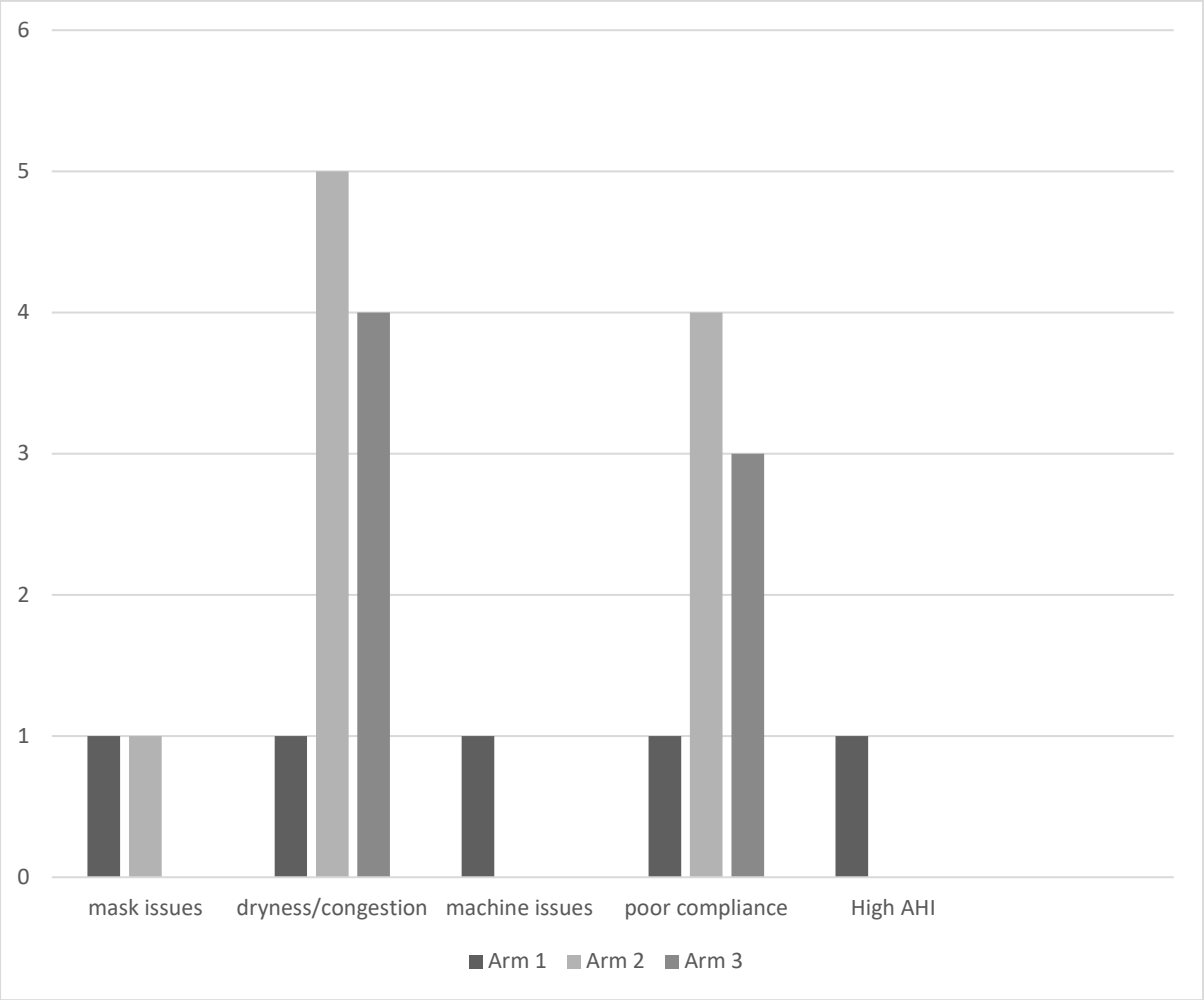

Table 1 -Baseline patient characteristics

	Total Group (N=90)	Standard Care Arm 1(n=30)	Telemedicine with Modem Arm 2 (n=29)	Telemedicine with Modem and Smart Device App (DreamMapper) Arm 3 (n=31)	P value
Age (y)	52 ± 13.13	58.50 ± 13.09	55.9 ± 13.80	53.74 ± 12.51	0.371
Gender (m/f)	61/29	19/11	22/7	20/11	0.525†
Weight (kg)	107.66 ± 22.32	108.50 ± 22.64	104.55 ± 20.84	109.74 ± 23.73	0.651
Height (cm)	172.69 ± 8.07	171.51 ± 8.70	174.51 ± 7.47	172.12 ± 7.94	0.324
BMI (kg/m^2)	36.4 ± 7.91	37.48 ± 8.62	34.57 ± 6.54	37.23 ± 8.28	0.299
Collar size (cm)	43.94 ± 4.47	44.22 ± 4.39	43.31 ± 4.40	44.29 ± 4.72	0.657
AHI (event/h)	43.5 ± 21.92	48.01 ± 23.61	33.75 ± 16.4	48.24 ± 22.34	0.013*
ESS	10.19 ± 5.75	12.27 ± 5.42	9.34 ± 4.93	8.97 ± 6.36	0.049*

Data presented as mean ± standard deviation (SD). Definitions of abbreviations: BMI = Body Mass Index, AHI= Apnoea/Hypopnoea Index, ESS =Epworth Sleepiness Score (out of 24). *P* values are calculated with a one-way ANOVA. *p<0.05 considered significant. † *p* value calculated with Pearson Chi-Square.

Table 2 – Compliance data at 1st follow up appointment of CPAP use (14 days ±7 days)

	In Group (N=90)	Standard Care Arm 1(n=30)	Telemedicine with Modem Arm 2 (n=29)	Telemedicine with Modem and Smart Device App (Dreammapper) Arm 3 (n=31)	p value
Daily usage (h, min)	6.18 ± 2.12	6.22 ± 2.15	5.47 ± 2.25	6.44 ± 1.54	0.256
Percentage of days used ≥ 4 hours (%)	78.78 ± 31.13	79.2 ± 29.70	70.7 ± 35.09	85.82 ± 27.55	0.172
