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Use of telemedicine to improve cpap non-adherence in patients with obstructive sleep apnea, a pilot study

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Use of Telemedicine to Improve CPAP Non-Adherence in Patients with Obstructive Sleep Apnea, A Pilot Study

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Abstract

The aim of this project is to improve continuous positive airway pressure (CPAP) non-adherence in patients newly diagnosed with obstructive sleep apnea. Obstructive sleep apnea (OSA) is caused by recurrent collapse of the upper airway during sleep. Untreated, OSA is associated with co-morbidity and decreased quality of life. The standard for OSA treatment is CPAP. Adherence to CPAP is not optimal. Applying telemedicine technology to monitor adherence of CPAP treatment, allows for early intervention. Prior research has shown mixed results with use of telemedicine on non-adherence rates.

This is a pilot study using telemedicine to monitor adherence data to trigger patient support throughout the first 3 months of CPAP therapy. In total, 56 newly diagnosed OSA patients were randomized to standard care (SC, n=23) or telemedicine (TM, n=33). SC received follow-up appointment at 6-weeks; those in TM had weekly data monitoring for the first 3 months, in addition to standard care. If CPAP use did not meet adherence criteria, a support phone call was conducted. Study results were compared to baseline non-adherence rates.

Study results did not show significant improvement in CPAP non-adherence rates with telemedicine intervention compared to standard care (p=0.43). There was improvement in non-adherence rates in both TM (8.0%) and SC (15.8%) arms at 3-months, from baseline non-adherence rate (22.8%).

Although the improvement seen in CPAP non-adherence rates was not significant, future studies with larger sample sizes may note more robust significance. Clinical significance related to increased adherence rates should not be undervalued.

Keywords. Telemedicine, obstructive sleep apnea, adherence, CPAP

Introduction and Background

Obstructive sleep apnea (OSA) is a chronic disorder affecting 2% to 4% of adult men and women (Epstein et al., 2009), with some reports estimating its prevalence at 15% in males and 5% in females (Frasnelli, Baty, Niedermann, Brutsche, & Schoch, 2016). OSA is caused by recurrent complete or partial collapse of the upper airway during sleep, leading to nocturnal hypoxemia, hypercapnia, and interrupted sleep; causing symptoms of snoring, witnessed apnea, and daytime sleepiness (Epstein et al., 2009). Untreated, moderate to severe obstructive sleep apnea is associated with various co-morbidities including coronary artery disease, heart failure, stroke, hypertension, and decreased quality of life; it also increases one's risk of motor vehicle crashes (Donovan, Boeder, Malhotra, & Patel, 2015). As directed by the American Academy of Sleep Medicine (AASM), positive airway pressure (PAP) is the preferred treatment for obstructive sleep apnea (Epstein et al., 2009). Modalities for PAP include continuous positive airway pressure (CPAP), auto-titrating positive airway pressure (APAP) and bi-level positive airway pressure (BiPAP). CPAP is used to refer to continuous positive airway pressure therapy; however, CPAP may also be used to encompass auto-titrating PAP therapy as well. A meta-analysis by Ip et al. (2012) reviewed 24 studies comparing adherence rates between APAP and CPAP users; 20 studies found no significant difference in therapy usage for those using APAP versus CPAP. Therefore, for ease of reference, CPAP will be used to refer to positive airway pressure therapy utilized by participants in this study.

Positive airway pressure is a highly effective treatment modality for OSA by providing positive pressure to the upper airway during sleep, thereby preventing collapse of the airway (Frasnelli et al., 2016). To maintain effectiveness and prevent symptoms, treatment must be maintained. Withdrawal of therapy results in recurrence of airway collapse and symptoms in most patients, therefore treatment adherence is crucial to therapy. A recent review to assess trends in CPAP adherence over the past 20 years showed an overall CPAP non-adherence rate at 34.1% (Rotenberg, Murariu, & Pang, 2016). Barriers to treatment adherence are often related to CPAP side effects, including intolerance to pressure, claustrophobia, displacement of mask, and machine noise (Turino et al., 2017). Non-adherence to CPAP has been observed to be established early on in treatment (Frasnelli et al., 2016), often within the first weeks. Initial close monitoring and follow up in the first weeks of CPAP treatment may improve initial and long-term adherence rates.

Multiple studies have shown use of telemedicine-based initiatives have resulted in significant improvement in treatment adherence after initial positive airway pressure (PAP) treatment initiation (Fox et al., 2012; Frasnelli et al., 2016; Isetta et al., 2017; Sparrow, Aloia, DeMolles, & Gottlieb, 2010; Woehrle et al., 2017). The basis for our study intervention stems from a study completed by Stepnowsky, Palau, Marler, and Gifford (2007) who conducted a pilot randomized controlled trial of the effect of wireless telemonitoring and interval follow up on CPAP adherence and efficacy in newly diagnosed OSA patients at a Veterans Affairs Healthcare System in San Diego. Although the study showed improved CPAP compliance and efficacy in the telemedicine arm

compared to the standard of care group, the findings were not significant; this was suspected to be due to the low study sample.

