

**POLYSOMNOGRAPH CHART VIEW BY PATIENTS: A NEW  
EDUCATIONAL STRATEGY TO IMPROVE COMPLIANCE IN SLEEP  
APNEA THERAPY**

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## **ABSTRACT**

**Background :** CPAP is currently the treatment of choice for Obstructive Sleep Apnea Syndrome (OSAS), but therapy adherence is poor. Many educational trials have been proposed to increase CPAP adherence. In our study we tested the hypothesis that polysomnograph (PSG) chart view by patients may improve adherence to CPAP therapy.

**Methods:** A controlled parallel group study was performed with 206 newly diagnosed OSAS patients, randomised into 2 groups (n = 103 each): standard (Group 1) or educational support (Group 2). Educational support group included the vision on the computer screen of 2 consecutive polysomnography charts for each patient: the first recorded during a standard diagnostic overnight polysomnography and the second during a full-night polysomnography with nasal CPAP therapy. In both cases, patient's attention was drawn only on the tracks of flow and oxyhemoglobin saturation. Clinical outcome was monitored by polysomnography at CPAP initiation and after 1, 3 and 12 months.

**Results:** After 12 months of therapy 76 % of the group 2, whereas only 52 % of the patients of group 1 returned for a follow-up visit ( $p < 0.001$  ). Statistical significance was reached already after 1 and 3 months. Moreover, CPAP usage (h/night) was higher in group 2 than in group 1 at each control visit.

**Conclusions :** PSG chart view by OSA patients can increase therapy adherence, as evaluated by rate of return for the follow-up visit and mean nightly CPAP usage.

**Keywords :** continuous positive airway pressure ; compliance ; obstructive sleep apnoea syndrome ; sleep apnoea diagnosis and treatment; behavioral interventions; patient education.

## **INTRODUCTION**

Obstructive sleep apnea (OSA) is a disorder characterized by recurrent episodes of upper airway obstruction during sleep, resulting in chronic intermittent hypoxia, sleep fragmentation, and daytime sleepiness [1]. This condition is present in as many as 2% of females and 4% of males in the general population [2] and is burdened with substantial associated morbidity and mortality [3]. Continuous positive airway pressure (CPAP) is the primary treatment for OSAS [4]. Indeed, it normalizes sleep architecture, reduces daytime sleepiness, improves daily function, reduces automobile accidents and improves quality of life [5]; decreases blood pressure and other cardiovascular events [6]. Unfortunately, literature data regarding CPAP compliance are not so encouraging [7,8]. Current evidence suggests that only 61.0 - 68.5% of those prescribed CPAP will accept their treatment [9]. Several studies tried to determine the percentage of patients that are compliant with CPAP treatment and estimated range from 46 to 80% [7,9,11-14]. Perhaps many people mistakenly believe that CPAP use will ‘heal’ their sleep breathing disorder, at which time they can discontinue its use [15]. Moreover it is known that patients do not consider OSAS as a health problem [16] and have a poor perception of the risk of illness [17].

Many studies demonstrated that patients’ perception of the benefits in symptoms following CPAP and their view of this treatment in terms of health value are related to better adherence [18,19]. On the other hand, new educational strategies [20,21] and intensive supports [22] have improved the long-term adherence to therapy with CPAP.

Given that the awareness of the disease plays a decisive role in CPAP compliance, we tested the hypothesis that polysomnograph (PSG) chart view by patients may improve adherence to CPAP treatment.

## **MATERIALS AND METHODS**

### **Patients**

We conducted a prospective, randomized, single-blind, controlled, parallel group trial. A total of 206 adult patients ( $\geq 19$  yr of age) with newly diagnosed OSA (apnea-hypopnea index [AHI] $\geq 15$  with or without corresponding daytime symptoms) were enrolled. Exclusion criteria were as follows: 1) diagnosis of COPD or any global respiratory failure; 2) central sleep apnoea syndrome; 3) previous diagnosis of congestive heart failure or cardiomyopathy; 4) any chronic neurological disorder ; 5) any severe mental or psychological impairment. All patients lived within 30 kilometers of Bari. Randomization of each patient was done with predetermined balanced blocks generated by tossing a coin. Patients were blinded to the group to which they were allocated.

