ORIGINAL ARTICLE

Effects of nocturnal wearing of dentures on the quality of sleep and oral-health-related quality in edentate elders with untreated sleep apnea: a randomized cross-over trial

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Abstract

Study Objectives: This study aims to assess whether the nocturnal wear of dentures has an effect on the quality of sleep and oral-health-related quality of life of the edentulous elderly with untreated sleep apnea.

Methods: A single-blind randomized cross-over design with two sequences and two periods was used. Participants (*n* = 77) were randomly assigned either to sequence 1 (nocturnal wear followed by nocturnal nonwear of the denture for 30–30 days) or sequence 2 (nocturnal nonwear followed by nocturnal wear of denture for 30–30 days). The primary sleep outcome was the quality of sleep, assessed through sleep fragmentation measured as Apnea–Hypopnea Index (AHI) and respiratory arousal from portable polysomnography. Secondary outcomes were daytime sleepiness, sleep quality (Pittsburgh Sleep Quality Index, PSQI) and oral-health-related quality of life measured by validated questionnaires.

Results: The mean paired difference in AHI scores for the period of wearing versus not wearing dentures at night was small 1.0 event per hour (*p* = 0.50; 95% confidence interval (CI) = −2.0 to 4.1). The mean respiratory arousal index was higher when wearing dentures at night than when not wearing dentures at night, with a mean paired difference of 2.3 events per hour (*p* = 0.05; 95% CI = 0.0 to 4.6). No difference in sleepiness and PSQI were noted. Wearing dentures at night resulted in a statistically significantly higher mean score of psychological discomfort when compared to not wearing dentures at night.

Conclusions: The results provide some support to usual practice guidelines to remove dentures at night in edentulous elders suffering from sleep apnea.

Clinical trial registration: NCT01868295.

Statement of Significance

Aging substantially increases the risk of tooth loss and sleep problems. Tooth loss can disturb sleep through the alteration of the lower face and upper airway. However, the effect of nocturnal wearing of dentures on the quality of sleep is still not well understood. While some studies suggest that sleeping without dentures can worsen sleep and breathing in toothless elders, there are also studies that have suggested the opposite. Hence, there is a lack of evidence-based practice guidelines on whether dentures should be used at night. The results of this randomized controlled trial provided important clinical implications about the nocturnal wearing of dentures in the edentate elderly population untreated for sleep apnea. The valuable information obtained from this trial will guide future diagnostic classification and treatment decision-making.

Introduction

The worldwide population is rapidly aging, with the majority of elders living longer than previous generations. Aging substantially increases the risk of tooth loss and obstructive sleep apnea (OSA). Some evidence shows that the prevalence of OSA is higher in edentate individuals than in nonedentate individuals [1]. In fact, the anatomical changes associated with edentulism could underline this association [2]. Loss of vertical dimension of occlusion due to complete tooth loss favors a rotational movement of the mandible and a reduction in the retropharyngeal space associated with impaired function of the upper airway dilatation muscles and diminished response to negative pressure stimulation [2, 3]. In the absence of teeth to delineate both the upper and lower arches, the tongue's form and function may be altered, thus resulting in impaired function of the oropharynx [4, 5]. Finally, age-specific compromised pharyngeal anatomy, upper-airway mucosal sensory dysfunction, and a decline in pharyngeal sensory discrimination and reflexes have been hypothesized to increase the vulnerability of edentate older adults to airway collapse [3, 6–8]. Many edentulous elders wear their denture at night, and limited evidence suggests there may be an effect of wearing a denture during sleep on sleep disturbance (denture effect). However, these findings have been inconsistent; some studies suggest that the use of a denture during sleep may lead to open bite and mouth breathing with a decrease in the tone of the pharyngeal muscles, thereby leading to the development or worsening of OSA [9–11], but according to others, sleep quality and pharyngeal patency are maintained by nocturnal denture use [5, 12, 13].

In 1999, a group of researchers [12] published a case series suggesting that, in edentate patients with OSA, the nocturnal wearing of the denture should be recommended. Although this publication was based on an extremely small number of elders with OSA (*n* = 6) [12], it has had an important impact on the practice, as indicated in the statement in the Journal of the American Dental Association: "Although I was taught that patients always should take their dentures out at night to preserve their bone structure, I have altered my practices and tell patients to keep their dentures in to preserve their airways" [14].