Problem Statement

Obstructive sleep apnea is a common condition among both men and women. (Epstein et al., 2009; Frasnelli et al., 2016). The condition is associated with a decreased quality of life, the development of certain co-morbid conditions and increases the risk of motor vehicle collisions. The gold standard treatment for OSA is continuous positive airway pressure, which alleviates the closing of the upper airway, thereby preventing apneic and hypoxic events from occurring (Epstein et al., 2009). Continuous use of CPAP is necessary for effective treatment; however patient non-adherence to CPAP treatment has remained persistently high over the past 20 years, with use often abating in the first months of treatment initiation (Rotenberg, Murariu, & Pang, 2016). Interventions including telemedicine technology, have been found to improve patient adherence rates to CPAP treatment. During this study, the researcher utilized a telemedicine-based intervention to track adherence data from patients' CPAP device to direct individualized follow-up care during the first 3 months of CPAP usage, to improve treatment adherence.

Objectives and Aims

The purpose of this study was to develop and pilot a telemedicine-based intervention to detect early non-adherence to CPAP usage in adults newly diagnosed with OSA, with provision of early support and troubleshooting, during the first 3 months of therapy, to deter therapy cessation.

Objectives:

- Analyze through telemedicine technology patient utilization of CPAP
- Initiate a patient-focused follow-up plan through telephone support, based on data obtained using telemedicine
- Compare non-adherence rates of patients followed by telemedicine intervention to those who have received standard care, to determine utility of telemedicine intervention in patients newly diagnosed with OSA starting CPAP treatment.

Review of Literature

A systematic review of literature was conducted to analyze recent studies and commentary related to telemedicine in the treatment of obstructive sleep apnea with positive airway pressure. Databases including Pubmed, Cochrane Library, Scopus, and CINAHL were reviewed. Key words included obstructive sleep apnea and telemedicine. An initial review included articles spanning the past 10 years, however this was narrowed to those within the past 5 years, to ensure the most recent literature was analyzed. Additional inclusion criteria included full text articles, studies completed on humans, adults, and written in the English language. A total of 24 articles were selected for review based on the above inclusion criteria. Most of the articles reviewed focused on studies of telemedicine interventions in the treatment/management of OSA. Studies focusing on telemedicine in the diagnosis of OSA and/or treatment of sleep apnea, tele-conferencing for initial and/or follow-up visits or CPAP training, and those discussing preference of CPAP data download, were excluded from the review. Those with primary outcomes related to improvement of concurrent co-morbidities were also excluded. The priority of

this project was the use of telemedicine technology in the monitoring of adherence to CPAP use in OSA patients, therefore the ten studies not related to this were excluded from the review.

Seven studies reviewed used web-based monitoring technology to retrieve data from patients' at-home CPAP devices to monitor adherence and/or efficacy of treatment (Anttalainen, Melkko, Hakko, Laitinen, & Saaresranta, 2016; Frasnelli et al., 2016; Hoet et al., 2017; Hwang et al., 2017; Munafo et al., 2016; Turino et al., 2017; Woehrle et al., 2017). The studies mainly focused on number of hours of CPAP usage per night (>4hours/day), average leak (>4liters/second), and apnea/hypopnea index (AHI) of less than 5/hour (or similar standard), to determine adherence and efficacy. In each of the studies, the benchmark for adherence was CPAP use of ≥4h/night (or non-adherence at<4h/night). Studies had pre-defined set points; if data fell outside of the set points an intervention was triggered. In all, but one, of the studies, the triggered intervention included a phone call from a member of the research team to provide support and troubleshooting advice to promote treatment adherence; the study by Hwang et al. (2017) used automated patient feedback. Three studies found improved adherence rates with use of telemedicine-based intervention versus standard care (Frasnelli et al., 2016; Hoet et al., 2017; Hwang et al., 2017). Other studies (Anttalainen et al., 2016; Munafo et al., 2016; Turino et al., 2017) found no significant improvement in CPAP adherence or efficacy with use of telemedicine intervention versus standard care. The study by Woehrle et al. (2017) found those in the standard care arm had a significantly higher rate of discontinued use of CPAP (11.0%) versus the telemedicine intervention arm (5.4%;

$p<0.001$). Although not significant, the Anttalainen et al. (2016) study found an increased termination rate (20%) versus 16.4% in the standard care arm in their study ($p=0.66$).

Two studies reviewed measured secondary endpoints of patient satisfaction (Munafo et al., 2016; Turino et al., 2017). The Munafo et al. (2016) study found those in the telemedicine arm felt the intervention met or exceeded their expectoration (92.8%), while 94.5% in the standard care group felt their expectations were met or exceeded in their care ($p=0.82$). Additional secondary endpoints using web-based telemedicine monitoring intervention included cost and manpower. In the Turino et al. (2017) study, the total average cost per patient in the telemedicine arm was 28% lower than that in the standard care group. By using the mobile phone network to transmit data to allow for monitoring and triggered intervention, Frasnelli et al. (2016) had no increased costs associated with their telemedicine intervention.

Another factor that must be considered when utilizing a telemedicine-based intervention is manpower needed to monitor data and provide support interventions. Although CPAP adherence was higher using the web-based telemedicine monitoring and subsequent support intervention versus standard care (191±147min/day vs 105±118min/day, $p=0.006$), the amount of time (i.e. manpower) used in the telemedicine arm was significantly greater than the standard care arm (210±42 min over 3 months versus 143±48 min, $p<0.0001$) (Fox et al., 2012). However, Munafo et al. (2016) found significantly lower labor use in the telemedicine arm versus the standard care arm (2.2±2.6 contacts per patient versus 7.8±4.1 contacts/patient, $p<0.0001$), corresponding to 59% less labor time required for those in the telemedicine arm than the standard care arm.