### **Design of the study**

Patients underwent standard diagnostic overnight polysomnography using a Compumedics E-Series System. The diagnostic night was followed directly by a second full-night PSG with nasal CPAP therapy, during which the CPAP adjustment was performed with manual titration [23]. Thereafter, patients were randomly allocated to the following groups: A) group 1 or standard support group (n=103); B) group 2 or educational support group (n=103).

*Standard support group:* Each patient was given by a sleep medicine physician a full explanation of the need for and benefits of CPAP therapy. This procedure required 10 minutes at the most. Prior to titration, patients received education by a nurse regarding machine operation and mask placement, and a 20 minute period of auto-CPAP exposure during the afternoon for pressure acclimatization.

*Educational support group:* As in the standard support group all patients were properly instructed about their pathological condition and associated risk factor. In addition, for each patient his/her two PSG charts obtained before (1<sup>st</sup> chart) (Figure 5), and with CPAP (2<sup>nd</sup> chart) (Figure 6) were shown on the computer screen ; at the same time, he/she received explanations by a sleep medicine physician in order to interpret correctly the classic PSG signs of apnea-hypopnea and their disappearance with CPAP. In particular, the patient primarily observed 10 minutes of the 1<sup>st</sup> chart in REM phase and then 10 minutes of the 2<sup>nd</sup> chart in the same phase. In both cases, his/her attention was drawn only on the tracks of flow and oxyhemoglobin saturation. This standardized procedure, taking no longer than 5 minutes, was performed for the whole group by one of the three responsible sleep physicians in charge.

In both groups, three follow up visits were performed after 1-, 3-, and 12-months of CPAP treatment. Anthropometric measures and the Epworth Sleepiness Scale (ESS) scores [24] were collected at the time of the diagnosis and during each follow up visit. Compliance data, obtained during each follow up visit, were as follows: retention rate was calculated as the number of patients who returned for follow up divided by the total number of patients; CPAP usage data were downloaded from the CPAP device. Any problems with CPAP treatment were addressed and CPAP data were reviewed with the patient without emphasizing the achievements .Patients who did not return for their follow up visit were considered as not compliant and dropped-out the study. ESS scores and CPAP usage data ,reported in results section, refer only to continuing users.

The study was approved by the Institutional Review Board of Bari University General Hospital and carried out in accordance with the principles of the Helsinki Declaration. All patients gave prior written informed consent to take part in the study.

### Statistical analysis

Analyses were intention-to-treat. Data are presented as mean  $\pm$  standard deviation (SD) unless otherwise indicated. Differences between groups were analyzed by a Student's t-test for independent samples for normally distributed variables and Mann-Whitney U tests for non-normally distributed variables. The chi-square test was used to compare proportions between groups. A p-value  $< 0.05$  was considered to be significant.

## RESULTS

Figure 1 shows the study flow chart. Baseline characteristics of the study population, including age, sex, body mass index (BMI), neck circumference, waist circumference, ESS, apnea-hypopnea index, oxygen desaturation index (ODI), and total sleep time with oxyhemoglobin saturation below 90% (TST90), are shown in Table 1, with no significant differences between the two groups. BMI, neck and waist circumference did not change significantly during the study. During the second full-night PSG with CPAP, the apnea-hypopnea index, ODI, and TST90 improved significantly in both groups to a similar degree (data not shown).

