Telehealth Services to Improve Nonadherence: A Placebo-Controlled Study

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ABSTRACT

The objective of this study was to test whether a telehealth intervention could improve the compliance with continuous positive airway pressure (CPAP) by patients with sleep apnea. These patients had been nonadherent for the initial 3 months of therapy even after receiving the initial standard and then supplemental audiotaped/videotaped patient education for adhering to CPAP nightly. The materials and methods included a randomized testing of experimental and placebo interventions. Interventions were delivered by nurses to two groups in their homes by telehealth over a 12-week period. The placebo intervention was used to control for Hawthorne effect, time and attention influences and the novelty of having telehealth in the home. Results following the telehealth interventions were that significantly more patients in the experimental group 1 ($n = 10$) than the placebo group 2 ($n = 9$) were adhering nightly to CPAP ($\chi^2 = 4.55$, $p = 0.033$). Group 1 patients reported greater satisfaction with their intervention. However, both groups rated telehealth delivery positively. The mean cost of each 20-minute telehealth visit was $30 while the total cost of the telehealth intervention for each patient was $420. These costs included telehealth equipment, initial installation, long-distance telephone charges, nurse salary, and intervention materials. Conclusions are that telehealth interventions are a potentially cost-effective service for increasing adherence to prescribed medical treatments. Replication studies with large samples and in other clinical groups are recommended.

INTRODUCTION

SLEEP APNEA affects approximately 18 million people in the United States and is increasing as the population ages.[1] According to the National Institutes of Health, office visits for sleep disorders/apnea rose from 710,000 in 1989 to 5,288,000 in 2001, an increase of 645%.[2] This increase is the result of improved methods of diagnosing with home monitoring and the increasing prevalence of sleep apnea in our aging population and in those with neck girth obesity.[3] Obstructive sleep apnea (OSA) has been associated with hypertension and doubled rates of stroke. The most serious consequence of not adhering each night to OSA treatment includes the immediate return of apnea, which precipitates an estimated 50,000 fatal cardiac arrhythmias annually.[4,5] This leads to significantly greater (46%) cardiac deaths than

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in the general population (16%). However, in a large, decade-long study patients who adhered nightly to continuous positive airway pressure (CPAP) had the same level of fatal and nonfatal cardiovascular events as in the healthy comparison group.[6]

Recent studies found sleep apnea is related to more than 800,000 traffic accidents, 60% involving personal injury or fatality, costing $15.9 billion annually.[7,8] Notably, adherence to CPAP treatment lowers OSA patients' traffic accident rates to levels comparable to those of the general public.[8–10] Although CPAP is the treatment of choice for OSA, adherence to CPAP remains poor, with rates reported to be as low as 40%.[11,12] This study was undertaken to improve CPAP adherence with a patient population known to have low adherence. The application of telehealth in homes has been found effective for patient education and monitoring health status. This study broadens the context for the use of telehealth home services, more specifically for increasing CPAP patients' adherence to prescribed medical treatments.

Previous CPAP adherence intervention research

To date, only a few studies have reported success with interventions designed to improve CPAP adherence. A recent extensive review[12] and a Corchane meta-analysis[13] evaluated the effectiveness of interventions for adherence. These reviews found CPAP equipment manufacturer improvements such as humidification, reduction in noise, and autotitrating airway pressure have eliminated machine-related nonadherence.[14,15] Yet, the vast majority of studies using only education interventions result in little, if any, improvement in CPAP adherence. One recent study used an education videotape at CPAP initiation and found greater adherence at 1 month.[16] However, studies across the last decade have consistently found that the third month on CPAP is when the greatest decrease in adherence occurs.[12] For example, a 3-day CPAP education program, followed by 3 months of behavioral reinforcement provided by telephone still resulted in no significant improvement in adherence at 3 months.[17] Even with the addition of motivational interventions, videotape reinforcement, and telephone follow-up, there has been little gain in CPAP adherence.[18]