As labor is another aspect of cost, this needs to be a factor when looking at a cost analysis for a web-based telemedicine intervention.

Theoretical Model

The Institute for Healthcare Improvement's Triple Aim Framework (IHI, 2017) was used to guide this pilot study. The IHI Triple Aim is a conceptual framework that aspires to optimize health system performance through three "aims": improving the patient experience of health care, improving the health of populations, and decreasing the per capita cost of health care (Figure 1). Within the three aims are several components of a healthcare system that can be targeted to improve specific aims. This project focuses on the component of patient-centered care, which is under the umbrella of the patient experience aim.

The IHI Triple Aim framework describes steps in a change process. The change process first entails identifying the target population in which the change intervention will take place; the next step is to identify the aim of the intervention and what measures will be used to determine if the change is effective (IHI, 2017). A study design must then be developed, followed by rapid testing and adaption, and if appropriate, adoption of the intervention, to ensure the needs of the target population are met.

Project Study and Design

This was a pilot, randomized comparison study of a telemedicine-based intervention to improve non-adherence of CPAP treatment in patients newly diagnosed with OSA using the steps outlined in the IHI Triple Aim change process described above.

Settings and Resources

The study took place at a hospital affiliated Sleep Center, which is part of a 255-bed community hospital in a mid-Atlantic state. The Center is accredited by the American Academy of Sleep Medicine (AASM) and combines both a sleep clinic and a sleep lab for the diagnosis and management of a full range of sleep disorders. CPAP user data was obtained via telemedicine; device data from participants' CPAP device is wirelessly uploaded to a secure, web-based data system coordinating with the manufacturer of the device provided to participants from their durable medical equipment (DME) supplier. Patient data can only be accessed through a secured site requiring login and password.

Study Population

Participants in the study were adults who had recently been diagnosed with moderate to severe obstructive sleep apnea through a home sleep apnea test (HSAT) or in-lab polysomnography (PSG), based on AASM criteria of an apnea-hypopnea index (AHI) ≥15 as moderate OSA and an AHI of ≥30 as severe OSA (Kapur et al., 2017). Participants were prescribed treatment with positive airway pressure (PAP) therapy.

The G*Power tool (Faul, Erdfelder, Lang, and Buchner, 2007) was used to determine sample size. Using a confidence interval of 95% and probability of 5%, a sample size of 74 participants was determined (Appendix A). Consecutive patients who met criteria were asked to participate; once consented, participants were randomized into the standard care (SC) arm or the telemedicine (TM) arm using GraftpPad software (2017). Participants randomized to group "1" were the standard care arm and those in group "2", the telemedicine arm (Appendix B).

Inclusion criteria:

- Adults, at least 18 years of age, newly diagnosed with moderate to severe OSA on HSAT or PSG
- Provision of CPAP device by DME with wireless data transmission capability
- English speaking

Exclusion criteria:

- Prior PAP use of any kind, including CPAP, APAP, bi-level or adaptive sero-ventilation
- Current use of prescribed supplemental oxygen
- Significant co-morbid medical condition(s) that could prevent/interfere with the participant using CPAP on a daily basis
- Home location being outside of wireless capability
- Sleep environment where the participant does not sleep in the same location on a frequent basis

Standard care group. Participants in the standard care (SC) group received the standard follow-up regimen currently used by the Sleep Center. Following diagnosis of moderate or severe OSA and the participant was prescribed CPAP therapy. Patients obtain equipment from a DME provider; they are fitted with a mask and given instructions on set up, use and care of the PAP machine. Devices are equipped with wireless data transmission technology. Patients are advised to call the DME with any equipment concerns and the Sleep Center with any other concerns or questions related to PAP use; they are seen back in clinic after 6 weeks to discuss adherence and efficacy, review device data, and to address any issues or questions they may have. If patients are

doing well, they are seen back yearly for monitoring, with more frequent follow-up if needed.

Telemedicine care group. In addition to standard care, participants randomized to the TM group received the intervention, which entailed an initial call to all participants after one week of PAP therapy. CPAP usage data was monitored weekly via a web-based database. Use of CPAP of less than 4 hours per night, on less than 70% of nights (or more than 2 days), in the preceding week of monitoring, was considered non-adherent and triggered a phone call from the research coordinator to provide support and troubleshooting as needed. Participants were seen back in clinic after 6 weeks, per standard care. Data monitoring, as outlined above, continued for the first 3 months of CPAP usage. The study period culminated with a phone call, by the author, to all participants from both study arms, at the end of 3 months, to discuss any questions or concerns and to survey satisfaction of their follow-up care.

Sources of Data

Participant data, such as gender, age, and weight were obtained from intake forms. Initial AHI was obtained from diagnostic sleep study. Prior to CPAP initiation a baseline Epworth Sleepiness Scale (ESS) score was obtained. The ESS is an 8-question self-administered questionnaire; respondents rate themselves on a 4-point scale (0-3) their likelihood of falling asleep during 8 daytime activities (Appendix C) (Johns, n.d.). The ESS is considered both reliable and valid in determining an individual's propensity for daytime sleepiness; it has a Cronbach alpha of 0.88 (Johns, 1992). A repeat ESS was completed at the 6-week follow-up visit and at 3 months, during the end of study phone call.