Retention Rate : After 1 month of therapy, 93.20 % of patients in the educational support group, whereas only 77.67 % of those in the standard support group, returned for follow-up ( $\chi = 9.98$  ;  $p < 0.002$  ). After 3 months of therapy, 87.37 % in group 2 remained in follow-up but only 68.93 % of the patients in group 1 ( $\chi = 10.26$  ;  $p < 0.002$  ). After 12 months of therapy, 76.70 % of the group 2 returned for a follow-up visit, but only 52.43% of patients of group 1 ( $\chi = 13.26$  ;  $p < 0.001$  ) (Figure 2 ).

CPAP usage : After 1 month patients in group 2 had higher mean CPAP usage (h/night) than those in group 1 ( $5.20 \pm 1.29$  vs  $4.24 \pm 0.76$  ;  $p < 0.01$  ). After 3 and 12 months significant

differences in CPAP use between the two groups persisted:  $5.25 \pm 0.91$  vs  $4.12 \pm 0.57$  ( $p < 0.01$ ) and  $5.24 \pm 0.85$  vs  $4.02 \pm 0.37$  ( $p < 0.01$ ) respectively (Figure 3). Furthermore, when we compared the percentage of patients who used CPAP more than *4 hours per night for > 70% of all nights*, we found that after 1 month 93.75 % of patients in the educational support group and 69 % of patients in the standard support group achieved the target ( $\chi = 13.06$ ;  $p < 0.001$ ). After 3 and 12 months significant differences in achieving the target still persisted: 96.67 % vs 71.43 % ( $\chi = 14.79$ ;  $p < 0.001$ ) and 97.47 % vs 74.07 % ( $\chi = 12.66$ ;  $p < 0.001$ ) respectively (Figure 4).

Daytime sleepiness, as measured by the ESS, was significantly reduced after 1 month in group 1 and to a similar extent in group 2 ( $4.37 \pm 0.30$  vs  $4.30 \pm 0.20$ ;  $p = \text{not significant}$ ). After 3 and 12 months of treatment, the ESS score remained substantially stable with no significant differences between the two groups (at 3 months:  $4.04 \pm 0.23$  vs  $4.14 \pm 0.31$ ;  $p = \text{not significant}$  and at 12 months:  $3.30 \pm 0.28$  vs  $3.10 \pm 0.35$ ;  $p = \text{not significant}$ ).

## **DISCUSSION**

The most important finding of the present study was the significantly higher percentage of patients in the educational support group who returned for follow up after 1-, 3-, and 12-months of CPAP treatment, compared to the standard support group. The higher retention rate observed among patients who have been shown their own PSG charts before/after CPAP, suggests that an increased knowledge and awareness of the obstructive sleep apnea, and its pathophysiological consequences, may be a key aspect of adherence to CPAP treatment. Some previous studies demonstrated the important role of educational support in CPAP compliance [21,22,25-27]. However, to our knowledge this is the first long term study in which patients viewed their own PSG charts pre-post CPAP, as educational support.

We found that 93% of them returned for follow up after 1 month of CPAP therapy, and 76% after 12 months. There are two possible explanations for such difference in terms of retention rate. First, the view of a PSG chart is certainly of paramount importance in order to realize the pathophysiological changes that occur during sleep in OSA patients; indeed, even a more detailed explanation of OSA and/or CPAP cannot disregard the visual experience of the classic polysomnographic signs of apnea/hypopnea, and their disappearance after CPAP. Second, it is conceivable that the view by patients of their own PSG charts before/after CPAP has a significant psychological impact on them, increasing the awareness of their condition, and therefore their motivation to adhere to the treatment. In support of this, in the recent study by Nadeem et al [28], the vision of the pathological track in the experimental arm (without post-CPAP chart vision that showed the resolution of the events) did not provide better results in terms of compliance, compared to the control arm.

At every follow-up visit, we observed a higher CPAP usage among patients in the educational support group; indeed, mean CPAP usage was on average 5 h/night in this group and 2 and 4 h/night in the standard group. On the other hand, it should be highlighted that, although standard criteria to define an optimal nightly duration of CPAP treatment have still not been established [26,29], it is considered as acceptable an application time of at least 4 h/night for 70% of nights [7,23,29,30]. Using this definition in our study we also confirmed a better compliance in the educational support group (Figure 4).

