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Title

Effect of an ambulatory diagnostic and treatment program in patients with Sleep Apnea

Authors

Ada L. Andreu [1], Eusebi Chiner [1], Jose N. Sancho-Chust [1], Esther Pastor [1], Monica Llombart [1], Elia Gomez-Merino [1], Cristina Senent [1], Ferran Barbé [2].

[1] Pulmonology Section. University Hospital of Sant Joan d'Alacant. Alicante (Spain).

[2] Respiratory Department, IRB Lleida (Lleida). CIBERES, ISCIII, Madrid (Spain).

Correspondence

Eusebi Chiner Vives.
Secció de Pneumologia. Hospital Universitari Sant Joan d'Alacant.
Ctra. Alacant-València s/n. CP: 03550. Sant Joan d'Alacant. Spain.
Fax: 965658750.
E-mail: chiner_eus@gva.es

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Abstract

This study was aimed to evaluate the efficacy of a home based program on clinical response, CPAP compliance and cost in a population of high pre-test probability of suffering obstructive sleep apnea syndrome (OSAS).

Patients were randomized into three groups: A: home respiratory polygraphy (RP) and home follow-up; B: hospital polysomnography and hospital follow-up; C: home RP and hospital follow-up. Evaluation during six months included: Epworth Sleepiness Scale (ESS), Functional Outcomes Sleep Questionnaire (FOSQ), and daily activity and symptom questionnaires. Compliance was assessed by memory cards (A) and using an hourly counter (B and C).

Sixty-six patients were included (22 per branch), 83% males, 52±10 years, 34±7kg/m^2, apnea-hypopnea index 43±20 $hour^{-1}$, CPAP pressure 8±2 cmH_2O, with no between-group differences. Clinical response showed: ESS 15±3 to 6±4, FOSQ 16±3 to 18±2, symptoms 43±7 to 25±7, activity 37±11 to 25±8. At the end, compliance was: A 73%, B 68% and C 57%. The cost per patient was: A=590±43€, B=894±11€ and C=644±93€ ($p<0.001$).

In conclusion, patients with a high initial probability of having OSAS can be diagnosed and treated in a home setting, with a high level of CPAP compliance and lower cost than using either a hospital-based approach or home RP/hospital follow-up.

Keywords: ambulatory program; CPAP; home based program; sleep apnea;

Introduction

Obstructive sleep apnea syndrome (OSAS) is a highly prevalent disease [1,2] that has been shown to be associated with a reduction in quality of life [3], the onset or worsening of hypertension [4,5], cardiovascular diseases [6] and stroke [7], increased traffic and workplace accidents [8,9] and mortality [10].

The gold standard for diagnosis is polysomnography (PSG) [11], but it is expensive, not available in all hospitals and frequently has long waiting lists [12]. Respiratory polygraphy (RP) is a cheaper and more accessible test and correlates well with PSG [13-15]. Home-based diagnostic strategies based on simple automated evaluation and treatment systems have also been proposed [16].

Treatment with continuous positive airway pressure (CPAP) has been shown to improve symptoms and quality of life, decrease traffic accidents, and may have a positive effect on cardiovascular morbidity [5,17,18]. The effectiveness of this treatment is directly related to compliance [19,20]. Strict follow-up is required for improvement, principally in the first few months [19]. Various strategies have been assayed to improve compliance, such as telephonic reinforcement, educational sessions, etc. [21-25].

The number of patients referred with suspected OSAS has increased considerably in recent years [26], overloading diagnostic and follow-up resources. To guarantee effective, efficient and integral care and management of patients, alternatives to traditional methods need to be considered [21,26].

The aim of this study was to ascertain, in a sample of moderate and severe OSAS patients, whether an ambulatory assessment program would be as effective for compliance and clinical response as a regular hospital program. Thus, we investigated whether this program was a realistic alternative to conventional hospital diagnosis and follow-up.

Material and methods

Study Subjects

All patients referred with a high level of clinical suspicion of OSAS, based on an Epworth Sleepiness Scale (ESS) score ≥ 12 and a Sleep Apnea Clinical Score (SACS) ≥ 15, were included [27]. Patients were recruited during a six-month period (approximately 12 patients referred each week to our Sleep Unit). During this period, 333 subjects were referred to our Sleep Unit, 250 of whom with a clinical suspicion of OSAS. After diagnostic procedures, 75% of these were diagnosed as having OSAS, while 25% were diagnosed with no OSAS. Of the OSAS patients, 30% were diagnosed with severe OSAS. The 30% of referred subjects with a clinical suspicion of OSAS also had a high pre-test probability of OSAS, based on the study's inclusion criteria. Patients with impaired lung function (chronic obstructive pulmonary disease, obesity-hypoventilation and restrictive disorders), associated pathologies (psychiatric disorders, neoplasms, restless leg syndrome, and other dyssomnias or parasomnias) and patients previously treated with CPAP were all excluded.