A systematic review [3] in 2017 on the effect of nocturnal wearing of dentures on sleep quality did not support the existence of such an effect, although when the analysis was restricted to patients with severe OSA at baseline, the results were indicative (if weakly) of a favorable effect of nocturnal wear of dentures on sleep quality. However, wearing dentures at night could be harmful to patients, since it reduces the protective effect of saliva and obstructs good oxygenation of the mucosa, which make the oral mucosa less resistant to mechanical and microbiological aggression, thus increasing the risk of chronic inflammatory changes within the mucosa [15–17], and increased risk of traumatic ulcers, denture stomatitis, alveolar bone resorption, oral candidiasis, and aspiration pneumonia in the edentate population [2, 18–25].

With a paucity of high-quality research addressing both edentulism and sleep disturbances, the effect of nocturnal denture-wearing on sleep quality has yet to be established. The limited number of studies on this topic, methodologic issues in them, and inconsistent results do not permit clinicians to engage in evidence-based decision-making when providing care for edentulous patients [2, 3]. Furthermore, this lack of knowledge could pose legal and ethical problems for clinicians who are involved in the care of the growing edentate population.

To enable the development of clinical practice guidelines, high-quality evidence is required. Therefore, we carried out a randomized controlled trial to assess the effects of wearing (versus not wearing) dentures at night on sleep breathing, on sleep quality and oral-health-related quality of life of elderly edentate individuals with untreated sleep apnea.

Methods

The Consolidated Standards of Reporting Trials (CONSORT) 2010 Statement and the extension for nonpharmacologic treatment have been used in reporting this trial [26].

Trial design and participants

The methodology of the trial has been described in detail in a previously published protocol [27]. Briefly, the trial used a single-blind randomized cross-over design with two sequences and two periods. The trial was registered in the US Clinical Trials Registry (NCT01868295) and was approved by the Université de Montréal Institutional Review Board. Edentate individuals, aged 65 years or older, with an untreated Apnea–Hypopnea Index (AHI) ≥10 were recruited into the trial from the Montreal Metropolitan area in Canada. The trial involved eligibility criteria screening via phone contact, baseline data collection including administration of trial questionnaires by trained research assistants, and a baseline portable overnight recording [level II polysomnography (PSG)] [28] by a trained sleep technologist at the participants' homes. Polysomnographic data was downloaded and scored using Embla REMLogic software (Natus Medical, USA) to assess AHI, snoring index, respiratory disturbance index, flow limitation, arousal related to respiratory efforts, and average and minimal oxygen saturation. These respiratory events were scored by Sleep Strategies Inc. (Ottawa, Canada), also blinded to allocation status, following the American Academy of Sleep Medicine 2012 guidelines [29].

The inclusion criteria were, in addition to AHI ≥10 described above: (1) having worn a complete set of dentures in the previous year only in the daytime, (2) consuming no alcohol and not working late at night on the day before polysomnography, (3) having an adequate understanding of written and spoken English or French, (4) being able to understand and respond to the questionnaires used in the study, and (5) agreeing to follow the research study instructions and to adhere to the allocated interventions. Exclusion criteria were: a score ≤24 on the Mini-Mental State Evaluation, any severe cardiologic, neurologic, psychological, or psychiatric condition, respiratory disease, acute airway infection or any health condition that jeopardizes sleep, or being under regular continuous positive airway pressure therapy or nocturnal supplemental oxygen, or using medications or any illicit drugs that affect sleep architecture or respiratory muscle activity, having sleepiness deemed to be unsafe and requiring urgent treatment, or feeling that the trial would negatively influence the person's private life [27]. Written informed consent was obtained from each eligible participant before enrolment into the study.

Randomization and blinding

Trial participants were randomly assigned to either sequence 1 (nocturnal wear of denture for 30 days followed by nocturnal nonwear of the denture for 30 days) or sequence 2 (nocturnal nonwear of the denture for 30 days followed by nocturnal wear of denture for 30 days (Figure 1), with no washout period (as no carry-over effect was expected based on the presumed mechanism of action of the intervention and our pilot data) [27].