In this regard, several randomized controlled trials showed significant clinical improvement with even the relatively low levels of CPAP usage as found in our standard support group [31,32]. This was confirmed in our study since we observed that CPAP treatment reduced daytime sleepiness (as measured by the ESS) in both groups to a similar extent.

It is important to remark that educational studies regarding CPAP compliance often include multiple simultaneous interventions (“packages”) [18]. In Hoy et al [22], subjects in the



educational support group received home nursing, and a 3-night CPAP trial, as well as educational support. In the study of Damjanovic et al [27], intensive support included optimizing the equipment, such as the correct use of humidifiers and mask fit, together with counseling and educational support. Differently, in the present study, educational support was based on a single and brief intervention in order to assess its specific contribution to CPAP compliance, avoiding related confounding factors.

Here some limitations need to be taken into account. First, the expression “retention rate” should be used with caution. In fact, the design of this study does not allow to know whether all the subjects who did not return for follow up were really not compliant to treatment.

On the other hand, it is likely that patients who do not return to clinic are not in compliance; in this regard, since several insurance companies require proof of periodic clinic attendance for coverage of CPAP machine rental, not compliant subjects lose the use of the machine [21]. Anyway, retention rate was considered a key indicator of CPAP therapy acceptance by different groups [21,27, 30]. Finally, in our study, CPAP compliance was not reinforced during the follow-up visits, so as not influence the outcome.

Second, only the reduced daytime sleepiness was considered as clinical outcome; thus, it is possible that significant clinical differences were present in terms of other symptoms, quality of life, cognitive function, and apnea-hypopnea index. However, the presence or not of excessive daytime sleepiness is considered to be a key factor in clinical evaluation of OSA subjects [33]; moreover, mean nightly CPAP usage was substantially adequate in both groups. All these considerations to some extent counterbalance our limitation.

This study did not include a cost–benefit analysis. However, this educational procedure does not entail any additional cost and it is not demanding (just five minutes more than the standard protocol). Hence it may be easily reproduced in any sleep medicine center.

Yet, to overcome the patient limits of interpreting the PSG charts, we considered to focus his/her attention only on the tracks of the flow and the oxyhemoglobin saturation.

It is necessary to remark that the present study included only patients with moderate to severe OSA, so results cannot be applied to mild OSA.

In conclusion, we demonstrated that the view of PSG chart by OSA patients can improve the long-term treatment compliance, as evaluated by retention rate and mean nightly CPAP usage.

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**Table 1 .** Patients characteristics at baseline

**Figure 1.** Chart of the study protocol.

**Figure 2.** Percentage of retention to follow-up visit at 1, 3 and 12 months for patients receiving educational support and standard support group .

**Figure 3.** Mean CPAP usage at 1, 3 and 12 months for patients receiving educational support and standard support group .

**Figure 4.** Percentage of CPAP use > 4h per night for > 70% of all nights at 1, 3 and 12 months for patients receiving educational support and standard support group.