Percentage (%) of patients achieving more than 4 hours a night at 1st follow up	91.1 (82/8)	96.7 (29/1)	82.7 (24/5)	93.5 (29/2)	0.147
Residual AHI	5.11 ± 4.06	5.50 ± 4.77	5.29 ± 4.40	4.56 ± 2.90	0.644
Mask leak (%)	3.87 ± 8.99	3.43 ± 7.49	4.96 ± 12.47	3.28 ± 6.20	0.733
ESS	4.84 ± 5.05	6.10 ± 6.49	5.11 ± 4.90	3.48 ± 3.05	0.126
Average appointment time (min, sec)	12.12 ± 6.48	16.67 ± 7.24	10.22 ± 5.77	9.52 ± 3.44	0.001**

Data presented as mean ± standard deviation (SD). Definitions of abbreviations: AHI= Apnoea/Hypopnoea Index ESS= Epworth Sleepiness Score. *p* values are calculated with a one-way ANOVA and using x^2 for percentage of patients achieving 4 hours. **p<0.001 considered significant.

Table 3 – Additional interventions

	In Group (N=90)	**Standard Care Arm 1(n=30)**	**Telemedicine with Modem Arm 2 (n=29)**	**Telemedicine with Modem and Smart Device App (Dreammapper) Arm 3 (n=31)**	**p value**
Number of additional appointments	0.48 ± 0.997 (42)	0.20 ± 0.484 (6)	0.86 ± 1.24 (24)	0.39 ± 1.02 (12)	0.03*
Additional appointment time (min, sec)	17.43 ± 10.56	12.00 ± 4.24	19.41 ± 11.68	18.00 ± 11.71	0.434
Initiated by clinician/patient % (patient num)	48/51 (11/12)	60/40 (3/2)	50/50 (6/6)	33/66 (2/4)	0.662
Mask changes % (patient num)	10 (9)	2.2 (2)	4.4 (4)	3.3 (3)	1.000
Humidification added % (patient num)	11.1 (10)	0 (0)	6.6 (6)	4.4 (4)	0.879

Data presented as mean ± standard deviation (SD) and absolute number. *p* values are calculated with a one-way ANOVA and using x^2 for initiated by clinician or patient. *p<0.05 considered significant.