A permuted-block randomization was carried out off-site (using SAS PROC PLAN), and each trial participant received a sequentially numbered, sealed, opaque, tamper-proof envelope containing a letter indicating the sequence of the interventions. All of the investigators and the other research-team members were "masked" to the group assignment for the duration of the trial, including the collection of data and data analysis. Although masking of the trial participants was not possible, they were
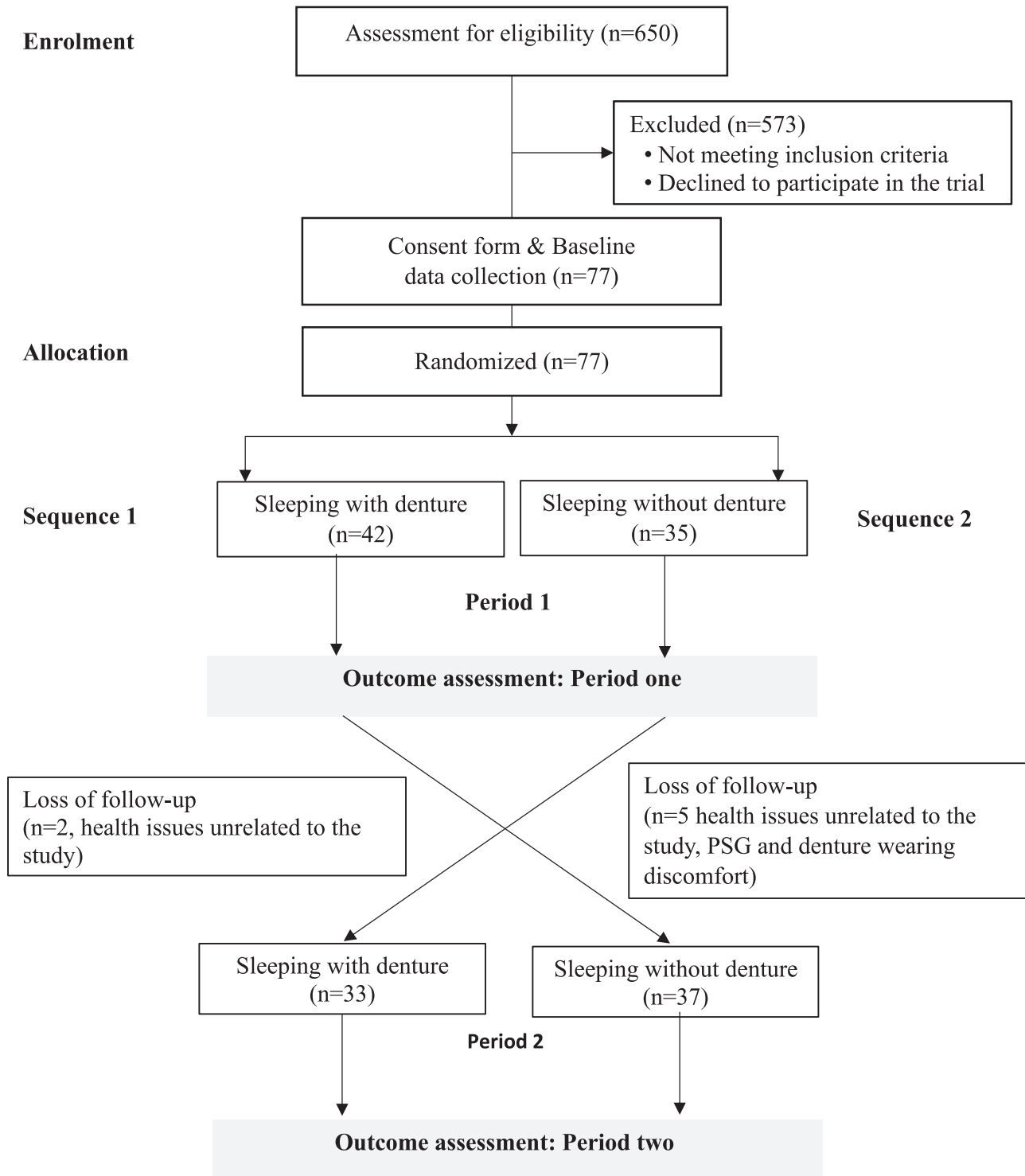

Figure 1. Trial flowchart.

asked not to discuss their assignment with the research staff, and their questions (if any) were answered by two independent clinicians responsible for compliance monitoring who was not involved in data collection and analysis. The intervention started one week after the baseline assessment. Follow-up data were collected at the end of each period by the sleep technologist and research assistants.