**Figure 5.** 10 minutes of the 1<sup>st</sup> chart in REM phase.

**Figure 6.** 10 minutes of the 2<sup>nd</sup> chart in REM phase.

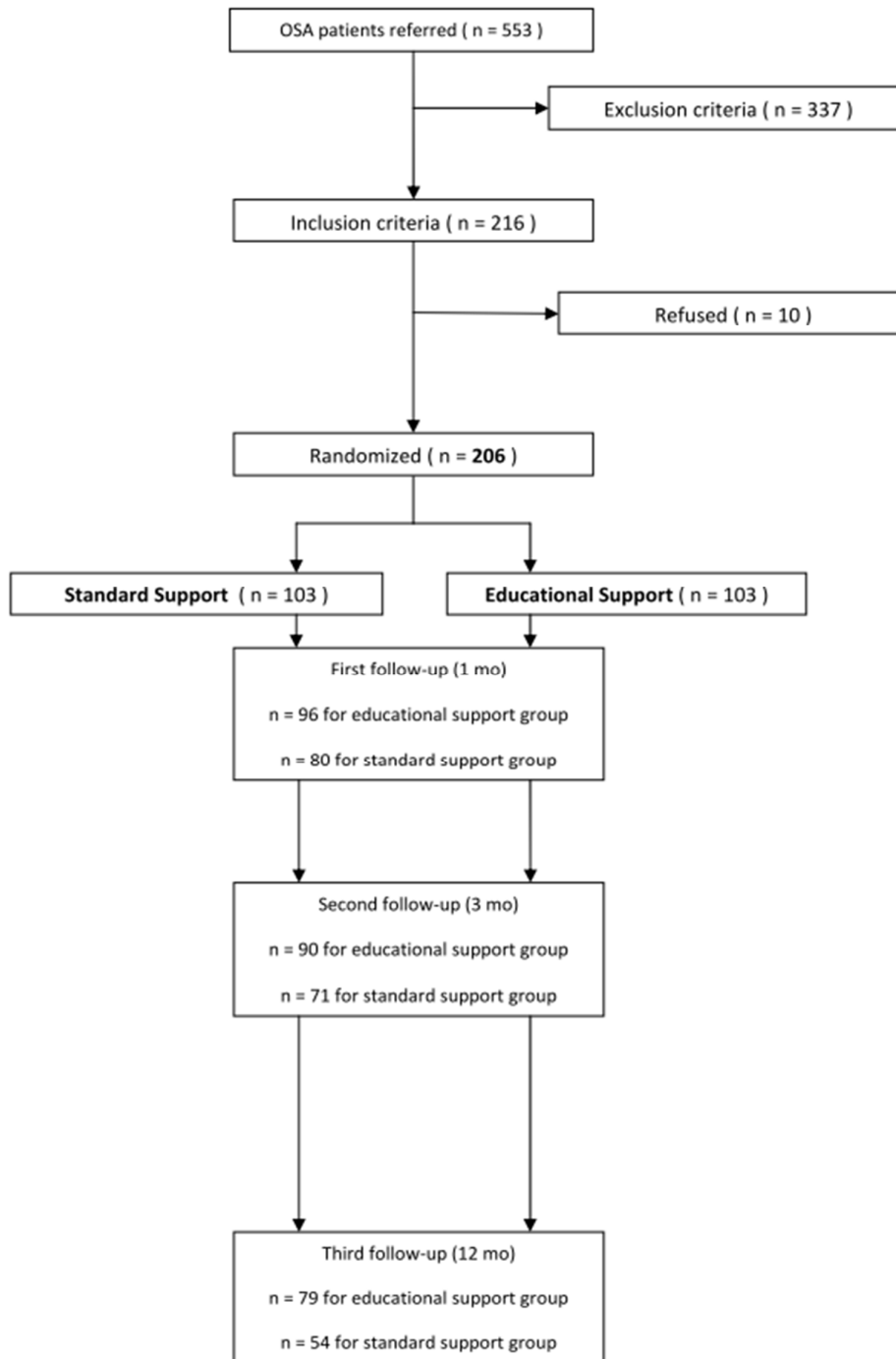
**Table 1 . Patients characteristic at baseline**