There is no standard metric defining adherence for CPAP usage, however multiple studies have shown that use of 4 hours per night or more improves patient reported quality of life, daytime sleepiness and neurocognitive function; greater improvement in cardiovascular disease conditions and diabetes have also been found when CPAP is used for more than 4 hours per night (Weaver, 2017). In addition, Medicare defines CPAP adherence as use of PAP ≥4 hours per night on 70% of nights, during a 30-day period, within the initial first 3 months of CPAP use (Department of Health and Human Services, 2016). Use of CPAP less than 4 hours/night, on less than 70% of nights, was the metric used to measure CPAP non-adherence in this study. Six-week and 3-month data were used for statistical analysis.

At the end of the study period the researcher phoned all participants, from both arms, providing additional support and/or troubleshooting, if needed, and to address any further patient issues or concerns. A 2-question satisfaction survey was conducted, using a 5-point Likert scale. Participants were asked to rate their satisfaction with their CPAP therapy and if they were satisfied with their initial follow-up care (Appendix D).

The Sleep Center's baseline adherence rate was determined for data comparison with study results. To obtain baseline Sleep Center non-adherence rate, 10 consecutive charts of newly diagnosed OSA patients who started CPAP treatment and met study criteria, were audited each month, of the 6 months prior to recruitment of study participants.

Data Analysis

Patient characteristics. Data analysis for baseline patient characteristics included gender, age, and weight. Statistical analysis of these characteristics included percentiles for gender; mean and standard deviation for age and weight. Percentiles for type of study and mean and standard deviation of baseline ESS and AHI is also calculated.

CPAP adherence. Adherence data evaluated include number of days of CPAP usage and number of days used more than 4h/night, which was collected from the web-based database at 6 weeks and again at 3 months. Analysis included mean and standard deviation for both measures and percentage of non-adherence at both time periods. Differences between week 6 and 3 months were compared using dependent *t*-test.

Patient satisfaction. Percentiles were reported for both end of study survey questions.

For all comparison analyses a *p*-value with 95% confidence interval was obtained. Significance was based on a *p*-value of <0.05.

Quality

To ensure participant confidentiality, research data was stored on the principal investigator's personal work computer, accessible only with personal badge or ID/password. Each participant was given a unique identifier based on the first 3 letters of their first name, first 3 letters of their last name and last two numbers in year of birth. A record of the participants and their identifier was kept on a password protected computer at the primary investigator's workplace. Data obtained from the telemedicine database is

a secured website that can only be accessed by granted users with a unique login and password.

Ethics and Human Subjects Protection

Potential risks to participants in this pilot study are deemed minimal, however may include inconvenience and/or perceived intrusion from researcher phone calls, lack of symptom improvement with CPAP therapy and the potential for cessation of CPAP therapy. Patient privacy was maintained through non-identifying patient coding as outlined above; data were collected through a secured database, which the patient enlists in as part of standard CPAP monitoring. Potential for breach of confidentiality is minimal. The intervention entailed close monitoring of data and providing support-based phone calls as needed. Data collection and monitoring was conducted by the primary investigator. The project followed protocols of both the Sleep Center organization and educational university Institutional Review Boards (IRB). Approval by the Review Boards was received prior to initiation of project or data collection. It is believed the potential benefits of the intervention outweighed any potential risks. Each participant provided informed consent prior to initiation of study protocol.

Timeline

Participants were recruited into the study from February 21 through June 30, 2018. Data monitoring was completed on October 3, 2018.

Budget

There were no additional costs incurred for this project by the patient, organization or researcher above and beyond those incurred with standard care. In-kind

costs of the primary investigator's time for data monitoring and analysis, as well time for providing phone support should be considered if intervention is to be adopted into practice.

Results

Fifty-seven of sixty charts were reviewed to obtain baseline adherence data for the Sleep Center; 7 of 10 charts were reviewed for the month of January 2018; only 7 charts met study criteria. The characteristics of patients evaluated for baseline (Table 1) did not differ to those in the study sample in relation to gender, age, weight, initial ESS, or initial AHI. There were significantly more patients whose OSA diagnosis was based on an HSAT versus PSG in the baseline chart review compared to the study sample ($p<0.00$). The baseline non-adherence rate for the Sleep Center at 6-weeks post CPAP initiation was 21.1%; the 3-month non-adherence rate was 22.8%.

Fifty-six patients consented to participate in the pilot study; 23 were randomized to the Standard care arm, 33 were randomized to the Telemedicine arm (Figure 2). Twelve participants were excluded from the study due to not picking up CPAP equipment (n=3), turning CPAP in prior to end of study period (n=4), not completing the end of study call (n=3), not obtaining equipment in time to complete data analysis (n=1), and one person was given a CPAP without wireless capability. Forty-four participants completed the study and were used for data analysis.

Overall, the characteristics of the participants did not differ between the SC and TM arms (Table 2), in relation to gender, age, weight, initial ESS, initial AHI or type of study. In the SC arm, 6-week non-adherence was 15.8% and 12.0% in TM ($p=0.72$)

(Table 3); 3-month non-adherence was 15.8% in SC and 8.0% TM (p=0.43). The SC and TM arms did not differ in 6-week or 3-month CPAP days used, or days used ≥4hr. Although there was not a significant difference in the 6-week ESS between the two groups (p=0.42), there was a significant difference at 3 months (p=0.04). The SC arm showed a mean increase from 5.0 to 6.5 (SD ±3.6 and ±4.1), the TM arm showed a mean decrease in ESS from 5.8 to 4.0 (SD ±3.6 and ±2.7). The groups also differed in AHI at 6-weeks (p=0.04), however not significantly at 3-months (p=0.14).

