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Patient Education Combined in a Music and Habit-Forming Intervention for Adherence to Continuous Positive Airway (CPAP) Prescribed for Sleep Apnea

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Abstract

Objective—As many as 50% of patients diagnosed with obstructive sleep apnea stop adhering to the prescribed medical treatment of CPAP (Continuous Positive Airway Pressure) within one to three weeks of onset. Thus, a theory based intervention using music to support habit formation was designed to improve CPAP adherence at onset. The intervention materials included directions for CPAP nightly use, a diary for recording nightly use and writing about CPAP benefits or problems. In addition, an audiotape with softly spoken instructions for placing the CPAP mask comfortably, using deep breathing and muscle relaxation along with the slowly decreasing music tempo was provided to listen to at bedtime each night.

Methods—Effects of this music intervention were tested in a randomized, placebo-controlled trial of 97 patients with 53 males (55%) and 44 females (45%). Moderate to severe apnea/hyponea scores (per sleep laboratory data) and medical diagnosis of OSA were required for study inclusion.

Results—Compared to placebo controls, a greater proportion of experimental patients were adhering ($\chi^2=14.67$, $p<.01$; a large difference, $\Phi=.39$) at the end of the first month of CPAP onset. There were no differences in CPAP adherence at 3 ($X^2=.065$, $p=.79$) and 6 ($X^2=.118$, $p=.73$) months. Patients' diary data and satisfaction survey results indicated the intervention was rated as helpful and guided formation of a relaxing, habitual routine of CPAP nightly use.

Conclusion—The intervention had a strong effect for improving adherence to CPAP at 1 month.

Practice Implications—Adherence at the onset of treatment is critical and the audio music intervention was easily administered. Other interventions that target problems interfering with longer-term CPAP adherence are needed.

Keywords

habit; adherence; noncompliance; CPAP; sleep apnea

1. Introduction

Obstructive sleep apnea (OSA) occurs due to collapsing tissues in the throat with repeated cessation of breathing, lasting greater than 10 seconds and having blood oxygen desaturations 3% below the patients' awake level. OSA affects millions of people in the United States and is escalating worldwide, especially in aging populations [1]. Each apneic episode (as many as 200 every hour) causes immediate sympathetic nervous system stimulation that results in gasps to open the closed throat. This repeated sympathetic stimulation has effects across the body and is associated with long-term cardiovascular and neurocognitive sequelae, such as hypertension, strokes and approximately 50,000 nighttime cardiac arrests annually [2–3]. In addition, European and North American studies have found that persons with untreated OSA have significantly greater health care costs, including 2.8 times more hospitalizations and twice the number of physician visits than those adhering to treatment [4–6].

The most common, medically-prescribed treatment for OSA is Continuous Positive Airway Pressure (CPAP). This treatment is a portable device that delivers positive pressure airflow through a small, anesthesia-type nose or face mask during sleep. This positive airflow maintains patency of the narrowed pharynx and sleep-relaxed throat muscles, thus preventing the obstruction that causes apneas. CPAP eliminates apneas and has known effectiveness in preventing the severe health sequelae of sleep apnea [2,7]. It is recommended that CPAP be used nightly and even during daytime naps [8–10]. Yet, CPAP has poor adherence that is frequently reported as low as 50% [11]. Annually, 20–30% of persons prescribed CPAP stop using the device within the first two weeks of treatment and another 20 to 30% stop use by 6 months [12,13]. Adjustment to the tight fitting mask, relaxing getting used to having the positive air pressure and routinely using CPAP each night are challenges to those newly prescribed this therapy. An onset intervention should be designed to address these problems that lead to stopping CPAP or poor nightly adherence during a patients initial month of use.

1.1. Serious Consequences of Non-Adherence to CPAP

Adults with even mild OSA (less than 5 apneas occurring every hour) experience greater incidence of serious cardiac arrhythmias, hypertension, strokes, myocardial infarctions and mortality [14–17]. Notably the majority of patients with OSA have 20 to 200 apneas every night [3]. Also, national transportation statistics indicate that individuals with untreated sleep apnea have seven times more automobile accidents with 60% involving personal injury or fatality [18–19]. In contrast, with adherence to nightly CPAP, which eliminates sleep apneas, individuals have traffic accident rates no higher than those of the general public [20–21].