Outcomes

The primary outcome was the quality of sleep, assessed through sleep fragmentation measured as AHI and respiratory arousal from portable polysomnography [29, 30]. Secondary outcomes were daytime sleepiness, perceived sleep quality and oral-health-related quality of life. The daytime sleepiness was measured using the Epworth Sleepiness Scale (ESS) [31]. The ESS is an eight-item, 4-point scale (0–3) with strong internal consistency and half-split reliability [32]. Participants were asked to rate their chance of dozing in eight different sedentary situations. Scores ≥10 suggest excessive daytime sleepiness [31]. Additionally, the Pittsburgh Sleep Quality Index (PSQI) questionnaire, a well-validated instrument, was used to measure perceived sleep quality over a one-month time interval [33]. This scale has seven components: (1) subjective quality, (2) sleep onset latency, (3) sleep duration, (4) sleep efficiency, (5) presence of sleep disturbances, (6) use of hypnotic–sedative medication, and (7) presence of daytime disturbances. The total scores of the PSQI range from 0 to 21, with lower scores indicating better quality of sleep [33].

Oral-health-related quality of life (OHRQoL) was measured by means of the oral health impact profile (OHIP-20). This instrument is a disease-specific measure of people's perceptions of the impact of denture wear in terms of physical, psychological, and social impacts on their quality of life. This reproducible oral health disease-specific instrument has been widely used in geriatric dental research and has been tested and cross-culturally validated in English- and French-speaking Canadians. The range of the scale is 20–120 points, with lower scores indicating better OHRQoL [34, 35].

Sample-size justification and statistical analyses

Assuming that (1) the minimal clinically important difference in the AHI score between the two interventions is five events per hour (based on the opinion of expert clinicians, Delphi method) [36], (2) the standard deviation of the distribution of the difference in AHI score between the interventions is 10.6 events per hour (based on estimates from pilot data) [11], and (3) the drop-out rate is 10%, a sample size of 70 trial participants would ensure a 0.90 power to reject the null hypothesis if it is indeed false, at a two-sided Bonferroni-adjusted α level of 0.0167 (to account for the use of three outcomes: sleep quality, daytime sleepiness, and oral-health-related quality of life).

Descriptive analyses for all variables were performed. Linear mixed models were fitted in SAS Proc Mixed (SAS version 9.4, SAS Institute, Inc.) to test the associations between the intervention and each of the trial outcomes. The model included indicators of the treatment group (nocturnal wear or nocturnal nonwear of dentures) and period as fixed-effects terms, and participant as a random-effects term. A sensitivity analysis

was done for primary and secondary outcomes with treatment group, sequence, and period as fixed-effects terms and participant as a random-effects term. In addition, we carried out subgroup analysis to investigate the potential heterogeneity of effect of the intervention across three baseline-AHI categories: mild (5 ≤ AHI < 14.9), moderate (15 ≤ AHI < 29.9), or severe (30 ≤ AHI) [37]. Modified intention-to-treat analyses were conducted (due to losses to follow-up) [38].

For analysis of the primary and secondary outcomes, a Bonferroni correction was used; accordingly, a two-sided α level of 0.0167 was used. An α level of 0.05 was used for all the other analyses.

Results

Between November 4, 2013 and June 28, 2018, 650 patients were assessed for trial eligibility, of whom 573 were ineligible or declined to participate. As shown in the trial Flowchart (Figure 1), a total of 77 patients were randomized, and seven patients were lost to follow-up. Thus, 70 patients (39 women and 31 men) with a mean age of 74.8 years (*SD*: 6.5 years) completed this clinical trial. Following baseline data gathering, participants were categorized according to their OSA severity: 19 mild, 27 moderate, and 24 severe.

The mean body mass index was 29.9 kg/m^2 (*SD*: 5.5 kg/m^2.) All participants wore removable dentures, with the mean duration of use 36.4 years (*SD*:19.5 years). Overall, the participants reported having good oral health, and only 3% had denture stomatitis. Moreover, 3% (two participants) reported being smokers, 13% (nine participants) reported stable cardiovascular disease, and 51% (36 participants) reported high blood pressure.