Methods

PSG (Somnostar Alpha 4100®, SensorMedics®, CA, USA) was carried out in the hospital setting under the supervision of a nurse, according to the guidelines by the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR) [28].

RP (Stardust polygraph, Respironics INC®) was carried out at home without direct vigilance, using a validated system [29]. An AHI > 15 was necessary to diagnose OSAS [30]. If the register was invalid a second RP was carried out.

Specific questionnaires validated in Spanish were used to evaluate ESS [31,32] quality of life, FOSQ [32,33] activity and symptoms [18], and the presence of snoring while under CPAP treatment.

Study Design

This work was a year-long, randomized, prospective study with three parallel arms. Patients were randomized into three groups, A, B or C (Figure 1):

Group A: home RP and home follow-up by a nurse from the Sleep Unit.

Group B: hospital PSG and hospital follow-up

Group C: home RP and hospital follow-up

The randomization assignments were computer generated using a block permutation method to select one of the three diagnostic and follow-up alternatives. Randomization was performed by the staff of our hospital's research unit, who had no direct participation in the study. To ensure an adequate blind, opaque and sealed envelopes were used. After a manual reading of the sleep study, patients were evaluated in a second ambulatory visit, given their CPAP treatment assignment and informed about the treatment, adverse effects and short- and long-term benefits. All patients fulfilled the CPAP treatment criteria [28]. CPAP pressure was calculated mathematically using the following equation: -5.12 + (0.13 x BMI) + (0.16 x neck circumference) + (0.04 x AHI) [34,35] and pressure was not change during follow-up. A CPAP humidifier was not used in any patients.

Group A was followed at home and patients were treated using a CPAP device (REMstar ® Pro, Philips Respironics) with a memory card (to store the number of hours of use, the number of days per week and the time of use). During each visit the nurse collected the memory card for later analysis and delivery to the supervising physician. The nurse also administered the questionnaires and interviewed patients about side effects. If poor compliance was reported by the patient (less than four hours per night for 70% of nights) or if the patient had a negative attitude to CPAP treatment, the nurse assessed the need for specialist reinforcement, either via a telephone call or in a scheduled visit, to improve compliance or resolve adverse effects (see supplementary data).

In the B and C groups (hospital follow-up), after the diagnosis, the working principles of CPAP were explained to the patients and a first adaptation was performed with the patient awake. Follow-up was done by physicians routinely in the Sleep Unit. The effective compliance was calculated using an hourly CPAP (REMstar® M, Philips Respironics) counter, and dividing the total hours registered on the counter by the number of days of treatment.

All patients (Groups A, B and C) were contacted at least once by the physician supervising the program via telephone during the first month.

Patients were classified as compliant if they completed at least four hours of treatment on 70% of the days of the week in the three groups [36].

Cost evaluation

The estimated costs of each strategy were calculated and compared between groups. The estimated costs of hospital visits, telephone calls and the PSG were obtained from the Financial Department of the San Juan de Alicante University Hospital and the previously

estimated data for our Unit [37]. The costs of home visits, the RP and the daily cost of CPAP were obtained directly from the company that provided home respiratory therapy [38].

Analysis

The main outcome was to evaluate the compliance between groups at six months of follow-up. The secondary outcomes were daytime sleepiness (ESS), quality of life as measured by the FOSQ, symptoms, and cost per patient and group.

The study was planned as a non-inferiority trial, in order to demonstrate that home-based follow-up produces similar compliance and outcomes to hospital-based follow-up, with the latter as the current standard strategy (active control). To calculate the sample size, a 5% margin in hours of CPAP use was considered to be the non-inferiority margin in the patients considered as compliant (with the following expected criteria: a loss of 5%, α error of 0.05 and a power of 0.9, taking into account that 30% of patients in each group could be poorly CPAP compliant or definitively abandon CPAP at some point during follow-up).

We estimated that a sample size of 75 consecutive patients who fulfill the inclusion criteria, 25 in each group, would be necessary to demonstrate equivalent clinical efficacy with respect to compliance with the three methodologies.