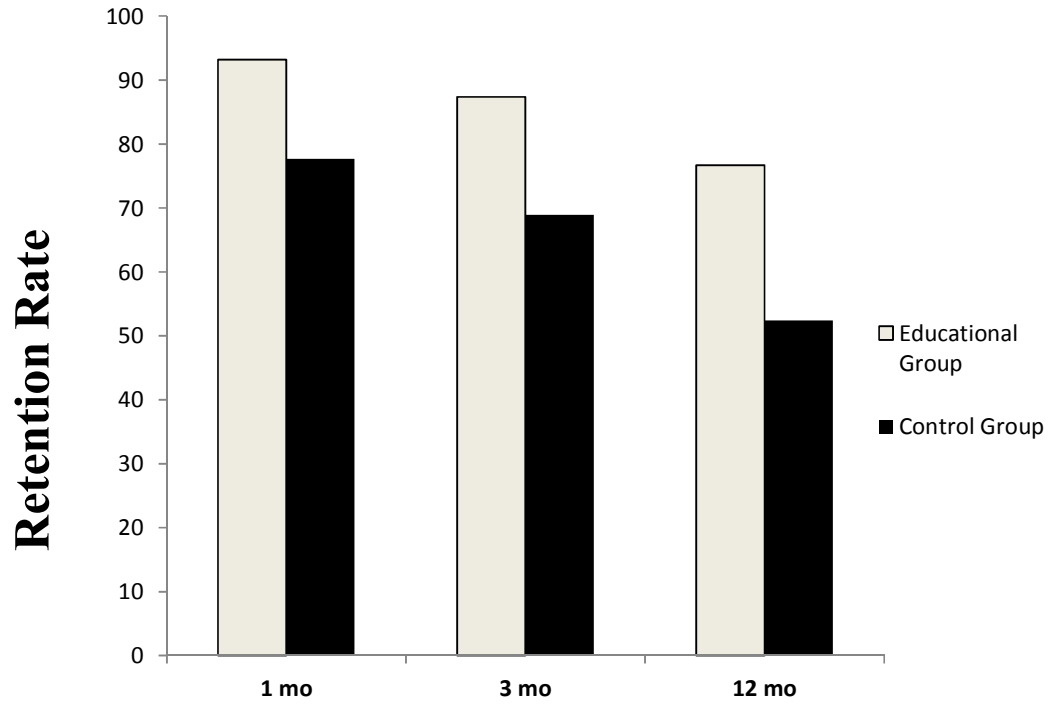
	<b>Educational Support Group ( n = 103 )</b>	<b>Standard Support Group ( n = 103 )</b>	<b>P Value</b>
Age	60.75 ± 8.6	61.85 ± 7.1	NS
Male %	77.67	72.81	NS
Female %	23.33	27.19	NS
BMI	33.9 ± 7.1	30.2 ± 5.1	NS
AHI	56.0 ± 5.2	52 ± 6.4	NS
ODI	40.1 ± 4.1	37 ± 5.8	NS
TST 90	15.0 ± 5.4	16.1 ± 6.7	NS
Neck Circ. (cm)	43.3 ± 2.0	43.0 ± 2.0	NS
Waist Circ. (cm)	108.0 ± 8.6	110.2 ± 7.8	NS
Epworth Sleepiness Score	11.2 ± 1.9	11.1 ± 1.7	NS