In the SC arm, there was a decrease in the mean number of CPAP days used at 6-weeks (96.2±5.0) and 3-months (93.3±8.9), although not significant (p=0.11) (Table 3). There was a significant decrease in number of days used ≥ 4hr (p=0.04) in the SC arm between 6-weeks (86.8±13.4) and 3-months (83.5±15.8). In the TM arm, number of CPAP days used at 6-weeks (96.7.5±6.2) and 3-months (97.0±4.1) did not differ (p=0.72), nor did they differ in use of ≥4hr between 6-weeks or 3-months (88.5±16.7, 89.9±13.1, p=0.96).

Overall, satisfaction with their CPAP treatment did not differ between the SC or the TM arms (p=0.67) or in their follow-up care (p=0.68). Most participants were either very satisfied or satisfied with their CPAP treatment (SC, 84.2%; TM, 88.0%) and their follow-up care (SC, 94.7%; TM 100%). Two participants in the TM arm were dissatisfied with their CPAP treatment; one participant in the SC arm was very dissatisfied with their CPAP treatment.

Discussion

Utilizing a telemedicine intervention to improve CPAP adherence in patients newly diagnosed with moderate to severe obstructive sleep apnea showed improvement in the Sleep Center's non-adherence rate in the first 3 months of CPAP use, although not to statistical significance. Prior studies have shown mixed results in improved adherence with use of telemedicine monitoring. Studies conducted by Frasnelli et al. (2016) and Hwang et al. (2017) show significant improvement in CPAP adherence in the first 3 months of use. The study conducted by Hoet et al. (2017) showed improved adherence rates in the first 3 months, although not to a significant degree. One study did not show improved adherence with telemedicine intervention (Munafo et al., 2016).

Baseline non-adherence for the Sleep Clinic was 21.1% at 6-weeks and 22.8% at 3-months. Although these rates are lower than the overall non-adherence rate of 34.1%, based on a systematic review spanning the past 20 years (Rotenberg, Murariu, & Pang, 2016), the authors set an arbitrary goal to improve the non-adherence rate at the Sleep Center to 15%, with our telemedicine intervention. This goal was met by the TM arm at both 6-weeks (12.0%) and at 3-months (8.0%); the non-adherence rate seen by the SC arm, without the telemedicine intervention was 15.8% at both 6-weeks and 3-months. Neither was a significant improvement from baseline (Table 1). It is possible both groups showed improvement due to a Hawthorne type effect, knowing they were in a research study. Although the degree of improvement due to the telemedicine intervention cannot be determined, we do see a lower non-adherence rate in the TM arm; this may be an indication that through initial frequent telemedicine monitoring, early intervention can be conducted through support and troubleshooting, to improve non-adherence rates.

Secondary outcome measures include Epworth Sleepiness Score and apnea/hypopnea index. The ESS is used to assess the patient's subjective tendency for daytime hypersomnolence; the AHI is an objective measure to determine effectiveness of CPAP therapy. There was a significant improvement in ESS scores, from initial, for both the SC and TM arms at 6-weeks and 3-months post CPAP initiation (SC 6-week 5±3.63, $p \leq 0.00$; 3-month 6.5±4.1, $p=0.01$; TM 6-week 5.8±3.6, $p \leq 0.00$; 3-month 4.0±2.7, $p \leq 0.00$). AHI also significantly improved from initial sleep study, with CPAP use, in both arms at 6-weeks and 3-months (SC 6-week 3.4±3.5, 3-month 3.4±3.8; TM 6-week 5.5±5.0, 3-month 4.1±3.0, $p \leq 0.00$ for all). This finding is not unexpected; however, it does reinforce the efficacy of CPAP therapy in the treatment of moderate to severe obstructive sleep apnea as well the subjective symptom of daytime sleepiness associated with OSA.

Patient satisfaction is an important metric for CPAP adherence. One area of satisfaction relates to the CPAP treatment itself. Common reasons for patient non-adherence to CPAP include poor tolerance to wearing mask at night, mask leaking, and patient lack of knowledge of health benefits with CPAP use (Chiner, Adreu, Sancho-Chust, Sanchez-de-la-Torre & Barbe, 2013). When patients are more comfortable using their CPAP machine and mask, they will likely utilize it more, leading to less symptoms, and having higher satisfaction with their CPAP therapy. In this pilot study, we saw high satisfaction scores for both the SC arm (57.9% very satisfied, 26.3 satisfied) and the TM arm (64% very satisfied, 24% satisfied) (Table 3). In addition, patients in the study were satisfied with their follow-up care after starting CPAP. Between both arms, only one participant rated their satisfaction in this realm as neither satisfied or dissatisfied, all other

responses were either very satisfied or satisfied. Initial patient education and follow-care may be a key factor in the Sleep Center's overall high patient satisfaction for both CPAP therapy and follow-up care. However, high satisfaction scores may have been due to participant apprehension to indicate dissatisfaction with their CPAP or follow-up care, as the researcher was also their provider. It is not clear if the telemedicine intervention was a factor in participant satisfaction.

Although the telemedicine intervention did not result in statistically significant improvement in adherence rates compared to baseline, clinical significance should not be under appreciated.