Seminal research reviews concluded that there were no significant differences between adherent and non-adherent CPAP patients with respect to age, gender, severity of sleep apnea, type of mask or the prescribed air pressure level [22,13]. However, being unable to adjust or to relax while using the CPAP device has been identified as a common and repeating cause of non-adherence to CPAP [23]. Clinical trial research has found that patients' who have a nurse come to their home to instruct them to use the CPAP routinely improved subsequent CPAP adherence [24]. Self-efficacy, social cognition and other psychological theories have been associated with adherence via increasing patients' knowledge, treatment commitment and

motivation for CPAP nightly use [25–27]. Nurses in home settings have intervened to improve CPAP inhalation ease, mask fit comfort, identify stressors, point out benefits and decrease CPAP side-effects [28]. However, the cost of having a nurse, respiratory therapist or even an aide in the home is prohibitive.

1.2. Use of Music Education to Repeatedly Guide CPAP Use Can Lead to Habitual Adherence

Using a music-based audiotope, patients can be provided with repeated, step-by-step instructions which guide arrangement of the equipment, the nightly CPAP bedtime procedures and assist them relax into sleep. Thus, a music based audiotope might assist patients by providing pleasant, restful back ground music supporting relaxation during their first CPAP onset. The audio tested in this study was carefully developed to include clear professional voiced and softly spoken instructions to guide comfortable CPAP mask placement and breathing with the CPAP positive pressure air flow. The instructions included guidance for major muscle relaxation and slow quiet deep breathing while the music tempo across the audiotope slowly reduces as natural sleeping heart rate does. Softly spoken messages on the audio also emphasize developing a nightly CPAP routine to encourage patients to continue their prescribed treatments.

Also music selected to accompany the spoken instructions was rated during development as more pleasing to patients than just a person reading these instructions. Music has been shown to increase relaxation and can soothe patients as they begin new health care treatments [29]. Listening to music with repetitive lyrics positively improves memory and health habits to the same degree (large effect) as daily treatment reminders [30–31]. Cognitive improvements, increased attention to tasks, reduced distractibility and anxiety also have been associated with music-based interventions [32–33]. The combination of step-by-step audio instructions with music for daily CPAP routines can guide behavior so that it becomes repeated and habitual.

1.3. Conceptual Framework

The Triandis Theory of Behavior [34] tenet is that adherence at onset of treatment emerges from knowledge of the consequences of non-adherence and from practicing repeated health treatment behaviors which then become habitual [35–37]. Researchers using Triandis Theory have empirically-verified that following routines which guide treatment use and sensitizes patients to benefits and non treatment risks result in adherence [38–39]. Thus, it follows that an intervention which informs patients about CPAP benefits, consequences of non-adherence and guides a habitual routine of relaxation and nightly CPAP use with soothing music would result in adherence (defined as using the CPAP device per accepted standard guidelines).

2. Methods

A placebo control, randomized study was used to test effects of this habit intervention on CPAP adherence. The placebo control patients were compared to the experimental group of patients who received the CPAP habit intervention. A placebo control intervention was designed to mimic the experimental intervention to ensure that any differences between groups was due to the intervention content and not just the novel approach (e.g., audio music) or extra time and attention associated with the study [40]. The placebo control intervention included the same audio-based, habit-promoting components as the experimental intervention except that the placebo content focused on a neutral health topic (routinely having the correct daily vitamin intake from food).

Table 1 illustrates that the experimental and placebo control intervention components are comparable in both materials and in time involved but distinct in educational content. Expert sleep specialists familiar with CPAP and a dietitian expert in vitamins both reviewed respective

intervention content. All materials were prepared using patient education quality control guidelines [41]. Prior to the study, several nurses not involved in this study rated materials as meeting the quality criteria for patient education. For research design consistency, the placebo control intervention was implemented using the same research procedures and the same data collection schedule [42].