According to the polysomnography analysis, the mean paired difference in AHI of study participants when they wore and did not wear dentures at night was 1.0 event per hour (*p* = 0.50, 95% confidence interval (CI) = −2.0 to 4.1) (Table 1). Table 2 shows the mean paired differences across OSA severity categories. Elders with severe OSA had highest mean paired difference favoring nonwearing denture.

The mean respiratory arousal index was higher when wearing dentures at night than when not wearing dentures at night, with a mean paired difference of 2.3 events per hour (95% CI = 0.0 to 4.6; Table 1). As per the subgroup analysis of respiratory arousal indices of the three OSA severity groups, the mean paired differences on sleeping with and without dentures were 1.9 events per hour (*p* = 0.12, 95% CI = −0.5 to 4.4) for mild, −0.6 event per hour (CI = −3.8 to 2.7) for moderate and 5.7 events per hour (CI = 0.0 to 11.5) for severe OSA groups (Table 3). In the severe OSA group, the mean respiratory arousal index was 18.8 (*SD*: 14.5) events per hour when sleeping without dentures and increased to 24.6 (*SD*: 13.9) events per hour during sleep with dentures.

The mean paired difference observed between ESS scores, when sleeping with dentures and without dentures was marginal at −0.1 (*p* = 0.71; 95% CI = −0.7 to 0.5) (Table 4). The mean paired difference for global PSQI scores between the interventions was also marginal at 0.2 (95% CI = −0.3 to 0.8) (Table 4). Moreover, for all participants, none of the PSQI subscores revealed any differences; these included overall sleep quality, sleep latency, sleep duration, usual sleep efficiency, sleep disturbance, sleep medication use, or daytime dysfunction due to sleepiness.

Table 1. Results of linear mixed regression modelling for the polysomnograpy data

	Nocturnal wearing of dentures (*n* = 70)	Nocturnal nonwearing of dentures (*n* = 70)	Mean paired difference (95% CI) *	*p*-value for intervention effect	*p*-value for period effect
Wake after sleep onset (min)	94.3 (51.5)	93.9 (52.2)	0.4 (–12.5 to 13.3)	0.95	0.90
Sleep efficiency (%)	72.6 (15.5)	72.7 (13.4)	0.0 (–3.4 to 3.5)	0.99	0.24
Stage 1 – N1 (%)	12.6 (7.2)	11.4 (7.0)	1.3 (–0.2 to 2.7)	0.09	0.83
Stage 2 – N2 (%)	68.9 (9.9)	69.6 (8.6)	–0.8 (–3.4 to 1.9)	0.56	0.09
Stage 3 – N3 (%)	6.9 (5.6)[I]	5.3 (4.6)[IV]	1.5 (–1.8 to 4.9)	0.34	0.79
Stage REM sleep – R (%)	16.5 (5.8)[II]	17.9 (7.1)[III]	–1.2 (–3.2 to 0.7)	0.21	0.20
Total arousal index (events/h)	23.6 (12.7)[II]	21.4 (13.2)[II]	2.2 (–0.8 to 5.2)	0.15	0.88
Respiratory Arousal Index (events/h)	14.2 (12.3)	11.9 (11.5)	2.3 (0.0 to 4.6)	0.05	0.85
Apnea–Hypopnea Index (events/h)	26.6 (17.9)	25.6 (16.4)	1.0 (–2.0 to 4.1)	0.50	0.69
NREM Apnea–Hypopnea Index (events/h)	24.7 (19.2)	23.3 (17.7)	1.4 (–1.9 to 4.6)	0.40	0.77
REM Apnea–Hypopnea Index (events/h)	34.3 (20.7)	33.8 (18.2)	1.0 (–3.5 to 5.6)	0.64	0.56
Oxygen Desaturation Index (events/h)	24.4 (17.0)[II]	23.8 (16.1)[II]	0.6 (–2.5 to 3.7)	0.69	0.74
Oxygen Desaturation Index supine (events/h)	29.4 (27.5) [v]	29.1 (21.6) [v]	–0.7 (–7.5 to 6.2)	0.84	0.75
Oxygen Desaturation Index nonsupine (events/h)	21.3 (16.7) [II]	22.3 (18.0) [II]	–1.0 (–5.4 to 3.3)	0.63	0.82
Snore time (%)	26.9 (22.5)	25.1 (23.4)	2.0 (–2.7 to 6.8)	0.39	0.06
Mean oxygen saturation (%)	92.9 (2.0)	92.7 (2.1)[II]	0.3 (0.0 to 0.6)	0.08	0.78
Saturation <90% (%)	33.6 (59.4)[III]	34.8 (59.0)[II]	–0.6 (–11.3 to 10.2)	0.92	1.00

