

# Educating Stroke/TIA Patients about Obstructive Sleep Apnea after Stroke: A Randomized Feasibility Study

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*Background:* Obstructive sleep apnea (OSA) occurs in about 70% of stroke and transient ischemic attack (TIA) patients and is associated with poor function and recurrent vascular events. Continuous Positive Airway Pressure (CPAP) has been shown to improve poststroke/TIA outcomes but adherence is generally poor. This study aimed to develop and conduct a preliminary assessment of educational materials for poststroke/TIA OSA. *Methods:* This blinded pilot study involved the randomization of stroke/TIA patients to either an intervention group (who viewed an educational pamphlet and slideshow) or a control group (standard of care). Patient ratings were used to evaluate the educational materials. Changes in knowledge, daytime sleepiness, functional outcomes of sleep, and CPAP use were assessed at baseline and 6 months. *Results:* Total 93% of eligible patients consented to participate. Forty-eight participants were randomized to the control group (n = 23) or intervention group (n = 25). In the intervention group, all patients agreed or strongly agreed that the information in the educational materials was useful and that the wording was easy to understand. There were no significant changes in knowledge, daytime sleepiness, and functional outcomes of sleep between both groups at 6 months. In those who used CPAP, there was no significant difference in mean hours of CPAP use at the 6-month follow-up. *Conclusions:* The educational program was feasible and easy to understand amongst stroke/TIA patients but did not lead to a significant change in outcomes or CPAP use. The lessons learned can be used to facilitate future development of educational materials and plan an adequately-powered trial.

**Key Words:** Obstructive sleep apnea—stroke—transient ischemic attack—CPAP adherence—patient education—video—pamphlet  
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## Introduction

Obstructive sleep apnea (OSA) is characterized by temporary interruption of airflow during sleep due to intermittent collapse of the upper airway.<sup>1</sup> OSA results in awakenings during sleep and apneic events that result in increased blood pressure, oxidative stress, and platelet activation, and impairment of vascular endothelial function.<sup>1</sup> OSA occurs in approximately 70% of patients with stroke and transient ischemic attack (TIA).<sup>2</sup> Untreated poststroke OSA can result in recurrent stroke,<sup>3</sup> early mortality,<sup>4</sup> functional impairment,<sup>5</sup> and prolonged hospitalization.<sup>6</sup> The gold standard treatment for OSA is continuous positive airway pressure (CPAP).<sup>7</sup> CPAP provides patients with a constant level of positive pneumatic pressure into the airways in order to prevent recurrent collapse.<sup>7</sup> Treating OSA in stroke patients with CPAP has been found to improve neurological recovery,<sup>8</sup> reduce daytime sleepiness,<sup>9</sup> reduce depressive symptoms,<sup>10</sup> and improve cognition.<sup>11</sup> In addition, the literature suggests that stroke patients with increased CPAP adherence, as defined as using CPAP for at least 4 hours per night, demonstrate overall improved outcomes.<sup>9-11</sup> However, despite the clinical importance of treating poststroke OSA using CPAP therapy, long-term CPAP adherence in stroke patients is generally poor.<sup>12,13</sup>

Given the consequences of leaving OSA untreated in stroke and TIA patients, we felt that it was important to develop a novel approach to promote CPAP adherence in this clinical population. One such approach would be to educate stroke and TIA patients about the harmful effects of OSA and the potential benefits of CPAP therapy. Outside of the stroke/TIA setting, a prior randomized controlled trial (RCT) found that patients with OSA who were enrolled in a brief motivational education program had better CPAP adherence compared to a control group due to increased knowledge and motivation.<sup>14</sup> Furthermore, another RCT concluded that viewing an educational video about OSA and CPAP significantly improved CPAP adherence in patients with OSA.<sup>15</sup> The use of an educational pamphlet on OSA for stroke patients was assessed in a small nonrandomized, single-group, pretest, and post-test study.<sup>16</sup> This brief educational pamphlet was found to improve patient knowledge and intention to discuss OSA screening with a physician. Despite these promising findings, there is a need to study the use of educational materials in stroke and TIA patients using an experimental design.

This is a randomized feasibility trial that served as a preliminary study to examine the feasibility of administering educational materials (pamphlet and animated slideshow) to stroke/TIA patients. We secondarily studied, in an exploratory fashion, the effect the educational materials had on patients' knowledge about poststroke sleep disorders, daytime sleepiness, functional outcomes of sleep, and adherence to CPAP.

## Methods

### *Ethics Approval*

This study was approved by the Sunnybrook Research Ethics Board and was conducted in accordance with the ethical standards in the Declaration of Helsinki. All study participants provided written informed consent prior to study participation.