2.1. Experimental and Placebo Control Interventions

2.1.1. The Habit-Promoting Experimental Audio Intervention: CPAP Every Day

—The CPAP intervention packet called, “Get In the Habit of CPAP Every Day,” included audiotaped music along with softly-spoken directions for using CPAP nightly. The sleep-inducing audio music entitled, “Building a Routine for Sleep Time.” The audio music guided patients in preparing the CPAP machine at bedtime and in creating a relaxing environment in congruence with music and lyrics. The 20-minute audio provides instructions for putting on the CPAP mask comfortably, correctly connecting air hoses and relaxing despite the ventilation equipment positive air pressure and noise. The audio first instructs the patient to practice breathing in deeply and then exhaling slowly for relaxation. Next, the patient is guided to relax his or her muscles slowly from toes to head, using repeated reminders for slow, deep breathing and spoken images of long restful sleep (e.g., “feel the gentle air pressure slowly filling your lungs”) to sensitize patients to CPAP benefits. The gradually decreasing music tempo induces relaxation by slowly reducing the rhythms to a typical resting heart rate cadence.

The intervention packet had informational handout sheets, CPAP use reminder placards and a 4-week diary for recording CPAP use. The diaries have pages for recording audio use and writing about their experiences with CPAP. Handouts in the packet list the health consequences of not using CPAP, such as the high risk of stroke and heart attack, falling asleep while driving, poor functioning on work activities due to sleepiness, or missing out on social activities due to fatigue or tiredness and an audio disc, including music that relaxes patients into sleep. Materials also provided information about benefits of adherence (increased alertness, energy for activities, less irritability). Thus, the intervention integrated CPAP benefit and non-use risk information, music relaxation and habit-promoting instructions as a guide to routine nightly use of CPAP [43–44].

2.2. The Placebo Control Intervention: Vitamins Every Day

This placebo intervention was used to mimic the daily activities in the experimental treatment condition including an audiotape. And the placebo packet information handouts are the same format and length but contain content on the neutral health topic of daily vitamin intake from meals. The reminder placards and 4-weekdiary were the same format except instructions were for writing about daily vitamin intake from food. Thus, this placebo controls for the time patients implement the intervention each day and the “attention” from the nurses administering the intervention.

The placebo control intervention packet, called “Get in the Habit of Daily Vitamins in Your Diet,” includes audio with spoken information about vitamins, colorful handouts with checklists of foods that contain specific types of vitamins and a daily diary. The vitamin intervention information, diary pages and the vitamin audio music are formatted identically to CPAP habit materials. This audiotape includes a definition of vitamins, an explanation of what vitamins do in the body, and information on Recommended Daily Allowances. Handouts provided information on the consequences of vitamin deficiencies or not having vitamins regularly in the diet and symptoms to report.

2.4. Sample

Inclusion criteria allowed enrollment of patients who had received a first-time medical diagnosis of OSA. Specifically patients were enrolled with an Apnea/Hypopnea Index (AHI) of 20 or greater. The AHI is the number of breathing pauses (or apneas) and the number of breathing slowdowns (hypopneas) per hour of sleep, obtained in a full sleep laboratory polysomnographic exam. Subjects had a first-time prescription for CPAP device with built in autotitration, set at the prescribed (sleep lab determined) pressure with a “smart card” for recording nightly CPAP use. Also patients were at least 18 years old or older, and had signed an informed consent for this study. Patients (n=7) were excluded due to positive screening for drug or alcohol abuse (which interferes with sleep) and 1 for depression requiring hospitalization.

Patients’ age ranged from 50 to 83, with a mean age of 63.4, SD= 7.95; 53 (55%) were male and 44 (45%) female. Table 2 reports demographics of age, gender, marital status, education and employment. There were no differences in these demographics between groups.

Table 3 indicates there were no differences between the experimental and placebo control groups on mean AHI scores or among categories of OSA severity. There were no group differences on clinical characteristics of subjects. Clinical characteristics included the presence of other chronic illnesses in addition to their OSA, their mental and physical health status, depression and Body Mass Index (BMI) scores.

2.5. Procedure

Following Institutional Review Board approval, patients receiving care from two large sleep laboratories were invited to participate; by nurses who had no knowledge of group assignment. Patients were randomly assigned to the intervention (n=55) or the placebo control group (n=42) using computerized random assignment program. All patients received the usual care which was the patient education normally provided by their CPAP sleep laboratory personnel. This included a pamphlet describing sleep apnea in general with limited information on OSA and demonstration of the CPAP equipment that would be delivered to their homes.

Patients were also taught to send in the small plastic “smart card” (the size and shape of a credit card) that slipped into their CPAP machine. These cards held computer chips that recorded the hours the pressure sensor timer indicated the mask was securely in place and the CPAP machine was turned on and providing positive airway pressure. Trained personnel used a software program to obtain nightly CPAP use of > or < 4 hours at 1, 2 and 6 months from these data cards. These personnel were blind to allocation of treatment.