[I] *n* = 22; [II] *n* = 69; [III] *n* = 67; [IV] *n* = 26; [v] *n* = 60. NREM = nonrapid eye movement sleep. REM = rapid eye movement sleep.
* Mean difference for the outcome at issue for the period of nocturnal wearing of dentures and of nocturnal nonwearing of dentures, adjusted for treatment and period. Linear mixed model with treatment group and period as fixed-effects terms and participant as a random-effects term.

Table 2. Results of linear mixed regression modelling for AHI as the outcome, according to baseline severity

OSA group	Nocturnal wearing of dentures	Nocturnal nonwearing of dentures	Mean paired difference (95% CI)*	*p*-value for intervention effect	*p*-value for period effect
Mild (*n* = 19)	14.6 (9.5)	13.6 (8.6)	1.1 (–2.8 to 5.0)	0.57	0.51
Moderate (*n* = 27)	19.2 (10.8)	21.7 (12.0)	–2.6 (–7.2 to 2.1)	0.27	0.60
Severe (*n* = 24)	44.4 (15.7)	39.5 (15.6)	5.1 (–2.1 to 12.3)	0.16	0.79

Data are mean (*SD*) or mean difference (95% CI).
* Mean difference for the outcome at issue for the period of nocturnal wearing of dentures and of nocturnal nonwearing of dentures, adjusted for treatment and period. Linear mixed model with treatment group and period as fixed- effects terms and participant as a random- effects term.

The mean paired difference in total OHIP scores when participants slept with dentures and without dentures was 2.0 (95% CI = –0.3 to 4.2; Table 5). Wearing dentures at night resulted in a higher mean score of psychological discomfort when compared to not wearing dentures at night (mean paired difference = 0.5; 95% CI = 0.1 to 0.8; Table 5). The sensitivity analyses' results were consistent with the primary analyses (Table 6).

Discussion

The purpose of this study was to investigate the effects of denture wearing at night on the quality of sleep and oral-health-related quality of life of elderly edentulous individuals with undiagnosed sleep apnea. The study results provide some support to usual practice guideline to continue to remove dentures at night in edentulous elders suffering from sleep apnea, since not wearing denture at night seems to not aggravate or improve the mean respiratory arousal indexes, with the exception of severe AHI group for respiratory arousal index, and on

psychological discomfort. Furthermore, there is strong pragmatic evidence that wearing denture at night might have a harmful effect on the oral health of edentulous individuals, which supports this conclusion.

The respiratory arousal threshold is a physiologic trait for OSA and is typically measured using invasive approaches, such as an esophageal pressure catheter [39]. According to a study by Edwards et al. [39], the clinical predictors for the respiratory arousal threshold are AHI, oxygen saturation, and a fraction of hypopnea events. Increased respiratory arousal frequency has been previously linked to higher emotional and physical fatigue in adult patients with OSA. The fact that in this trial nocturnal wear of denture led to increased respiratory arousal in elders may explain their increased psychological discomfort as well. While AHI was considered as a predictor for OSA severity, it has been recently questioned for not recording the specific clinical features of OSA [40].

Our analysis found no statistically significant difference in the mean AHI of participants sleeping with or without dentures at night. Our subgroup analysis also did not reveal any major

Table 3. Effect of nocturnal wear of dentures on Respiratory Arousal Index (RAI) according to baseline patient severity

OSA group	Nocturnal wearing of dentures	Nocturnal nonwearing of dentures	Mean paired difference (95% CI)*	p-value for intervention effect	p-value for period effect
Mild (n = 19)	7.1 (6.5)	5.2 (4.2)	1.9 (−0.5 to 4.4)	0.12	0.27
Moderate (n = 27)	10.0 (6.7)	10.5 (8.7)	−0.6 (−3.8 to 2.7)	0.72	0.64
Severe (n = 24)	24.6 (13.9)	18.8 (14.5)	5.7 (0.0 to 11.5)	0.05	0.98

Data are mean (SD) or mean difference (95% CI).
* Mean difference for the outcome at issue for the period of nocturnal wearing of dentures and of nocturnal non wearing of dentures, adjusted for treatment and period. Linear mixed model with treatment group and period as fixed- effects terms and participant as a random- effects term.