To compare the number of hours of CPAP use between the three groups, analysis of variance (ANOVA) or the Kruskal-Wallis test were used when appropriate, with a subsequent pairwise comparison of means. Numerical data were expressed as means and standard deviations ($X \pm SD$). The effect or dependent variable was the number of hours on the CPAP counter. The same tests were used to compare numeric variables: BMI, neck circumference, Epworth and FOSQ scores, costs in euros and symptom questionnaires. One-way ANOVA and the Newman-Keuls test for pairwise comparisons were used to assess FOSQ changes over time in each of the groups. The chi-squared or Fischer's exact tests were used for categorical variables. All analyses were done by intention to treat. A p-value < 0.05 was considered statistically significant.

Ethical Issues

The study was approved by the Ethics and Clinical Trials Committee of the San Juan de Alicante University Hospital and informed consent was obtained from all included patients. Trial registry: Clinical Trials.gov; No: NCT01001858 (URL: www.clinicaltrials.gov).

Results

Figure 2 shows the study flowchart. Sixty-six patients were eligible for randomization. A patient in Group C was excluded for presenting an AHI < 8 $hour^{-1}$ and refusing to undergo a PSG, one from Group A died due to causes unrelated to OSAS, five were lost to follow-up (one in Group A, one in B and three in C). One patient from Group A attended the final visit, but had abandoned treatment and was considered non-compliant (Figure 2). The remaining 58 completed the program. The baseline characteristics of patients who were not enrolled were similar to those who were randomized (data not shown).

The demographic characteristics and questionnaire scores at baseline are shown in Tables 1 and 2, with no differences between groups.

The AHI, desaturation index and CPAP pressure values were not different between groups (Table 3). The number of patients with severe OSAS (AHI > 30 $hours^{-1}$) was 13 in group A, 17 in B and 15 in C (p = n.s.).

Table 4 shows the compliance at each point of follow-up. At one month, 19 subjects (86%) were compliant in Group A, 13 (59%) in B and 13 (62%) in C; at three months 19 (86%), 16 (73%) and 14 (67%) respectively, and at six months 16 (73%), 15 (68%) and 12 (57%) were compliant, without significant differences between groups at each point of follow-up.

At the end of the study, 83% of patients presented good or very good tolerance for CPAP treatment. Among the adverse effects reported, dryness was the most frequent (54%), followed by nasal congestion (40%), leakage (26%) and abrasions (25%). Up to 86% of patients presented some adverse effect at some point in follow-up. Despite this, of the patients who completed the study, 91% of patients were satisfied or very satisfied with the treatment.

When analyzing the questionnaire scores over the six months of follow-up, significant differences were seen in all the groups during the study. There was an improvement in sleepiness as measured by the ESS ($P<0.001$), the global FOSQ score ($p<0.001$) and the activity ($p<0.001$) and symptom ($p<0.001$) scores. When the scores were compared transversally, analyzing the differences in scores between the three groups at each of the visits, no differences were found, except for the symptom questionnaire between Group A and Group C at one-month follow-up, although these differences disappeared in later visits (Table 2).

Five patients in Group A and one in Group C needed a second RP for a definitive diagnosis. One patient in Group C finally needed a PSG after two invalid polygraphies. Patients were contacted by phone on 24 occasions in Group A. Of these, 21 were made as reinforcement during the first month of the program, and three at the recommendation of the nurse or at the decision of the physician after studying the compliance and secondary effects records submitted. In Groups B and C, contacts were made 17 and 13 times, respectively. Nine patients in Group A required extra visits as compared to five patients in Group C. None of the patients in Group B needed extra visits (Table 5).

After analyzing the data on all the groups and the costs of each of the strategies, the differences in costs were statistically significant (ANOVA $p<0.001$), with the most expensive strategy being in Group B (849±11 €), with significant differences ($p<0.001$) from Groups A (590±43 €), and C (644±93 €). The difference in costs between A and C was also statistically significant ($p<0.05$).

Discussion

The most relevant contribution of our study is that, in patients with a high probability of OSAS, the strategy of home diagnosis and follow-up (group C) is as effective as the hospital follow-up model used in the majority of centers (groups A and B), without reducing compliance and at a lower cost. The number of cases referred for suspected OSAS and later diagnosis is very high, producing a high level of treatment demand and consequent waiting lists [12]. This work shows that an alternative home follow-up method does not affect the quality of clinical treatment and response.