Following signing of consents patients were contacted by a research nurse. Our research nurses were trained to administer either the study experimental or placebo control interventions according to research protocols over the telephone. During the telephone administration of each intervention patients were asked to follow along with the instructions and the intervention packet materials, which had been mailed to them prior to the telephone session.

Nurses instructed the experimental patients to listen to the music audio with softly spoken instructions, when they first went to bed and turned on their CPAP machine. Nurses directed the placebo control subjects to listen to the vitamin audio prior to the evening meal.

All patients were instructed to write in their diaries every day for 4 weeks. Patients were given pre-paid, addressed envelopes for returning the completed diary pages to the research center. Research nurses contacted patients by telephone monthly reminding them to use their respective intervention, write in their diary and return their diary pages by mail to the research center. These nurses were blinded to the data and evaluations subjects mailed in.

All patients evaluated their satisfaction with the CPAP or placebo control intervention using an anonymous survey. All patients in both groups received a \$50.00 honorarium for participation. None of the patients were offered any funds, nor did they ask for funds, to cover costs of their CPAP equipment.

2.6. Measures

2.6.1. Adherence—The definition of adherence to CPAP (4 or more hours per night and at least 9 of each 14 nights of ventilator use) which is based on the American Association of Sleep Disorder standards for CPAP use was measured by a ventilator timer-recorder [4]. Data from patient ventilator-timer recorders were used to classify patients as CPAP adherent or non-adherent at 1, 3 and 6 months. The CPAP nightly use data were collected to differentiate between onset (1 month) and longer term (3 and 6 month) adherence rates.

2.6.2. Written Diary Data—Patients' were asked to write briefly in a diary daily on topics related to uses of their respective intervention. Each diary had a four-week calendar with weekly checklists for recording their audio use and written comments. For example, many experimental subjects wrote about using the audio music to relax while the placebo control group wrote about information they had heard about vitamins.

2.6.3 Clinical Characteristics Measures—The SF-12 health survey was completed by all subjects to compare the groups on health status. The SF-12 is a shorter version of the internationally used 36-item short-form (SF-36) health survey. The 12-items in the SF-12 are summarized as 2 scores: a physical health score and a mental health score. This instrument does not yield a total score. The physical scale includes role limitations due to physical health problems, bodily pain, and general health. The mental scale reflects vitality, social functioning, role limitations due to emotional problems, and mental health (psychological distress and psychological well-being). Based on results from the international populations both scales yield a standardized mean score of mean=50 and SD=10. Higher scores indicate better health status. Also subjects' chronic illness history was used to compare the groups on the number of their co-morbid conditions.

Depression was measured using the CES-D, a standard screening instrument developed by NIH and used worldwide. There are population based and well established norms of scores on CES-D for levels of depression from mild to severe. Depression associated with sleep disorders such as OSA is common. Symptoms of depression include inability to concentrate, poor appetite, restless sleep, lack of hope, fearfulness, low mood, sadness, crying for unknown reasons, and/or not feeling valued. Sleepiness can often mask the symptoms of depression related to with recurrent episodes of fatigue.

2.6.4. Patient Satisfaction Survey—The patient satisfaction survey questionnaire was used to elicit patients' ratings of the helpfulness and usefulness of either the vitamin or the CPAP habit intervention. Patients rated if completing the one month diary/checklist was bothersome. Patients were asked to rate the instructions in their audio interventions. Specifically, study patients were asked if their respective intervention instructions helped them to make a routine of nightly CPAP use (experimental group) or of daily checking their vitamin intake from food (placebo control group). Patients were also asked whether they would continue the interventions after the first month of using the diary/checklist and audio. This type of intervention evaluation survey had been previously tested and rated as valid by an expert panel [39].

2.6.5. Data Analysis—Analysis for comparing the frequency of subjects' CPAP adherence between the experimental and placebo groups were completed using chi-square with strict .01

level of significance for each of the three times that adherence was measured at 1, 3 and 6 months. Content analysis was used to summarize patients' written comments from intervention diaries [45]. A research nurse, not involved with the clinical trial, tabulated data from the anonymous evaluation survey about patients' satisfaction and summarized comments about the interventions found in the written diaries.