In contrast, one study having nurses in homes for 3 nights to provide onsite education and address patient's problems with CPAP, significantly improved adherence in 13 of 17 (76.4%) subjects.[19] Similarly, in our previous telehealth study, patients rated the CPAP problem-solving guidance as highly beneficial.[20] That study tested the capability of assessing CPAP equipment via telehealth. Results from evaluating the telehealth screen resolution found nurses were able to observe the integrity of CPAP equipment clearly and to direct the patient to correct poor CPAP mask placement. Furthermore, the telehealth microphones used were able to detect CPAP tubing air leaks.[20] Likewise, accurate measurement of patients' digital oximetry and vitals signs was found equally as reliable as the nurse present in the home during data collection. An earlier descriptive study found 26 commonly repeating but treatable problems that resulted in poor CPAP adherence. Each was addressed in this study, using the advantages of telehealth audio/visual interactions.

Telehealth was deemed to be a potentially important service for assisting patients in improving adherence; even after initial standard and then supplemental education had failed to maintain adherence over 3 months. The framework guiding this study was based on classic adherence theory verifying that education, reinforcement and notably the guided and repeated use of a prescribed health therapy (in this case CPAP) leads to daily habits of long-term adherence.[22,23]

MATERIALS AND METHODS

The objective of this random placebo-controlled study was to determine if patients who were nonadherent during their first 3 months of CPAP, would increase adherence after 12 weeks of weekly in-home telehealth sessions. All subjects in this study had been given initial standard patient education about the CPAP equipment and its nightly prescription. This was followed by supplemental reinforcement

at 2 and 4 weeks about nightly adherence via audiotape/videotape education.

After the University of Kansas Medical Center's Institutional Review Board approval, the random assignment process began. Subject criteria were patients with new OSA diagnosis, first CPAP prescription, initial and supplemental CPAP education, and nonadherence to CPAP for 3 months. All patients meeting study criteria were invited to participate. The purpose and procedures of the study were explained to the patients and all agreed to participate by signing informed consent. Nurses familiar with clinical trial research and CPAP care were trained to administer the interventions via telehealth equipment according to the structured study protocols.[20]

Design

A randomized, placebo-controlled research design was used. Group 2 intervention was used to control for the potential influence of the novelty of having telehealth in the home,[24] and to equalize the Hawthorne effect of "being observed" through telehealth. Also, group 2 intervention was designed to mimic the group 1 intervention by having the same number of telehealth visits, using the same research procedures and data collection schedule as well as the same telehealth equipment.[25]

The only difference between group 1 and group 2 was that the content of Group 2 stressed the importance of daily vitamin intake from meals (a neutral health topic) but not daily CPAP use. The placebo is an important research design feature, as study results are often criticized because the outcomes could be the result of the novelty of being observed or the increased time and attention from nursing staff, rather than the actual telehealth intervention itself.[25,26]

At the end of the telehealth visits, patients were asked to complete a confidential satisfaction questionnaire about the intervention and their opinions on the telehealth transmissions.[27] Patients received $50 for participation.

Sample

All subjects agreeing to participate were patients newly diagnosed with OSA, prescribed CPAP for the first time but who had been nonadherent across 3 months, even after initial education on CPAP use and supplemental audiotaped/videotaped reinforcement at 2 and 4 weeks. Nonadherence was measured according to the American Academy of Sleep Medicine task force report as: recorded as less than 4 hours of CPAP use per night for fewer than 9 of 14 consecutive nights' use.[28] Of the 19 subjects enrolling, 10 were randomized to group 1 and 9 to group 2.

Equipment

The telehealth equipment used was manufactured by 8 × 8, Inc. (Santa Clara, CA). These telehealth units are equipped with small, built-in two-way cameras that allow the nurse to see the patient at home and the patient to see the nurse. The unit weighs 2.75 pounds and was easily installed by the nurse when delivered. The telemonitor modem transmitted the telehealth audio and video signals via single telephone line at 15 frames per second. This speed creates a 2- to 3-second delay between speech and reception. This equipment was selected for its technical reliability, portability, and the low cost per unit ($300.00).[29] The telehealth units used in this study were connected through the home residential telephone line.