The diagnosis of OSAS using a simplified methodology in the home has shown to be valid [13-15]. Although the PSG continues to be the gold standard for diagnosis [11], unsupervised ambulatory RP is accepted in patients with a high probability of OSAS [39]. In addition, we know that the treatment response appears not to be influenced by the type of diagnostic test (PSG/RP) [40], but the response to different follow-up strategies after the start of CPAP therapy is still unknown.

The proportion of poor CPAP compliers is variable and ranges from 30% to 50% of patients [19,41]. We estimated a mean 70% proportion of compliers in each arm of the study. Different methods have been used to improve compliance: educational sessions, telephone reinforcement, written information, video, etc., with heterogeneous results [21-24,42]. Not all authors have been able to identify differences between intervention and non-intervention groups [43]. Still, in most cases it seems clear that some type of reinforcement can improve compliance, especially in the first few months of therapy [19].

In our study, we wanted to reinforce the role of the nurse as a fundamental pillar of the follow-up strategies. Other authors have designed programs that include nurses in patient assessment. Hoy et al randomized a group of patients diagnosed with OSAS into two groups: with and without educational sessions, concluding that an intensive program by nurses could improve compliance [44]. Although it is difficult to know if the differences were due exclusively to the nurses' participation or to the set of additional measures used. Tomlinson et al, studied 150 patients that had started CPAP treatment and were referred to a hospital nurse for follow-up. The authors concluded that a follow-up program by nursing is cost effective, but the study was not controlled and their nursing team did not attend home visits [45]. Damjanovic et al, randomized 100 patients into four groups formed according to the type of assessment used (standard or intensive support). The intensive support group

presented a significantly greater number of hours and days of CPAP use than the standard group [46].

Some other authors were unable to find significant differences between interventions in these types of programs [47]. It is possible that in the future new technologies such as telemedicine will have a key role in these programs [48,49], contributing to an increase in adherence [50]. In this regard, other recent studies have shown similar results to those presented in this work, supporting the validity of our approach [25,51,52].

Our strategy is comparable to regular hospital assessment, with the advantage of reducing provider congestion, making full and rapid treatment of patients with adherence problems or side effects possible, and to redirect time and resources to patients with specific needs. In addition, nurse visits and memory cards allow a better understanding of CPAP use patterns. With regard to patients, the positive reinforcement and reduced travel inherent in having nurses make home visits, as well as the possibility of being treated by the supervising physician either over the phone or in the hospital, make adherence and compliance in the home monitoring group favourable, with values greater even than those obtained with the conventional approach, and at a lower cost. In this sense, nurses play a key role, but the current nursing shortage fuel the search for professionals who can deliver and coordinate care effectively, and community health workers could play a role as an alternate to nurses [53].

There are some potential limitations in our study. Patients were randomized based on clinical suspicion, before confirmation by diagnostic testing. Although all but one case were confirmed, this strategy would be difficult to use in patients with an intermediate risk of illness. Nevertheless, it is estimated that 80% of patients with OSAS remain undiagnosed and there is a high percentage of severely ill patients in that group that could benefit from this strategy. Moreover, home diagnosis may lead to a large enough number of invalid tests that one of the arms of the study becomes more expensive, which is why personnel training and selection and validation of the best polygraphs are very important. In this sense, the number of invalid studies in our work was consistent with rates reported in the literature and the polygraph was previously validated. Geographic access may also be a barrier, although telemedicine can play a key role. AHI scores in group C were slightly higher than in the other groups, even though the differences were not statistically significant, nor were the differences in the numbers of patients with severe OSAS between groups. Another potential limitation was that the patients started CPAP at a pressure calculated using a mathematical formula, which could have influenced compliance. However, this technique was applied to all three groups equally and so it was not considered necessary to make later changes, depending on

clinical response. Moreover, when compliance was evaluated, the fact that the home group had a memory card could have led to more accuracy in readings, due to recording of both real and effective use. Nevertheless, in the mixed and hospital follow-up groups, compliance was also evaluated using accepted objective methods from more universal clinical practice (although in the future the use of a memory card will be widespread) and furthermore the differences in time of use between groups were not significant.

We conclude that a home diagnosis and follow-up program in patients with a high probability of OSAS, with nurses coordinated with the Sleep Unit, is as effective as conventional assessment, and could also be more efficient.