3. Results

3.0 Comparisons of Subject Demographic & Clinical Characteristics by Group

Baseline demographic (age, gender, education, marital and employment status) did not vary across groups (table 2). These subjects were typical of many CPAP populations being older (M=63 years), majority male and married with high school education. Likewise, none of the clinical characteristics (table 3) of the subjects were significantly different between groups.

Specifically, these subjects had moderate and severe AHI scores, depression scores across all ranges including moderate to severe and Body Mass Index categories all above normal. Mean AHI did not indicate one group had greater sleep apnea severity than the other.

Mean mental and physical status scores did not vary between groups. These subjects' mental health scores aligned with internationally established norms. However, both groups had mean physical condition scores were 11 to 12 points below the international norm score of 50. This sample having low physical condition scores likely reflects the severe fatigue and the multiple chronic diseases afflicting these patients with sleep apnea. These characteristics were consistent with other reported CPAP populations.

3.1. CPAP Adherence

More intervention group (89%) than placebo control (55%) subjects were adhering to CPAP one month after the habit intervention was given ($\chi^2 = 14.67$, $p < .01$). This represents a large, between group difference of 34% which calculates to a large effect size or Phi score of .39. This difference indicates a strong effect from CPAP habit intervention at 1 month. However, there were no differences in adherence between the groups at 3 months ($\chi^2 = .065$, $p = .79$) or at 6 months ($\chi^2 = .118$, $p = .73$) using intent-to-treat analyses. Table 4 lists the numbers of patients adhering at each time. This table lists drop-outs from the groups who were not adhering, stopped CPAP or were lost to contact (none at 1 month, 2 from the experimental and 1 from placebo at 3 months and 11 from the experimental and 13 from the placebo at 6 months).

3.2. Intervention Audio Music/Diary Use

All patients completed the 4 week diary checklist. For both groups, patients checked they had used the audio on average for 2 weeks, with the experimental (SD= 2.3 weeks) and placebo control (SD= 2 weeks). The reported use between groups was not statistically different ($p = .314$).

3.3. Written Themes in Diaries and Comments about the Interventions

Topics most often written about in experimental patients' diaries were coded into 3 themes: CPAP problems, importance of relaxing, and little perceived CPAP benefit. The majority (N=89%) of the experimental patients rated themselves as "very relaxed" after listening to the CPAP audio music. One patient who rated himself as "not being relaxed" by the audio music stated that the music kept him awake. A few subjects reported and that their family members (n=6) used the audio music to relax themselves to sleep. Some patients recommended having the audio come with various types of music (e.g., country, soft rock, classical).

The most common reasons written about using the intervention were categorized as “the checklists helped make a good routine,” that the diary “is a good record to look back over” and “the music is relaxing.” In terms of CPAP benefit, it was noted from diaries that the majority took at least two weeks to begin to check that they “felt less fatigued” during the day, with 3 patients stating, “I would have quit this machine if it wasn’t for the music tape.”

The most common reasons written about using the placebo intervention was that “the instructions” or “the nurses asked me to do this.” The topics most frequently occurring in placebo control patients’ vitamin diaries were coded into three common themes: expense, time and family. Specifically, written were: “vegetables/fruits are costly” and family “won’t always eat them”. It was time consuming to “really think” and “add up” vitamins in food. Patients wrote that getting into the routine of “checking daily intake” or “adding up the recommended amounts of vitamins” in food is “not easy.”

3.4. Patient Intervention Satisfaction Anonymous Survey Responses

The majority of all patients (76.8% of experimental and 68% of placebo control) rated their respective intervention as helpful and the information given in the audiotape and handouts as useful. However, more of the placebo control patients (45%) than the experimental patients (14.5%) indicated that using the intervention every day was “bothersome.”

All experimental patient ratings (100%) indicated that use of the audio music helped them relax for sleep of using CPAP every night. However, only 24.8% of the experimental patients indicated they would use the audio music beyond month one. While only half (12%) that many placebo control patients indicated they would continue to use the vitamin audio tape after the first month.

Notably the majority (73.8%) of experimental patients indicated that the softly spoken instructions in the audio helped them “get into the routine” for nightly CPAP use. And again many fewer (34.4%) placebo subjects indicated the instructions listened to in the audio at meal time helped them get into a routine for checking their daily vitamin intake from food.