### *Study Design*

This study was a blinded, RCT in patients with a history of stroke or TIA who were having poststroke/TIA sleep complaints. Patients were recruited, consented, randomized, and completed baseline or follow-up testing prior to their clinic appointment. Recruited patients were randomized 1:1 to either the intervention group (educational materials) or the control group (usual care). The treating physician (MIB) and the outcome assessors were blinded to the treatment allocation of the study participants. Patients in the intervention group viewed a 5-minute animated slideshow and received an educational pamphlet. Furthermore, patients in the intervention group were asked to provide feedback regarding the animated slideshow and pamphlet. In contrast, patients in the control group received no additional education (outside of that provided via usual care) but were otherwise treated identically to those in the intervention group. Six months following their initial visit, study participants were seen by a different research assistant (who was blinded to the treatment allocation of the study participants) for a follow-up visit where they completed the same questionnaire package as during the baseline assessment.

### *Study Population*

We recruited patients who had sustained a stroke or TIA and were experiencing sleep complaints. Patients were excluded if they had any of the following: (1) significant physical or cognitive impairment that would restrict their ability to comply with the study protocol; (2) aphasia; (3) inability to communicate in English; (4) facial/bulbar weakness; (5) life expectancy of less than 6 months, which was the duration of the study.

### *Intervention*

In order to develop the educational materials for the intervention group, a review of existing literature on poststroke/TIA sleep disorders was conducted to compile information relevant to the study goals. Information such as risk factors, symptoms, consequences and treatment of poststroke/TIA OSA was gathered. In addition, we assembled a list of good sleep hygiene practices. All information was condensed into a pamphlet and adapted into a 5-minute animated slideshow (please see supplementary material). The educational materials were revised in

accordance with feedback received over the course of multiple consultations with patients and the research team.

### *Outcomes*

The primary outcome of this study was to assess whether the use of educational materials on sleep disorders was feasible and easy to use in a stroke/TIA population. The secondary outcomes of this study were to assess the efficacy of the educational materials in an exploratory fashion. Specifically, we aimed to evaluate whether the educational materials improved knowledge about post-stroke/TIA OSA, improved daytime sleepiness, and improved functional outcomes of sleep over a 6-month period. In addition, in those who were using CPAP, adherence to CPAP at 6 months was compared between the study groups.

### *Assessments*

Feasibility was assessed by comparing the number of patients who agreed to participate in the study with the number of patients who were eligible for participation in the study. In addition, we also compared the number of patients enrolled at baseline with the number of patients who completed the 6-month follow-up assessment in both study arms. Participants in the intervention group were provided with an evaluation form after they viewed the educational materials to assess the ease of use of the educational materials. Specifically, this evaluation form allowed participants to rate their overall perception of the usability of the educational materials and its impact on their knowledge using a Likert scale.

Baseline and 6-month follow-up questionnaire packages were used to explore the secondary outcomes of this study. These questionnaire packages consisted of the Sleep Disorders Knowledge Test for Stroke/TIA (SDKTS) that we developed, the Functional Outcomes of Sleep Questionnaire (FOSQ),<sup>17</sup> and the Epworth Sleepiness Scale (ESS).<sup>18</sup> The SDKTS/TIA was developed based off information that was included in the educational pamphlet and animated slideshow, described in the Intervention section (please see supplementary material for the SDKTS). The FOSQ, which measures consequences of sleep disorders on daily life, ranges from a score of 5-20<sup>17</sup>; a FOSQ score less than 18 indicates that there is a negative effect of sleepiness on daily life<sup>19</sup> and a 1-unit difference in the FOSQ score is considered clinically significant.<sup>20</sup> The Epworth Sleepiness Score measures daytime sleepiness and ranges from 0 to 24, in which higher scores indicate greater daytime sleepiness<sup>18</sup>; an ESS of 10 or more is indicative of excessive daytime sleepiness and a 2-unit difference in the ESS is considered clinically significant.<sup>21</sup> CPAP adherence was measured by asking the participants who used CPAP to track the number of hours they used CPAP per week. Participants were considered to be

adherent to CPAP if they used CPAP for at least 4 hours per night or at least 28 hours per week.<sup>13</sup>

### *Statistical Analysis*

Categorical variables were displayed as counts (%) and were compared using chi-square analyses. The normality of continuous variables was assessed using the Shapiro-Wilk Test, with a *P* value of more than .05 on this test indicating a normally distributed variable. Normally distributed continuous variables were reported as mean  $\pm$  SD and were compared using *t* tests. Non-normally distributed continuous variables were reported as median (range) and were compared using Mann Whitney *U* tests. Statistical significance was set as a *P* value less than .05. All data was analyzed using the Statistical Package for the Social Sciences version 24.0 (IBM, Ontario, Canada).