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Legends

Figure 1. Study Protocol. SACS: Sleep Apnea Clinical Score; RP: respiratory polygraphy; PSG: polysomnography;

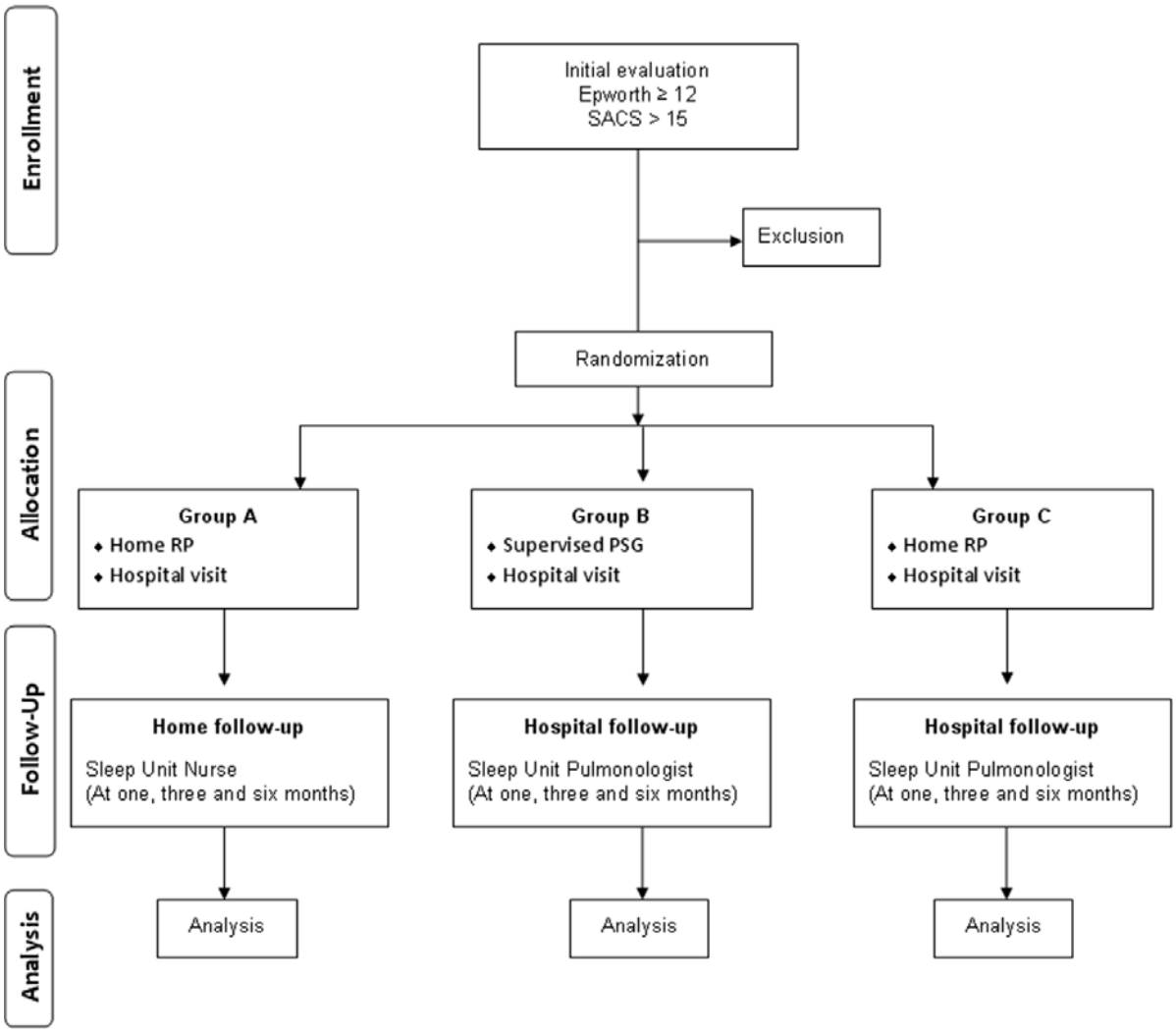
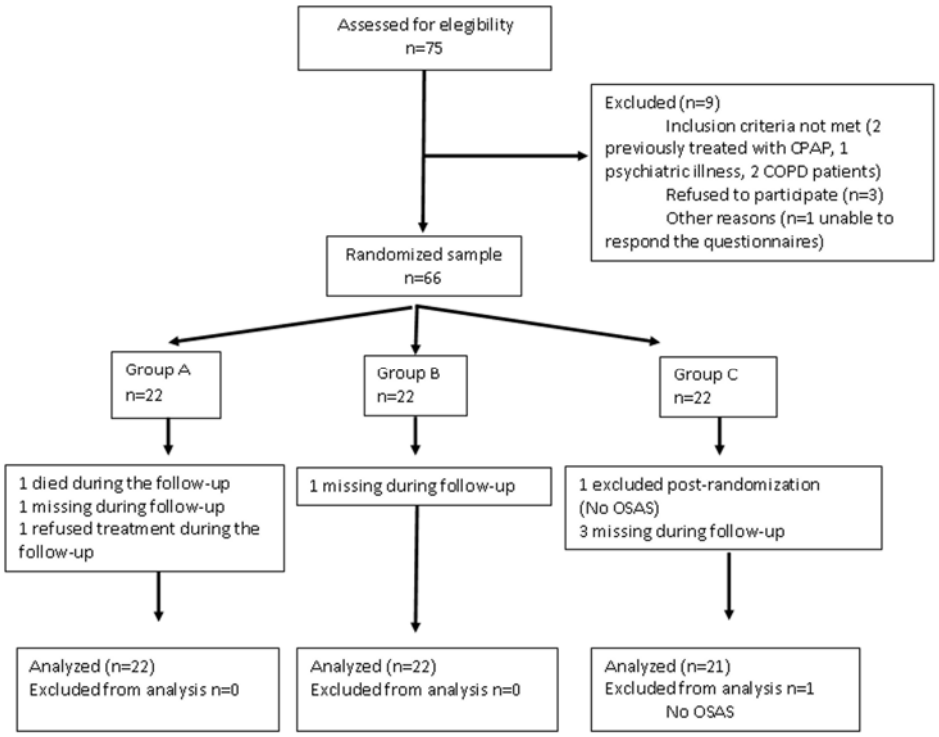