Table 4. Effect of nocturnal wear of dentures on daytime sleepiness (Epworth Sleepiness Scale) and sleep quality (Pittsburgh Sleep Quality Index)

	Nocturnal wearing of dentures (n = 70)	Nocturnal nonwearing of dentures (n = 68)	Mean paired difference (95% CI)*	p-value for intervention effect	p-value for period effect
Epworth Sleepiness Scale score	6.1 (4.1)	6.3 (4.3)	−0.1 (−0.7 to 0.5)	0.71	0.13
Pittsburgh Seep Quality Index score	5.0 (3.4)	4.8 (3.6)	0.2 (−0.3 to 0.8)	0.38	0.36
Subscores for seven elements:					
• Overall sleep quality	1.0 (0.6)	1.0 (0.6)	0.0 (−0.1 to 0.2)	0.55	0.74
• Sleep latency	0.8 (0.9)	0.6 (0.8)	0.1 (0.0 to 0.3)	0.12	0.07
• Sleep duration	0.6 (0.9)	0.6 (1.0)	−0.1 (−0.2 to 0.1)	0.48	0.62
• Usual sleep efficiency	0.7 (1.0)	0.7 (1.1)	0.0 (−0.3 to 0.2)	0.65	0.76
• Sleep disturbance	1.4 (0.6)	1.3 (0.6)	0.1 (−0.1 to 0.2)	0.44	0.73
• Sleep medication use	0.3 (0.8)	0.3 (0.9)	0.0 (−0.2 to 0.2)	0.99	0.35
• Daytime dysfunction due to sleepiness	0.6 (0.9)	0.5 (0.8)	0.0 (−0.2 to 0.2)	0.67	0.19

Data are mean (SD) or mean difference (95% CI).
* Mean difference for the outcome at issue for the period of nocturnal wearing of dentures and of nocturnal non wearing of dentures, adjusted for treatment and period. Linear mixed model with treatment group and period as fixed- effects terms and participant as a random- effects term.

Table 5. Effect of nocturnal wear of dentures on OHIP scores

	Nocturnal wearing of dentures (n = 70)	Nocturnal nonwearing of dentures (n = 69)	Mean paired difference (95% CI)*	p-value for intervention effect	p-value for period effect
Total score	39.0 (18.4)	36.6 (18.7)	2.0 (−0.3 to 4.2)	0.09	0.99
Functional limitation	7.8 (3.8)	7.2 (3.6)	0.5 (−0.1 to 1.0)	0.09	0.91
Physical pain	9.7 (4.9)	9.1 (4.5)	0.5 (−0.3 to 1.3)	0.24	0.86
Psychological discomfort	4.2 (2.6)	3.7 (2.3)	0.5 (0.1 to 0.8)	**0.01**	**0.23**
Physical disability	7.1 (4.0)	6.6 (4.1)	0.4 (−0.2 to 1.0)	0.15	0.86
Psychological disability	3.8 (2.2)	3.5 (2.1)	0.2 (−0.2 to 0.6)	0.24	0.92
Social disability	3.7 (1.9)	3.8 (2.4)	−0.1 (−0.4 to 0.2)	0.57	0.46
Handicap	2.7 (1.6)	2.7 (1.8)	0.1 (−0.2 to 0.3)	0.63	0.30

Data are mean (SD) or mean difference (95% CI).
* Mean difference for the outcome at issue for the period of nocturnal wearing of dentures and of nocturnal non wearing of dentures, adjusted for treatment and period. Linear mixed model with treatment group and period as fixed- effects terms and participant as a random- effects term.