## **Results**

### *Patient Demographics*

Participants (*n* = 48) had a mean ( $\pm$ SD) age of 68.9 ( $\pm$ 11.5) years with 60% of the patient population being male and 94% presenting with a stroke as opposed to a TIA. The average number of days between stroke/TIA and study enrollment was 260 days in the control group and 337 days in the intervention group. Total 60% of participants in the control group and 68% of participants in the intervention group were recruited to the study during a follow-up visit (as opposed to an initial consultation). [Table 1](#) displays the demographic information of the study population. No significant differences were found between the participants in the intervention and control groups in all demographic variables examined.

### *Feasibility for use of Educational Materials in Stroke/TIA Patients*

[Figure 1](#) highlights the number of participants at each stage of the study. Throughout a 4-month span, we identified 54 patients who met the inclusion criteria for this study. Of the 54 eligible patients, 50 patients agreed to participate in the study and provided informed consent. Forty-eight participants out of the 50 who consented, completed baseline assessments, and were randomized to either the control group (standard of care) (*n* = 23) or the intervention group (viewed animated slideshow and pamphlet) (*n* = 25). Four participants dropped out prior to the 6-month follow-up assessment in the control group and no participants dropped out from the intervention group.

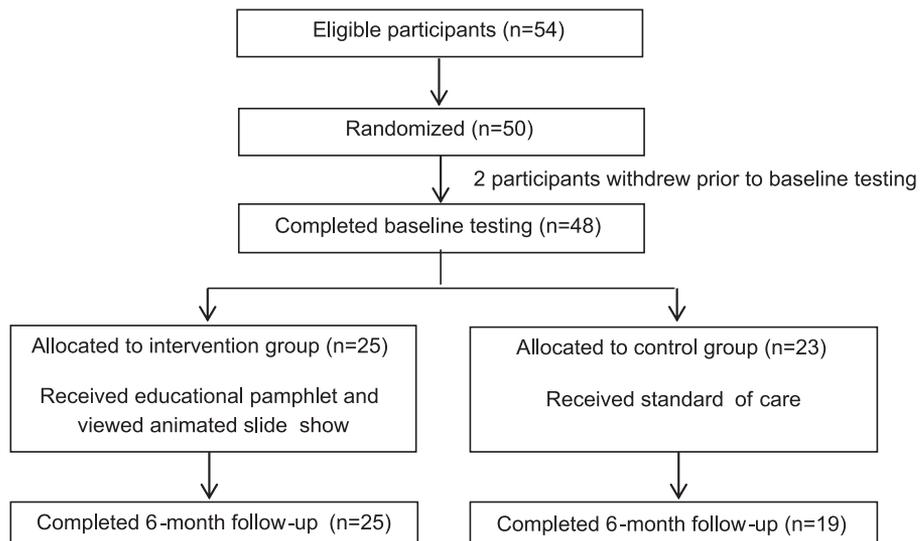
### *Ease of use and Patient Satisfaction with Educational Materials*

Ease of use for the educational materials was evaluated in the intervention group. All 25 participants in the

**Table 1.** Demographics and prior medical history of participants

	Control (n = 23)	Intervention (n = 25)
Mean y of age (IQR)	66.0 (19.0)	71 (12.0)
Sex		
Males	16 (70%)	14 (56%)
Females	7 (30%)	11 (44%)
Mean y of education $\pm$ SD	16.1 $\pm$ 3.8 (n = 17)	16.6 $\pm$ 3.3 (n = 18)
Stroke versus TIA	23 (100%)	22 (91.7%) (n = 24)
Obstructive sleep apnea		
None (%)	10 (43%)	10 (40%)
Treated with CPAP (%)	10 (43%)	7 (28%)
Untreated (%)	3 (14%)	8 (32%)
Hypertension		
None (%)	8 (35%)	7 (28%)
Treated (%)	15 (65%)	17 (68%)
Untreated (%)	0 (0%)	1 (4%)
Hyperlipidemia		
None (%)	6 (26%)	10 (40%)
Treated (%)	17 (74%)	13 (52%)
Untreated (%)	0 (0%)	2 (8%)
Diabetes		
None (%)	15 (65%)	18 (72%)
Treated (%)	8 (35%)	7 (28%)
Untreated (%)	0 (0%)	0 (0%)
Smoking		
Never	12 (52%)	14 (56%)
Prior (quit > 15 y ago)	7 (31%)	8 (32%)
Prior (quit $\leq$ 15 y ago)	3 (13%)	2 (8%)
Current	1 (4%)	1 (4%)
Atrial fibrillation		
None	18 (78%)	23 (92%)
Anticoagulated	4 (18%)	1 (4%)
Not anticoagulated	1 (4%)	1 (4%)
Prior MI	0 (0%)	3 (12%)

Abbreviations: IQR, Interquartile Range.