Intervention and research protocol standardization

Standardized research protocols were used to administer each of the telehealth sessions to all subjects. Thus, the interventions were delivered uniformly even though the content in the telehealth sessions was distinctly different for group 1 and group 2. Sessions were scheduled three times during the first week and then once per week for the next 11, for a total of 12 weeks. The scheduling of the 3 sessions during the first week allowed patients time to become comfortable with telehealth in their homes. The 12-week administration period was based on the minimum time frame considered necessary to firmly establish habitual health treatment behavior.[30] Each telehealth visit was designed to be completed in 30 minutes or less. The telehealth nurse sessions were standardized to be the same across both groups, except for content

taught, as described below and compared in Table 1. The protocols for standardizing the sessions are available upon request.

Group 1 telehealth intervention session content: CPAP every night

Group 1 consisted of short, two-way telehealth sessions between the patient in their home and the research nurse for a period of 12 weeks. The three telehealth sessions during the first week were directed at reinforcing nightly, bedtime routine for CPAP. After standardized protocols, the nurse visually assessed the patient, guided correct CPAP routine, and determined whether the CPAP mask fits properly. The nurse described consequences of nonadherence and how to manage barriers to CPAP use (e.g., how to manage dry throat and adjust CPAP equipment). The benefits of nightly CPAP use on general health were emphasized.

During the remaining weeks, home telehealth sessions were held once per week using standardized content guidelines with time for responding to patient's concerns. These remaining intervention sessions consisted of demonstrating and practicing how to manage common problems in CPAP (e.g., how to clean the tubing). Nurses also instructed patients on simple problem-solving checklists to use when new problems arise. During the last two visits the nurse had the patient demonstrate how to manage the barriers to CPAP use that they had repeatedly experienced and counseled them on ways of overcoming other common nonadherence factors. The nurse also emphasized long-term use of problem-solving checklists.

Group 2 telehealth intervention session content: vitamins every day

Group 2 was formatted using protocols that paralleled the experimental intervention and followed the same 12-week, short telehealth session schedule. This intervention provided information on a neutral health topic (i.e., the importance of daily vitamin intake) which mimicked the materials/activities in group 1 (Table 1). The consequences of vitamin deficiencies and symptoms of deficiencies were also discussed. The same, simple problem-solving approach as in group 1 intervention was provided. However, the checklist content listed methods to overcome barriers to obtaining optimal daily levels of vitamins with proper meal planning. Expert dietitians reviewed the vitamin content for accuracy.

Outcome measurements

The adherence outcome measurement comes from subjects' CPAP ventilator timer-recorder. Also described below is the patient satisfaction survey about their intervention and their opinions about telehealth transmissions.

Adherence. The definition of adherence was 4 or more hours per night of CPAP use for at least

Table 1. Group 1 and Group 2 Intervention Materials/Activities

Experimental (group 1)	*Placebo/vitamin group (group 2)*
Review of CPAP problem-solving video	Review of vitamin video
Telehealth instructions for CPAP bedtime routine	Telehealth instructions for mealtime vitamin-monitoring routine
Week 1–3 visits, next 11 weeks 1 visit	*Week 1–3 visits, next 11 weeks 1 visit*
CPAP benefits pamphlet	Vitamin benefits pamphlet
CPAP problem solving diary & checklists	Vitamin problem solving diary & checklists
Visual motivational handouts	*Visual motivational handouts*
Proclamation for nightly CPAP use	Proclamation for daily vitamin intake
Consequences of untreated OSA	Consequences of vitamin deficiency
Mnemonic reminder placards	Mnemonic reminder placards
CPAP checklist and reminder	Vitamin checklist and reminder
Top 10 principles for CPAP use	Top 10 principles for vitamin use
Consequences checklist	Consequences checklist
Anonymous evaluation	Anonymous evaluation

CPAP, continuous positive airway pressure; OSA, obstructive sleep apnea.

9 of 14 nights. This is an 80% use rate that has been considered effective in OSA.[28] Data from patient CPAP timer-recorders were used to classify subjects as adherent or nonadherent (below 4 hours per night or fewer than 9 of 14 nights of CPAP use).