Cost Analysis

Cost analysis and feasibility was conducted at the study site, to determine if the piloted telemedicine intervention would be appropriate for nursing staff to incorporate into their current work flow. Using data obtained during study period, it was approximated 13-14 new patients would be added to the 3-month monitoring cycle per month. At any given time, there would be 39-42 patients being monitored on a weekly basis (Table 4).

Assuming 2-3 minutes per patient for data monitoring, 78-126 minutes (1.3-2.1 hours) per week, would be spent by the nurse on this aspect of the intervention (Table 4). In addition to data monitoring, the nurse will make support phone calls to those patients whose data indicates non-adherence to their CPAP therapy. Again, using data obtained during the pilot study, nursing time spent on support phone calls will be approximately

17-33 minutes per week. In total, 1.5-2.5 hours of nursing time per week, or 18-30 minutes per day, would need to be allocated to implement the telemedicine intervention.

The monetary cost of implementing the intervention will vary depending on how many nurses will be involved and type of nursing education. The Sleep Center employees one Licensed Practical Nurse (LPN); at a rate of $15-$17 per hour. Spending 1.5-2.5 hours per week on tele-monitoring and support calls to patients, would cost $22.50-$42.50 per week ($96.75-$182.75 per month).

Although it may not appear to be a significant cost financially or in nursing time, to implement the telemedicine intervention as standard of care, including the intervention into the current nursing workflow at the Sleep Center is unlikely to occur at this time. Although it has been shown to be an effective intervention in improving patient non-adherence rates to CPAP therapy for newly diagnosed OSA patients, there currently is not adequate nursing staff available to effectively take on this added responsibility. At present, there is one LPN rooming patients for 2 providers at the Sleep Center (this can range from 30-40 patients per day). In addition to this, the returns patient phone calls, does medication prior authorizations, and monitors quality assurance (QA) tracking data for the Sleep Center's accreditation. Until additional nursing staff can be added, the manpower needed to effectively take on this responsibility, is currently not available.

Strengths and Limitations

Strengths of the study include its utilization of the IHI Triple Aim framework. This framework focuses on the core national aims of improved patient healthcare experience, improved population health and reduced healthcare costs. The intervention

outcomes are measurable with data collection through secure data received wirelessly, directly from the patients' CPAP device to a secured database and website. Benefits to the patient include improved adherence to CPAP therapy, improved quality of life and decreased risk of co-morbidities.

Limitations of the study include a small sample size (n=56), which did not meet goal of the sample size of 74 calculated in the power analysis. The sample size may have been too small to have enough power. Having a larger sample may have shown statistical improvement in CPAP adherence rates. Future studies should allow for ample time for participant recruitment and completion of data analysis. Due to time constraints, participant recruitment and data analysis had to be completed within a specific timeframe. Additionally, this pilot study only follows patients during their first 3 months of CPAP therapy, longer duration for monitoring may prove to be more efficacious to long-term CPAP adherence.

There is potential for non-sustainability of the intervention due to manpower needed to maintain intervention outside of the pilot period. Modifying the intervention to be less time consuming for nursing staff may be an option. One potential option would be use of an automated monitoring system that wirelessly receives CPAP device data. These applications can send messages to both patients and providers if use or device settings fall outside of provider customized parameters. Although these applications may save nursing time, there are added direct costs to the organization for use of the application. Considerations for alternate telemedicine interventions should account for personnel and associated costs to maintain the monitoring regimen.

Conclusion

Obstructive sleep apnea is a chronic condition, common among both men and women. OSA can potentially negatively contribute to other co-morbidities including hypertension, heart disease, stroke, diabetes and can increase the risk of motor vehicle crashes. Positive airway pressure is the standard treatment for OSA; treatment must be ongoing to effectively treat the symptoms and effects of OSA. However, treatment adherence rates are poor, with patients often discontinuing therapy early on. Initiatives to improve adherence rates are essential.

The advent of telemedicine technology has provided the ability to assist adherence initiatives. The telemedicine intervention developed for this study, improved CPAP adherence rates from baseline and compared to the standard care group, through the first 3 months of CPAP use. Although not significant in this small sample population, future studies with larger sample sizes, may further support the trend seen in this pilot study. Alternative telemedicine monitoring options should also be considered and piloted to determine utility and feasibility of automated telemedicine monitoring systems.

Nurse Practitioners specializing in Sleep Medicine may consider use of telemedicine-based monitoring for initial follow-up care in patients newly diagnosed with moderate to severe obstructive sleep apnea. Use of telemedicine may allow for early support and troubleshooting in this patient population, thereby improving non-adherence rates to CPAP treatment.