**Figure 1.** Participant flow through the study.

intervention group were able to watch the 5-minute animated slideshow from start to finish without any interruptions or personal difficulties. Out of the 24 participants in the intervention group who filled out an evaluation form after viewing the educational materials, 75% “strongly agreed” and 25% “agreed” that the information covered in the educational materials were useful. Total 71% of participants strongly agreed and 29% agreed that the words used in both the pamphlet and animated slideshow were easy to understand. With regards to their perceived understanding and knowledge gained from viewing the educational materials, 96% of participants either agreed or strongly agreed that they understood what sleep apnea is, 100% were able to understand the harmful effects of sleep apnea, and 100% learned some tips to improve their sleep hygiene.

*Knowledge About Poststroke Sleep Disorders, Sleepiness, and Functional Outcomes*

The mean difference in scores on the SDKTS/TIA, ESS, and FOSQ between baseline and 6-month follow-up was compared between the control and intervention groups (Table 2). An independent *t* test revealed no significant change in knowledge about sleep disorders between the intervention group and the control group (*P* = .352). Likewise, change scores for the ESS (*P* = .185) and FOSQ (*P* = .412) also did not significantly differ between the 2 groups.

*CPAP Adherence*

The number of hours of CPAP used per week was reported by participants in the intervention and control groups. CPAP adherence was determined in participants who were started on CPAP between study recruitment and the 6-month follow-up, as well as in those who were prescribed CPAP prior to the commencement of the study. At the 6-month follow-up, the mean hours of CPAP use per week in the control group was 41.9 hours per week compared to 36.4 hours per week in the intervention group, which was not a statistically significant difference (*P* = .506).

In the intervention group, 5 participants started CPAP prior to study enrolment, and 3 participants started CPAP during the study period. Out of these 8 participants who were using CPAP, 5 were adherent with CPAP at the 6-month follow-up. In the control group, 8 participants started CPAP prior to the study and 2 participants started CPAP during the study period. Of the 10 participants, 9 participants were adherent to CPAP at the 6-month follow-up. There was no significant difference in CPAP adherence at the 6-month follow-up between the control and intervention groups (*P* = .206).

**Discussion**

This is the first randomized feasibility study to evaluate the use of an educational pamphlet and animated slideshow in poststroke/TIA OSA. This trial found that an educational intervention (involving a pamphlet and animated slideshow) was feasible and easy to use in stroke and TIA patients. A total of 93% of patients who met the eligibility criteria were interested in participating in this study and were recruited. Study participants in the intervention group found the pamphlet and animated slideshow easy to understand and they felt that they were able to gain an understanding about OSA and its harmful effects after viewing the educational materials. Although the concept of educating stroke/TIA patients is promising and feasible, significant benefits were not observed in this study in knowledge acquisition, daytime sleepiness, functional outcomes of sleep, or CPAP adherence.

Overall, the study participants in the control group and intervention group did not differ with regards to their knowledge about poststroke/TIA sleep disorders at baseline and at the 6-month follow-up. In addition, there was no significant change in level of daytime sleepiness, as measured by the ESS, between the control group and intervention group. On average, both groups did not display excessive daytime sleepiness at the start of study enrollment since the mean ESS scores at baseline was 4.5 in the control group and 4.4 in the intervention group, out of a maximum ESS score of 24. With regards to functional outcomes of sleep, which was assessed by using the FOSQ, there was also no significant difference between the control and intervention groups at baseline and at the

**Table 2.** Mean outcome scores and differences in control and intervention groups

	Intervention group (n = 25)			Control group (n = 19)			<i>P</i> value
	Baseline mean	Six-month follow-up mean	Mean difference	Baseline mean	Six-month follow-up mean	Mean difference	
Sleep disorders knowledge test for stroke/TIA	16.5 ± 3.7	17.1 ± 4.5	.6 ± 4.8	15.1 ± 4.1	17.0 ± 4.2	1.9 ± 3.8	.352
Epworth sleepiness scale	4.4 ± 2.6	3.9 ± 3.2	-.5 (2.8)	4.5 ± 3.7	5.1 ± 3.6	.6 (2.6)	.185
Functional outcomes of sleep questionnaire	19.0 ± 1.4	18.8 ± 1.6	-.2 ± 1.3	17.8 ± 2.7	17.9 ± 2.2	.1 ± 1.5	.412

6-month follow-up. Furthermore, there was no significant difference in the mean number of hours that CPAP was used per week at the 6-month follow-up period between participants in both study groups who were prescribed CPAP either prior to study enrollment or during the study period.