Patient satisfaction survey. The patient satisfaction questionnaire elicited patients' rating of the helpfulness of the telehealth visits.[27] Questions were asked about the clarity of the telehealth transmission (e.g., their ability to understand what was being shown and to ask questions). Also all were asked if they found the telehealth visits to be an intrusion on their privacy. Patients also evaluated the quality of the nursing contact over telehealth. They were asked to compare the telehealth nurse's understanding of their health problems and whether it would have been better if nurses had visited in person. This survey asks patients to evaluate their experiences with previous face-to-face home visits compared to the telehealth sessions used in this study.

Data analysis

The χ^2 statistical test was used to compare the numbers of adherent patients between the two groups. The *t* test statistical analysis was used for comparing two groups on mean scores to detect any differences in age and severity of sleep apnea between these two groups. The percentage of responses on the anonymous patient satisfaction survey was calculated. A research nurse, blinded to the study, summarized comments from the survey evaluation using written data analysis methods or content analysis.[31] Traditional cost accounting methods were used to tabulate costs, including telehealth equipment, travel costs to install the telehealth, nurse salary, mailing expenses, and telephone charges.

RESULTS

Group 1 and group 2 were compared using two group *t* test statistics to assure there were no between-group differences. Mean ages of the two groups did not differ. Patient ages ranged from 50 to 83, with a mean of 63 ± 7.95. All patients' respiratory distress index (RDI) scores were all in the severe range with scores not differing significantly between groups 1 and 2 (t test = 0.737, $p = 0.471$). These results indicate there was no significant difference between group 1 and group 2 on age or severity of sleep apnea. Thus, age or severity of sleep apnea did not influence outcomes of adherence.

CPAP Adherence

A higher percentage of group 1 than group 2 subjects were adhering to CPAP after the telehealth interventions ($\chi^2 = 4.55$, $p = 0.033$). Specifically, 90% ($n = 9$ of 10) of group 1 compared to 44% ($n = 4$ of 9) of group 2 subjects were adherent after the telehealth sessions. Based on the proportional difference between groups the telehealth sessions had a moderate to large positive impact on adherence (as seen by the statistical analysis of effect size, $\phi = 0.45$).

Telehealth sessions

Sessions ranged from 15–30 minutes (mode, 22 minutes). The total number of telehealth sessions in the study was 261 and there were only 3 episodes of transmission problems, each easily corrected. One of group 1 patients' truck driving occupation stopped him from having a regular weekday for each telehealth session, but all telehealth sessions were completed. One patient in group 2 canceled one of the three sessions scheduled for the initial week.

Details of CPAP equipment were clearly visible through the telehealth screen, including putting the CPAP tubing together, checking mask fittings, listening for air flow, performing equipment cleaning, and machine maintenance. All patients rated the telehealth monitor as easy to use. All subjects rated it easy to ask the nurse questions, understand what the nurse was saying and indicated that the materials projected to them over the telehealth monitor were clearly seen.

Patient satisfaction survey responses

One patient in group 1 and one patient in group 2 did not return the evaluation survey,

the remaining satisfaction questionnaires (n = 17) were summarized. The majority of both groups (100% group 1 versus 75% of group 2) rated the telehealth sessions positively. Fewer patients from group 2 (62.5%) than group 1 (100%) indicated that the telehealth sessions helped them learn how to problem solve. Most patients in both groups (87.5% group 1, 75% group 2) rated the length of the sessions as appropriate. One group 2 patient rated, on the survey, that telehealth had been an intrusion on privacy; however, no written comment was given about this concern. Group 1 patients (100%) rated that their care would not have been different if the nurse visited in person. In contrast, two group 2 patients (22.2%) indicated preference for face-to-face visits.

Written comments in satisfaction survey

Comments written by patients were summarized. The majority of patients gave positive comments, "With telehealth you don't feel alone, and your confidence increases. Trust is very important. It's real to see [the nurse]." A group 1 patient wrote, "It means so much to have you [the nurse] to talk to about the way I feel—there are so many emotions with this CPAP." "The first 3–4 [of CPAP] weeks are scary," described another. "It is [CPAP] confining, a forever thing . . . you realize it is a serious condition and there are a lot of emotions."