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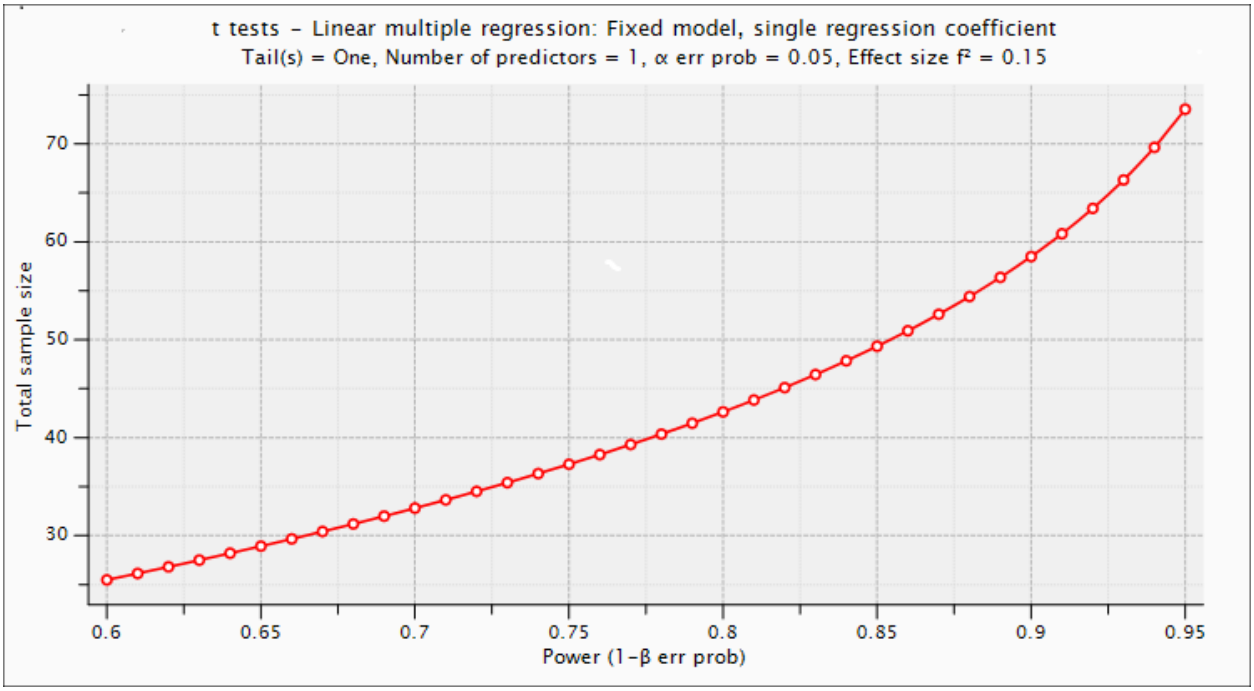
Appendix A

G*3 Power-Plot: Sample Size



Appendix B

Participant Randomization Schedule

QuickCalcs

1. Select category 2. Choose calculator 3. Enter data **4. View results**

Random numbers

Each value was randomly selected, with an equal chance of choosing any integer between 1 and 2.

Row #	A
1	2
2	2
3	2
4	2
5	2
6	2
7	1
8	2
9	2
10	2
11	2
12	2
13	1
14	2
15	1
16	2
17	1
18	2
19	2
20	2
21	1
22	1
23	1
24	2
25	1
26	2
27	1
28	2
29	1

30	1
31	1
32	2
33	2
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35	2
36	2
37	2
38	2
39	2
40	1
41	1
42	2
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44	2
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46	2
47	2
48	1
49	1
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51	2
52	1
53	2
54	1
55	1
56	2
57	1
58	1
59	1
60	1
61	1
62	1
63	2
64	1
65	2
66	1
67	2
68	1
69	1

70	2
71	2
72	1
73	2
74	1
75	1
76	2
77	2
78	2
79	1
80	1

Appendix C

Epworth Sleepiness Scale

Name: _____ Today's date: _____

Your age (Yrs): _____ Your sex (Male = M, Female = F): _____

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired?

This refers to your usual way of life in recent times.

Even if you haven't done some of these things recently try to work out how they would have affected you.

Use the following scale to choose the **most appropriate number** for each situation:

0 = would **never** doze
1 = **slight chance** of dozing
2 = **moderate chance** of dozing
3 = **high chance** of dozing

It is important that you answer each question as best you can.

Situation	Chance of Dozing (0-3)
Sitting and reading	
Watching TV	
Sitting, inactive in a public place (e.g. a theatre or a meeting)	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after a lunch without alcohol	
In a car, while stopped for a few minutes in the traffic	

THANK YOU FOR YOUR COOPERATION

Developed by Dr. Murray Johns

Image retrieved from

https://www.google.com/url?sa=i&rct=j&q=&esrc=s&source=images&cd=&cad=rja&uact=8&ved=0ahUKEwiejJPs0_DWAhUMNiYKHXuWCfAQjRwIBw&url=http%3A%2F%2Fepworthsleepinessscale.com%2Fabout-the-ess%2F&psig=AOvVaw2ksYbyG3Od8GLKmf-VG7TL&ust=1508089102678084

Appendix D

Post-Intervention Patient Satisfaction Survey

1. Please rate your satisfaction with your CPAP device/therapy?
    a. 1=very satisfied
    b. 2=satisfied
    c. 3=neither satisfied nor dissatisfied
    d. 4=dissatisfied
    e. 5=very dissatisfied
2. Please rate your satisfaction with your follow up care since starting CPAP?
    a. 1=very satisfied
    b. 2=satisfied
    c. 3=neither satisfied nor dissatisfied
    d. 4=dissatisfied
    e. 5=very dissatisfied

Table 1

Comparison of baseline and study samples

Characteristic	Baseline (n=57)	Study (n=44)	*p* value
Gender, females (%)	36.8	38.6	0.85
Age, years (mean±SD[a])	54.7±12.2	55.7±14.7	0.58
Initial weight, lbs[b] (mean±SD)	261.8±61.8	244.5±56.9	0.10
Initial ESS[c]	11.2±5.6	9.9±5.2	0.21
Initial AHI[d] (mean±SD)	43.2±26.2	38.6±20.6	0.63
Study, PSG[e] (%)/HSAT[f] (%)	9 (15.8)/48 (84.2)	26 (59.1)/18 (40.9)	0.00
Non-adherence 6 weeks, *n* (%)	12 (21.1)	6 (13.6)	0.34
SC[g]		3 (15.8)	0.62
TM[h]		3 (12.0)	0.33
Non-adherence at 3 months, *n*, (%)	13 (22.8)	5 (11.4)	0.14
SC		3 (15.8)	0.52
TM		2 (8.0)	0.11