4. Discussion and conclusion

4.1. Discussion

The audio music intervention guiding the habitual use of CPAP was acceptable to patients and led to 89% of experimental patients adhering at 1 month of CPAP treatment. National guidelines state that between 70 and 85% is the highest likely, achievable adherence rate for CPAP use at 1 year [11,12]. This intervention helped patients establish CPAP routine and had a strong effect on adherence at 1 month [46]. Research on health habits reveal the initial stimulus that is used to initiate a new health behavior is rarely needed after the habit is established [47]. And habits are established by some persons very quickly, on average within two weeks but longer or never for others [48].

However, only one-quarter of the experimental patients indicated they would use the audio music after one month. Only 12 % of placebo patients indicated they would use their audiotape after 1 month. Possibly for the experimental patients, the supportive soothing instructions on the tape had already reinforced the nightly routine for CPAP use; but listening to the same music became too repetitive. Although the standard music on the audiotape was regarded as soothing by all patients, some suggested it would be good to have a variety of music choices [49–50].

The experimental intervention was evaluated by the majority of subjects as supporting them to form a bedtime routine for using CPAP each night, based on the audiotape softly spoken

instructions. In contrast, very few of the placebo patients rated their intervention as supporting them to establish a daily routine for checking their vitamin in-take. This is not surprising considering that listening to the placebo audiotape daily was rated as bothersome by nearly half those subjects. Educational placebos are often rated a bother as these interventions are designed to control for the time and attention given the experimental group. However, the placebo can not include the topic of immediate health concern for the patient but rather typically has simple information that is on a neutral health topic.

In this study, there were no measures of sleep quality or of the impact of the type of music used [51,52]. Such potential mediating factors could be measured in future studies to better understand the mechanisms of intervention effect [53]. Also there was decay in the intervention effect since there were no significant group differences in CPAP adherence at 3 or 6 months. Thus the adherence rates across the months in experimental group had wide range from 54.5% to 89%. This wide range might relate to the methodological issue of categorizing subjects lost to contact as non-adherent. This conservative approach of potentially labeling some one as non adherent, when they may in fact, still be using there CPAP but have been lost to contact due to moving to their retirement home during the colder months, is an issue to consider when measuring drop outs in future studies.

Even so, there were few drop outs (11 experimental and 13 placebo subjects) from the study. A greater number of drop outs occurred at 6 months resulting in poor adherence rates in both groups at that time period. This suggests that this intervention addressed only adherence in the first month of CPAP treatment which is an important improvement.

However, in order to improve long-term adherence, other interventions are most likely needed at 3 and 6 months. Such interventions could guide patients in solving the common recurring, yet treatable problems, found after onset phase of CPAP treatment [54]. For example, instructing patients on cleaning their CPAP mask and tubing or on solving other problems interfering with longer-term CPAP use (e.g., dry nares, stuffy nose) could be emphasized in later months.

4.2. Conclusion

The music and habit-reinforcing intervention improved patients' 1 month adherence to CPAP, at percentages greater than typically reported at onset of treatment. The large effect of the intervention is especially critical for the first month of treatment when rates of stopping CPAP are high. Decay or lack of intervention effect was found at the 3 and 6 month follow up. In the future, follow-up interventions should be targeted for managing varied populations and additional problems identified in previous research to interfere with long-term CPAP use [54,55]. The intervention was targeted to establish a relaxing habit of nightly CPAP use and was derived from as empirically established theoretical model. It is important to replicate these findings in larger samples to identify consistent outcomes. Also the study should be expanded to measure any mediating variables such a sleep quality or type of music used.

4.3. Practice Implications

Greater adherence at the beginning of treatment was achieved in the group randomly assigned to use this experimental diary/music tape/intervention [56]. The audio music was accepted and rated as helpful by patients for establishing nightly routine of CPAP use. Considering the mortality, morbidity and public safety issues of sleep apnea, more comprehensive interventions must be tested to improve nightly habitual CPAP use and reinforce long-term adherence.