Comments on the quality of the nursing relationship and communication over the telehealth were overwhelmingly positive. All patients in both groups rated personal contact with their nurse over telehealth as good. In group 2, patients commented positively about the nursing relationship, "I have a nurse I can count on and talk to," one patient commented. "I'm sad it is over," wrote another. However, one group 2 patient stated, "I would have preferred a personal visit" but "telehealth is the next best thing." Another group 2 patient wrote, "It [telehealth] was not for me—but may have been helpful to others."

Cost of the telehealth intervention

The cost of each telehealth monitor, including installation in the home was $300 per unit. The remaining intervention costs included the intervention education materials and survey mailings. Telephone charges for conducting one telehealth session averaged $9.52 (mean = 20 minutes, 3-cent per minute). The nurse was compensated $25.00 per hour to administer the intervention. The total cost of the 14 telehealth sessions for 1 patient was $420, or $30.17 per session. No costs for equipment refurbishment or sterilization were included in this cost analysis. Such costs vary with the type of teleheath equipment.

DISCUSSION

This study confirms that a structured telehealth service has potential to improve CPAP adherence. There were significant advantages of using this telehealth service that allows for nurse guidance of problem-solving strategies, visual equipment evaluation and for measuring the patients' nightly adherence. Being able to direct the patient in problem-solving to overcome common barriers to nightly use was judged a key factor facilitated by telehealth. In addition, nurses were able to see barriers to adherence in the home that patients were unaware of. For example, nurses identified that patients who had equipment near cold air ducts complained of chilling and that cold dry air could be drawn in through the machine. This was easily seen and corrected with resulting improvements in adherence.

It is also likely that the effectiveness of this intervention was related to the telehealth sessions lasting over 12 weeks. The framework for this study indicates that adherence to prescribed health treatments diminish, unless these are reinforced and practiced over time, so that a habit of daily use is established. Extensive data indicate that habits are typically acquired after consistent use over the 12-week study period.[30] In addition, barriers to CPAP adherence can be expected to recur across time, so patients' problem-solving ability will need to be reinforced over several weeks.

This study suggests that the visual aspects of telehealth are advantageous for reinforcing adherence. This aligns with previous study results that found it was technically feasible to evaluate CPAP equipment using this low-end telehealth equipment.[20] There was universal agreement in both subject groups indicating

patients felt a good sense of personal contact with the nurse and that telehealth did not diminish the nurse's ability to understand their health problems.

Although the sample size was small, the difference in the proportions between the two groups was statistically significant at the level of a moderate effect ($\phi = 0.45$). Also, comparison to a placebo control group indicates that the effect was due to the intervention and not the novelty of being observed or additional time/attention with the nurse.[32] Yet, power should be increased by conducting studies with larger samples to confirm these findings. Therefore, these conclusions are limited to this study and can not be generalized without replication of findings in larger studies.

Using the least expensive equipment, the 14 telehealth sessions for a single patient in this study cost $420. This amount is much lower than the typical $1,500 that would be charged for the same number of face-to-face nurse visits (including travel expenses). Also, compared to the cost of a single hospitalization for a complication resulting from poor CPAP adherence, this telehealth intervention meets the criteria of cost-effectiveness.[33] Furthermore, Medicare and Blue Cross-Blue Shield are calling for studies using telehealth to improve patients' adherence to their prescribed medical regimes.

This study broadens the context for extending telehealth services for increasing adherence to prescribed medical treatments. Telehealth represents a potentially cost-effective method of routine clinical follow-up, a way to visually illustrate problem-solving and for providing support for long-term adherence. Notably nonadherence is a significant, costly and universal problem in all chronic illness management.[34] Future research should test other telehealth delivered adherence interventions in larger samples. Telehealth services are a promising option for delivering adherence support that is critical to management of all chronic illness.

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