Figure 2. Study Flowchart. COPD: chronic obstructive pulmonary disease; OSAS: Obstructive Sleep Apnea syndrome.



Tables

Table 1. Demographic characteristics of patients.

	ALL PTS	**GROUP A**	**GROUP B**	**GROUP C**	**p values**
N	65	22	22	21	-
Age (years)	52±10	52±11	53±9	51±10	ns
Male	54 (83%)	18 (82%)	21 (96%)	15 (71%)	ns
Female	11 (17%)	4 (18%)	1 (4%)	6 (29%)	ns
BMI (kg/m^2)	34 ±7	32 ±5	34±7	36±7	ns
Neck (cm)	45.5± 3.5	45.4± 3.7	45.3±3.3	45.9±3.2	ns
Hypertension	32 (49%)	11 (50%)	12 (55%)	9 (43%)	ns
Habitual Snoring (%)	100	100	100	100	ns
SACS	40 ±26	41 ±29	39 ±25	41 ±25	ns

Definition of abbreviations: PTS: Patients; BMI: Body Mass Index; SACS: Sleep Apnea Clinical Score; ns: non significant. Numerical values expressed as mean ± standard deviation (X±SD).

Table 2. Baseline and follow-up scoring of questionnaires.

Questionnaire	Month of Follow-up	ALL PTS. N	(X ± SD)	GROUP A N	(X ± SD)	GROUP B N	(X ± SD)	GROUP C N	(X ± SD)	p values
ESS	**BASELINE** †	**65**	**15 ± 3**	**22**	**15 ± 3**	**22**	**16 ± 4**	**21**	**16± 3**	ns
	ONE MONTH	62	8 ± 5	20	6 ± 4	22	9 ± 5	20	9± 5	ns
	THREE MONTHS	64	7 ± 5	22	8 ± 6	22	6 ± 5	20	7± 5	ns
	SIX MONTHS	59	6 ± 4	22	6 ± 5	20	6 ± 4	17	5 ± 4	ns
FOSQ	**BASELINE** †	**65**	**16 ± 3**	**22**	**16 ± 3**	**22**	**16 ± 3**	**21**	**16 ± 3**	ns
	ONE MONTH	61	18 ±3	18	18± 2	22	18 ±3	21	17± 2	ns
	THREE MONTHS	62	18 ±2	21	18 ±2	21	18± 2	20	18 ±2	ns
	SIX MONTHS	57	18± 2	20	18 ±2	20	18 ±2	17	19 ±1	ns
- Activity Level	**BASELINE** †	**65**	**3.1 ± 0.6**	**22**	**3.2 ± 0.6**	**22**	**3.1 ± 0.6**	**21**	**2.9 ± 0.6**	ns
	ONE MONTH	61	3.4 ± 0.6	18	3.5 ± 0.5	22	3.5 ± 0.6	21	3.3 ± 0.5	ns
	THREE MONTHS	62	3.6 ± 0.4	21	3.6 ± 0.6	21	3.6 ± 0.4	20	3.5 ± 0.4	ns
	SIX MONTHS	57	3.6 ± 0.4	20	3.7 ± 0.4	20	3.6 ± 0.4	17	3.7 ± 0.3	ns
- Vigilance	**BASELINE** †	**65**	**2.7 ± 0.7**	**22**	**2.7 ± 0.7**	**22**	**2.8 ± 0.7**	**21**	**2.7 ± 0.7**	ns
	ONE MONTH	61	3.4 ± 0.7	18	3.5 ± 0.7	22	3.4 ± 0.7	21	3.4 ± 0.6	ns
	THREE MONTHS	62	3.5 ± 0.6	21	3.4 ± 0.7	21	3.6 ± 0.5	20	3.5 ± 0.5	ns
	SIX MONTHS	57	3.6 ± 0.6	20	3.5 ± 0.6	20	3.6 ± 0.6	17	3.6 ± 0.5	ns