Table 6. Sensitivity analysis for primary and secondary outcomes

	Nocturnal wearing of dentures	Nocturnal nonwearing of dentures	Paired difference (95% CI)*	p-value for intervention effect	p-value for period effect	Sequence p-value
Apnea–Hypopnea Index (events/h)	26.6 (17.9)	25.6 (16.4)	1.0 (−2.0 to 4.1)	0.50	0.69	0.59
Epworth Sleepiness Scale score	6.1 (4.1)	6.3 (4.3)	−0.1 (−0.7 to 0.5)	0.71	0.13	0.91
Pittsburgh Seep Quality Index	5.0 (3.4)	4.8 (3.6)	0.2 (−0.3 to 0.8)	0.38	0.36	0.88
OHIP total score	39.0 (18.4)	36.6 (18.7)	1.9 (−0.3 to 4.2)	0.09	0.99	0.23

Data are mean (SD) or mean difference (95% CI).
* Mean difference for the outcome at issue for the period of nocturnal wearing of dentures and of nocturnal nonwearing of dentures, adjusted for treatment and period. Linear mixed model with treatment group and period as fixed- effects terms and participant as a random- effects term.

AHI difference in elders with mild, moderate, or severe OSA. However, recently, Chen et al. [9] conducted a trial among 30 edentulous patients sleeping with and without dentures on two consecutive nights. This trial reported statistically significantly higher average AHI for sleeping with dentures (mean:16.3 events per hour) compared to sleeping without dentures (mean: 13.4 events per hour) [9]. Particularly, participants with mild OSA experienced statistically significant worsening of AHI when they wore dentures at night [9]. Similarly, in a randomized controlled trial conducted by Almeida et al. [11] among 23 edentulous elders, patients with mild cases showed worsening of AHI with dentures, and the majority of patients had an increase in AHI > 20%, with a mean increase from 8.9 to 16.6 events/h. For the moderate/severe group using dentures at night, 53% worsened, 13% improved, and 33% had no change in their AHI [11].

Conversely, in a case series of six edentulous patient, Bucca et al. noted a difference in mean AHI when sleeping without dentures relative to sleeping with dentures (mean: 20 events per hour vs 13 events per hour) [12]. Later, in the same group's quasi-experimental trial study, 48 edentulous participants slept with and without dentures on two consecutive nights and had significantly higher AHI when sleeping without dentures (mean: 17.4; *SD*: 3.6/h) compared to sleeping with dentures (mean: 11.0; *SD*: 2.3/h) [5].

This variability in the results across studies may be attributed to the sample selection. In our study, the sample was limited to only edentulous patient with OSA (AHI ≥ 10), whereas previous studies except one have included mostly milder OSA cases and even patients with normal AHI reading [11]. Our results confirm the results of our previous study in a general population of healthy, independently living edentulous elders [10], indicating that in general, edentulous elders have good sleep quality, independent of nocturnal prosthesis wear.

Appropriate cautionary measures were taken in this trial. The steering and data monitoring committees were formed independently of each other. An a priori reason for safety concerns was the use of this potentially fragile population. Accordingly, we modified the AHI inclusion criteria from the published protocol [27] to represent all categories of OSA severity and to describe and interpret the subgroup analyses to avoid unwarranted conclusions.

The main strength of our study was the high adherence rate and the use of home-based polysomnography to measure the primary outcome of the study. Moreover, various strategies to ensure adherence were used, and consent was sought only in individuals who were truly willing to follow through with their assigned interventions. All participants received oral and written information on the risk of poor sleep quality and on OSA, the need for the development of practice guidelines, and the importance of the accuracy of the data that they would provide. In our study, the sleep technologist installed the device at participants' homes on the evening of recording, verifying electrode impedance and signal quality. This approach allowed us to maximize the participation of seniors and increased their adherence to the trial procedures. Moreover, the sleep technologist in charge of participants' sleep recordings encouraged participant compliance by twice-weekly telephone calls and home visits. Finally, our losses to follow-up were small [41].

Authors' contribution

E.E. contributed to the study design, study coordination, logistics handling, supervision in data collection, analysis and interpretation of the data, manuscript drafting and critical revision of manuscript. G.L. participated in study design, interpretation of the data and critical review of the manuscript. J.S.F. contributed to interpretation of results and critical revision of manuscript. I.K. was involved in development of the statistical approach, supervision of randomization, data management, data analyses, interpretation of results and critical revision of manuscript. P.H.R. contributed to the statistical analyses, interpretation of data, critical revision of manuscript. F.R.A. participated in data analyses, interpretation of the data and critical review of the manuscript. N.T.H. contributed to the study design, supervision of sleep data gathering, analysis and interpretation of sleep measures and revising manuscript. All authors approved the final version of the manuscript.

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