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TABLE 1
GROUP 1 AND GROUP 2 INTERVENTION MATERIALS/ACTIVITIES

Experimental (group 1)	Placebo/vitamin group (group 2)
CPAP benefits pamphlet	Vitamin benefits pamphlet
CPAP problem solving diary & checklists	Vitamin problem solving diary & checklists
Consequences of untreated OSA	Consequences of vitamin deficiency
Nightly Use reminder placards	Daily consumption reminder placards
One Month CPAP checklist and diary	One Month Vitamin checklist and diary
Anonymous evaluation	Anonymous evaluation

Table 2

Baseline Demographic Characteristics of Patients in the Experimental and in the Placebo Control Group

Demographic Characteristics	Experimental Group	Placebo Group	P values
Mean Age in Years	63 years (SD= 6.94)	63 years (SD= 7.15)	p=.169
Gender (% female)	36.4%	48.5%	p=.401
(% male)	63.6%	51.5%	
Marital Status:			p=.493
• married	65.2%	69.4%	
• separated/divorce/widowed	23.0%	30.6%	
• never married	1.8%	0%	
Education – had High school and/or college	92%	89.3%	p=.711
Employed	49.2%	59.5%	p=.591

Table 3

Baseline Clinical Characteristics of Patients in the Experimental and in the Placebo Control Group with Percentage Comparisons or Mean Scores and Standard Deviation (+/-) and Group comparisons (P values)

Characteristics	Experimental Group	Placebo Group	P values
Patients with 2 medical diagnoses¹ plus OSA	40.4%	38.7%	p=.672
SF-12 Mental Health Scores²	48.5 (+/-11.0)	52.1 (+/-11.9)	p=.169
SF-12 Physical Condition Scores²	37.2 (+/-12.3)	39.85 (+/-13.3)	p=.422
Apnea/Hypopnea Index (AHI) Mean & Median Scores³	52.3 Median=30.4	47.3 Median=30.0	p=.263
Apnea/Hypopnea Index (AHI) Categories³			p=.920
Moderate (20–39)	60.4%	58.8%	
Severe (>40)	39.6%	41.2%	
CES-D Depression Mean Score and severity categories⁴:	11.4 (+/- 11.9)	10.8 (+/-11.4)	p=.118
< 12 no depression	68.8%	70.4%	
12–16 mild depression	10.2%	10.4%	
17–30 moderate depression	12.5%	15.4%	
>31 severe depression	8.2%	4.8%	
Body Mass Index⁵			p=.969
From 18.5 to 29 (overweight)	18.5%	20.0%	
From 30 to 39 (obese)	59.0%	61.8%	
> 40 (morbid obesity)	22.5%	18.2%	

¹ Patients with 2 chronic diseases, most frequently either High Blood Pressure, Congestive Heart Failure or Diabetes in addition to their new diagnosis of OSA

² SF12 international scale of mental health and physical health (international normed mean scores for healthy adults for mental health status =50 and for physical health status =50)

³ Apnea/Hypopnea Index (AHI) median scores and categories per American Academy of Medicine established on national norms. Depression screening scores using CES-D category score ranges based on international norms

⁴ Depression screening scores using CES-D category score ranges based on international norms

⁵ Body Mass Index (BMI) categories ranges based on international categories

Table 4
Numbers (N) and Percentages (%) of Patients Adhering to CPAP per Group at 1, 3, 6 Months Following Intervention Administration

Group	1 Month [*]	3 Months ^{**}	6 Months ^{***}
Experimental Subjects at Baseline (N=55)	N=49 (89.0%)	N=30 (54.5%)	N=41 (74.5%)
Placebo Control Subjects at Baseline Subjects (N=42)	N=23 (54.9%)	N=24 (57.1%)	N=30 (71.4%)

The baseline N listed in bold for each group was used in the intent-to-treat analyses for each group:

^{*} Significantly more experimental subjects adhered at 1 month; $X^2=14.67$, $p<.01$

^{**} No significant difference between groups, at 3 months; $X^2=.065$, $p=.79$

^{***} No significant difference between groups, at 6 months; $X^2=.118$, $p=.73$

No subjects had dropped out of the study at one month post intervention. Subjects who dropped out from the study (numbers listed below) had either stopped using CPAP, had less than 4 hours of CPAP use, or were lost to contact. Per the intent-to-treat analysis all dropouts remained in each analysis. Dropouts lost to contact were counted as non-adherent.

¹ 2 subjects dropped from the experimental and 1 from placebo group at 3 months (total = 3).

² 11 subjects dropped from the experimental and 13 from the placebo group at 6 months (total = 24).