-Intimacy and Sexual Relationships	**BASELINE** ‡	**65**	**3.1 ± 1**	**22**	**3.2 ± 1.1**	**22**	**3.3 ± 0.7**	**21**	**3 ± 1.3**	ns
	ONE MONTH	61	3.3 ± 1.1	18	3.3 ± 1.4	22	3.5 ± 0.7	21	3.1 ± 1.2	ns
	THREE MONTHS	62	3.3 ± 1.2	21	3.1 ± 1.5	21	3.5 ± 1.0	20	3.3 ± 1.3	ns
	SIX MONTHS	57	3.3 ± 1.3	20	3.1 ± 1.4	20	3.3 ± 1.1	17	3.4 ± 1.3	ns
-General Productivity	**BASELINE** †	**65**	**3.4 ± 0.6**	**22**	**3.5 ± 0.5**	**22**	**3.3 ± 0.6**	**21**	**3.3± 0.6**	ns
	ONE MONTH	61	3.6 ± 0.5	18	3.7 ± 0.5	22	3.7 ± 0.4	21	3.5 ± 0.4	ns
	THREE MONTHS	62	3.7 ± 0.4	21	3.8 ± 0.4	21	3.7 ± 0.5	20	3.7 ± 0.3	ns
	SIX MONTHS	57	3.8 ± 0.3	20	3.8 ± 0.3	20	3.7 ± 0.4	17	3.8 ± 0.3	ns
-Social Outcomes	**BASELINE** §	**65**	**3.4 ± 0.8**	**22**	**3.6 ± 0.8**	**22**	**3.4 ± 0.8**	**21**	**3.3± 0.8**	ns
	ONE MONTH	61	3.7 ± 0.7	18	3.6 ± 1.0	22	3.7 ± 0.8	21	3.7 ± 0.5	ns
	THREE MONTHS	62	3.7 ± 0.6	21	3.7 ± 0.9	21	3.8 ± 0.4	20	3.7 ± 0.5	ns
	SIX MONTHS	57	3.8 ± 0.7	20	3.8 ± 0.9	20	3.7 ± 0.5	17	3.8 ± 0.5	ns
Activity Questionnaire	**BASELINE** †	**65**	**37±11**	**22**	**34±10**	**22**	**39 ±12**	**21**	**37± 10**	ns
	ONE MONTH	63	29 ± 10	20	26±10	22	29±10	21	31±11	ns
	THREE MONTHS	63	26 ± 9	22	26±11	22	25±6	20	27±8	ns
	SIX MONTHS	59	25 ± 8	22	25 ± 9	22	26 ± 8	17	25 ± 6	ns
Symptom Questionnaire	**BASELINE** †	**65**	**43 ±7**	**22**	**43 ±6**	**22**	**43 ±8**	**21**	**43± 7**	ns
	ONE MONTH	63	28 ± 9	20	23 ± 7*	22	29±10	21	31±10*	*p=0.03
	THREE MONTHS	63	26 ± 7	22	24±6	22	27±7	20	28±8	ns
	SIX MONTHS	59	25 ± 7	22	23 ± 5	22	25 ± 8	17	26 ± 6	ns

Definition of abbreviations: PTS: Patients; FOSQ: Functional Outcomes Sleep Questionnaire; ESS: Epworth Sleepiness Scale. ns: non significant. *: <0.05 between A and C at one month of follow-up. Differences found between the baseline visit and each follow-up visit, in whole study population. †: $p<0.001$ between baseline results and each of the follow-up visits; ‡: differences in the "privacy" item between baseline and follow-up visits; §: $p<0.05$ between the baseline visit and one month visit, $p<0.01$ between baseline and three month visit, and $p<0.001$ between baseline and six month visit.