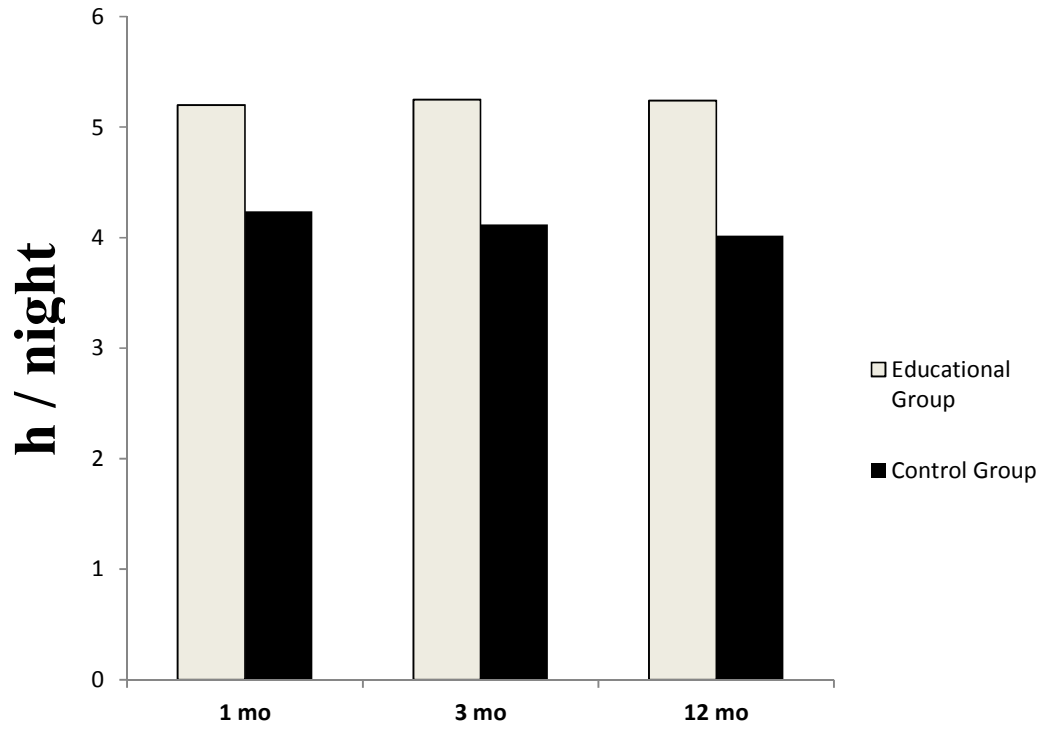
*BMI* body mass index , *AHI* apnea–hypopnea index, *ODI* oxygen desaturation index, *TST 90* total sleep time with oxyhemoglobin saturation below 90% , *NS* not significant