There are some plausible reasons that may explain the lack of significant differences between the control group and intervention group. First, this study may have lacked statistical power. However, since this is a preliminary feasibility study, a sample size calculation was not conducted since the results from this study will be used to develop a larger RCT. Second, there are some possible changes that can be made to the educational materials in order to improve their effect. For example, it may be more beneficial for patients to have the animated slideshow as a conversational video with real patient actors, as has been previously developed in a nonstroke clinical setting.<sup>15</sup> Furthermore, the educational slideshow and its animations may also not have been explicit enough to warn the viewers about the harmful effects of sleep apnea. In addition, the 5-minute animated slideshow may not have given participants the opportunity to understand, reflect, and synthesize the information being presented. This may be due to the didactic nature of the educational materials, which involves the patient passively receiving standardized information that is provided to all patients. Knowledge acquisition to this patient population may be improved by facilitating a patient-centered education model, as successfully implemented in Type 2 Diabetes patients.<sup>22</sup> In patient-centered education, the patient plays an active role in their learning because they work with healthcare professionals to develop learning plans that involve personalized concerns, knowledge gaps, and priorities.<sup>22</sup> A review of information provision in stroke patients and their caregivers also suggested that actively involving patients and providing the opportunity for follow-up for clarification and reinforcement of information should be a part of standard practice.<sup>23</sup>

Another potential explanation for why benefits were not observed may be due to possible limitations with the SDKTS/TIA, which was created for this study by the study authors to assess knowledge acquisition. Since the validity of this test has not been evaluated, it is possible that this test may not have been sensitive enough to evaluate changes in knowledge over time. Prior studies that have evaluated the impact of educational interventions on CPAP adherence in patients with OSA have not examined patients' knowledge as a mediating variable of interest.<sup>15,24</sup> Therefore, there is a need to further study how to appropriately assess sleep-related knowledge acquisition in a stroke/TIA patient population in order to facilitate the evaluation of future educational interventions. Development of a standardized knowledge test for patients may help us understand potential mechanisms by which educational interventions may influence important clinical outcomes such as CPAP adherence. In addition, the

knowledge test can also be linked to a patient-centered approach to education, discussed above, by personalizing the questions to address the patient's specific concerns and preferences for information.

Furthermore, it may have been more appropriate in this study to have excluded participants who were already using CPAP prior to study enrollment. Since CPAP adherence after 1 month is indicative of long-term CPAP use,<sup>12</sup> this may have explained why participants who were already using CPAP prior to the start of the study did not show any significant changes in CPAP adherence after receiving the educational intervention. Another potential change to the inclusion criteria would have been to only recruit patients after they had undergone an in-laboratory overnight sleep study and had been formally diagnosed with OSA. Since stroke patients with OSA generally do not report greater daytime sleepiness and have lower body-mass index (as compared to nonstroke patients with OSA),<sup>25</sup> they are less likely to think they have a sleep disorder to begin with and therefore would not be as interested or motivated to learn about OSA. This was seen in this study population since participants did not display excessive daytime sleepiness at baseline and also felt that their sleep did not have a major impact on their everyday activities. Therefore, trying to provide education to patients with newly diagnosed poststroke/TIA OSA may increase the likeliness that patients would be more invested in learning about OSA and CPAP use.

## Conclusions

Overall, educating patients about poststroke/TIA OSA remains an understudied area of research that can have potential benefits in the stroke/TIA patient population. Educational materials used in this study were found to be feasible and were easy to use by stroke and TIA patients. Unfortunately, our exploratory analysis did not find any significant change in the secondary outcomes (knowledge, daytime sleepiness, functional outcomes of sleep, and CPAP use). Given the change in outcomes produced in the intervention and control groups in this preliminary trial, we will now be able to calculate a sample size that would be needed to develop a future trial that is adequately powered. In addition, the lessons learned from this study can be used to refine the existing educational materials and study protocol.

## Declaration of Competing Interest

The authors have no conflicts of interest to disclose.

## Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:[10.1016/j.jstrokecerebrovasdis.2019.104317](https://doi.org/10.1016/j.jstrokecerebrovasdis.2019.104317).

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