[a] Standard deviation

[b]pounds

[c]Epworth Sleepiness Scale

[d]Apnea-hypopnea index

[e]Polysomnography

[f]Home sleep apnea test

[g]Standard care

[h]Home sleep apnea test

Table 2

Participant baseline characteristics

Characteristic	Standard Care arm (n=19)	Telemedicine arm (n=25)	*p* value
Gender, females (%)	42.1	37.5	0.68
Age, years (mean±SD[a])	51.4±13.8	60.0±14.2	0.09
Initial weight, lbs[b] (mean±SD)	244.6±51.6	240.9±60.4	0.80
Initial ESS[c] (mean±SD)	11.3±5.5	8.8±4.9	0.11
Initial AHI[d] (mean±SD)	37.27±18.8	38.0±21.1	0.86
Type of study, PSG[e](%)/HSAT[f](%)	*9(47.4)/10(52.6)*	17(68)/8(32)	0.17

Table 3

6-week and 3-month results

Characteristic	Standard Care arm (n=19)	Telemedicine arm (n=25)	*p* value
6-week ESS (mean±SD)	5.0±3.6	5.8±3.6	0.42
6-week AHI (mean±SD)	3.4±3.5	5.5±5.0	0.04
6-week days used, % (mean±SD)	96.2±5.0	96.7±6.2	0.24
6-week days used ≥4hr[a], % (mean±SD)	86.8±13.4	88.5±16.7	0.37
Non-adherence at 6 weeks, *n* (%)	3/19 (15.8)	3/25 (12.0)	0.72
3-month ESS (mean±SD)	6.5±4.1	4.0±2.7	0.04
3-month AHI (mean±SD)	3.4±3.8	4.1±3.0	0.14
3-month days used, % (mean±SD)	93.3±8.9	97.0±4.1	0.12
3-month days used ≥4hr, % (mean±SD)	83.5±15.8	89.9±13.1	0.10
Non-adherence at 3 months, *n* (%)	3/19 (15.8)	2/25 (8.0)	0.43
Survey question #1, *n* (%)			0.67
Very satisfied	11/19 (57.9)	16/25 (64)	
Satisfied	5/19 (26.3)	6/25 (24)	
Neither satisfied or dissatisfied	2/19 (10.5)	1/25 (4)	
Dissatisfied	0/19 (0)	2/25 (8)	
Very dissatisfied	1/19 (5.3)	0/25 (0)	
Survey question #2 (%)			0.68
Very satisfied	16/19 (84.2)	22/25 (88)	
Satisfied	2/19 (10.5)	3/25 (12)	
Neither satisfied or dissatisfied	1/19 (5.3)	0/25 (0)	
Dissatisfied	0/19 (0)	0/25 (0)	
Very dissatisfied	0/19 (0)	0/25 (0)	

[a]Hour

Table 4

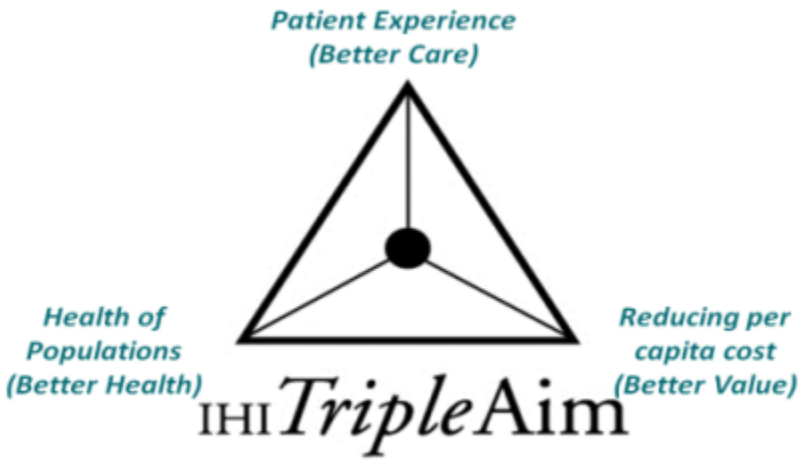
Study data and cost analysis projections

	Study data	Cost analysis projections
New OSA[a] dx, weekly (monthly)	3 (13)	3 (13-14)
Patients in weekly monitoring cycle	40	39-42
Time for data monitoring (hours)	1.3-2	1.3-2.1
Number of support phone calls needed per week	4	4-5
Number of unsuccessful phone calls per week	1-2	1-2
Time for unsuccessful phone calls per week (minutes)	1-4	1-4
Number of successful phone calls per week	2-3	2-3
Time for successful phone calls per week: 0-3 minutes: 4-6 minutes: 7+ minutes: Total:	 1-6 4-6 7+ 12-19	 1-6 4-6 7+ 12-19
Total time for phone calls per week (hours)	0.2-0.4	0.2-0.4

[a] Obstructive sleep apnea

Figure 1

The IHI Triple Aim



Framework developed by the Institute for Healthcare Improvement

Image retrieved from
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Figure 2

Participant flow through study