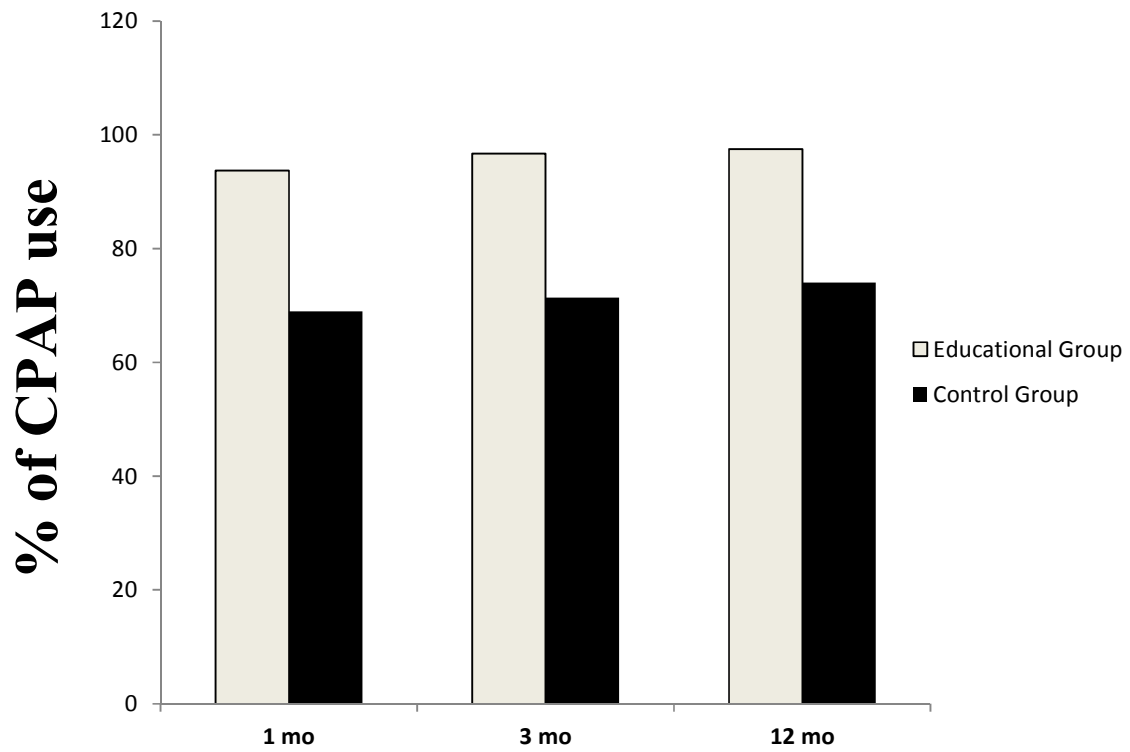


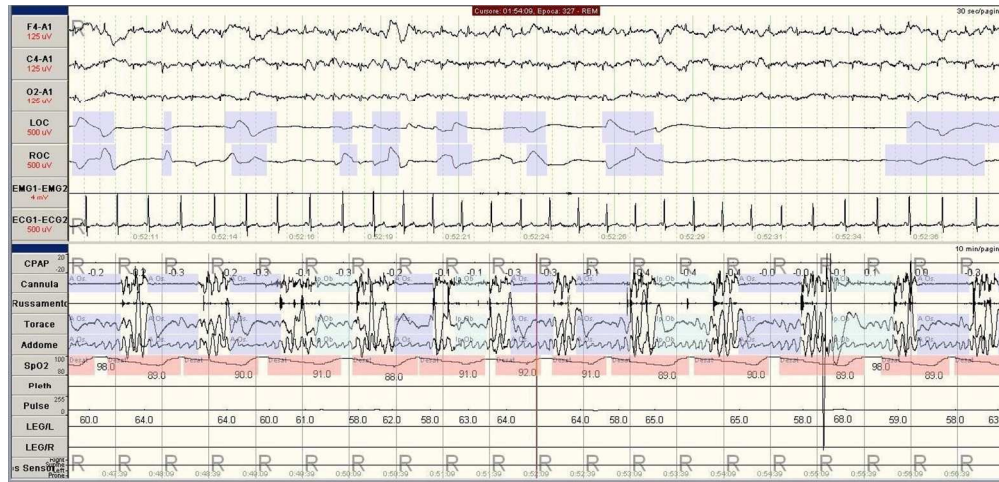
**Figure 1.** Chart of the study protocol.



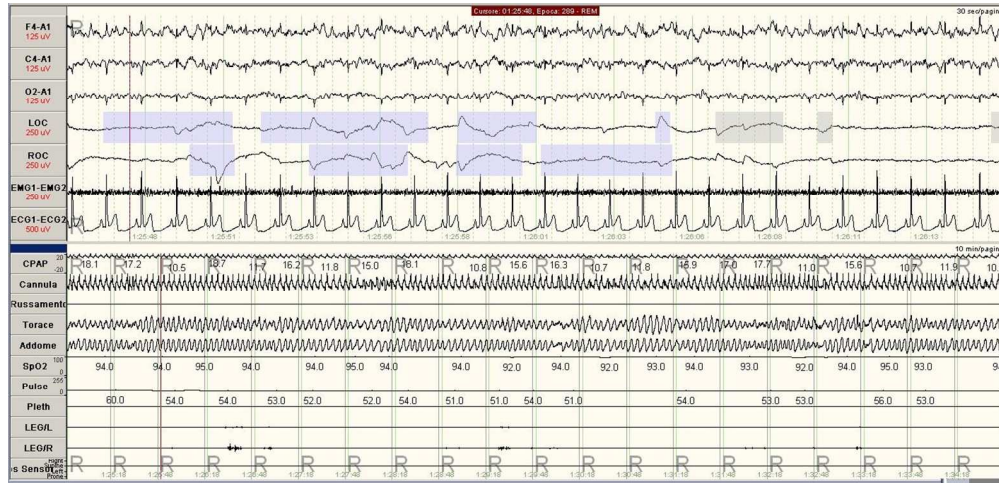








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