Table 3. Results of the diagnostic test and pressure prescribed in the initial visit

	ALL PATIENTS		**GROUP A**		**GROUP B**		**GROUP C**		
	N	(X± SD) [Range]	**N**	(X± SD) [Range]	**N**	(X± SD) [Range]	**N**	(X±SD) [Range]	**p**
Study duration (min)	65	421±77 [291-533]	22	396±56 [332-461]	22	469 ± 53 [410-533]	21	396± 93 [291-485]	0.03* 0.03+
AHI (hours^{-1})	65	43 ±20 [15-95]	22	37 ±18 [17-70]	22	44 ± 19 [15-83]	21	48± 23 [16-95]	ns
ODI (hours^{-1})	64	44 ±26 [10-82]	22	38 ±25 [10-69]	21	39 ±27 [11-75]	21	52± 26 [12-82]	ns
PCPAP (cmH2O)	65	8.1 ±1.6 [5-13]	22	7.6 ±1.5 [5-11]	22	8.1 ± 1.7 [5-12]	21	8.7± 1.6 [6-13]	ns

Definition of abbreviations: PTS: Patients; AHI: apnea hypopnea index; ODI: oxygen desaturation index; CPAP: continuous positive airway pressure; ns: non significant. *: $p < 0.05$ between A and B; +: $p < 0.05$ between B and C.

Table 4. Compliance with CPAP treatment expressed in minutes for each of the groups at each point of follow-up, and mean compliance in the compliant and non-compliant groups.

Hourly counter (min)	**ALL PATIENTS**		**GROUP A**		**GROUP B**		**GROUP C**		
	N	(X± SD)	**N**	(X± SD)	**N**	(X± SD)	**N**	(X± SD)	**p**
One Month	65	268 ±118	22	300±85	22	256 ± 152	21	240± 109	
Compliant	45	307±83[a]	19	312±69[b]	13	333±95[a]	13	274±85[b]	
Non-compliant	20	72±54	3	78±52	9	57±42	8	95±82	ns
Three months	65	274 ±113	22	297±91	22	274 ± 133	21	246± 111	
Compliant	49	314±84[a]	19	320±75[b]	16	328±95[a]	14	289±82[a]	
Non-compliant	16	112±55	3	151±13	6	103±75	7	95±39	ns
Six months	65	262±109	22	271±130	22	252±100	21	263± 112	
Compliant	43	308±88[a]	16	326±85[a]	15	282±90[c]	12	315±89[b]	
Non-compliant	22	122±49	6	93±71	7	139±17	9	138±27	ns

The differences in time of CPAP use were statistically significant in all groups and at all follow-up points, with the following levels of significance: [a] $p<0.001$, [b] $p<0.005$, [c] $p=0.006$.

Definition of abbreviations: PTS: Patients; ns: non significant

Table 5. Summary of tests, visits and extra calls by group and cost.

FIXED COSTS (EUROS)			
	Group A	Group B	Group C
Initial visit, follow-up visits, diagnostic test	3828	10230	4977
Daily CPAP cost	8237	8237	7862
ADDITIONAL COSTS (number of RP, PSG, visits and additional phone calls, by group)			
RP	5	0	1
PSG	0	0	1
Extra visits	9	0	5
Extra calls	24	17	13
TOTAL SUM OF COSTS: FIXED PLUS ADDITIONAL (EUROS)			
Fixed	3828	10230	4977
Aditional	918	204	666
CPAP	8237	8237	7862
Total	12983	18671	13505
Cost per patient	590	849	644

All costs were calculated by the Financial Department of the San Juan de Alicante University Hospital. Cost of each intervention: First visit 45€, Follow-up or extra visits 30€, Home Visits 9€, PSG 300€, RP 72€, Telephone calls 12€.

Definition of abbreviations: CPAP: continuous positive airway pressure; RP: respiratory polygraphy; PSG: polysomnography;