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Original Article**Effects of aerobic exercise on home-based sleep among overweight and obese men with chronic insomnia symptoms: A randomized controlled trial**

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Highlights

- Six-month regular exercise improved sleep among overweight and obese men with insomnia symptoms.
- The improvement of sleep was shown mainly as eased difficulty in initiating sleep.
- Body weight and fat mass did not change through such exercise intervention.

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ABSTRACT

Objective: To determine the effect of a 6-month aerobic exercise program on home-based sleep quality among overweight and obese men with chronic insomnia symptoms.

Methods: Participants were 45 Finnish men (93% had body mass index ≥ 25) aged 30–65 years, with chronic (≥ 3 months) insomnia symptoms as classified by the DSM-IV criteria. Participants were randomized into an exercise ($n = 24$) or control group ($n = 21$). The exercise group received 6-month aerobic exercise intervention with 1–5 sessions per week of 30–60 minutes duration. The control group was instructed to maintain habitual lifestyle behaviors during the study period. Seven-night home sleep was measured with a piezoelectric bed sensor and sleep diary. Other assessments included the modified Basic Nordic Sleep Questionnaire, a health and behavior questionnaire, physical activity and diet diaries, anthropometry, fat mass, and physical fitness. Analysis of covariance controlling for baseline values, and repeated-measures analysis of variance were implemented for time-by-group comparisons and within-group comparisons, respectively.

Results: At 6 months, the exercise group showed reduced objective sleep onset latency ($p = 0.010$) and lowered frequency of difficulty initiating sleep ($p = 0.021$) than controls. Although a time-by-group difference was not significant, exercisers showed shorter objective wake after sleep onset ($p = 0.004$), reduced subjective nocturnal awakenings ($p = 0.010$), improved

objective sleep efficiency ($p < 0.001$), and improved morning-rated subjective sleep quality ($p = 0.042$) at 6 months than baseline.

Conclusions: A 6-month aerobic exercise can improve sleep, mainly by mitigating difficulty of initiating sleep among overweight and obese men with chronic insomnia symptoms.

Trial registration: Monitoring and treatment of obesity related sleep disorders;

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1. Introduction

Insomnia is one of the most common sleep disorders. The prevalence of chronic insomnia is between 6% and 7% among the European and US populations [1,2]. Between the years of 2003 and 2010, healthcare visits related to insomnia rose by 13% among American adults [3]. In Finland, the prevalence of insomnia diagnosed according to the DSM-IV criteria was 11.7%, which was 1.5–2 times higher than in non-Nordic European countries [4]. More recently, complaints of insomnia were reported by nearly a quarter of the middle-aged Finnish population [5].

The existence of a relationship between insomnia and such lifestyle factors as obesity and physical inactivity has been noticed and studied during recent years. A population-based study revealed an association between increased body mass index (BMI) and higher risk for insomnia over a 10- to 13-year follow-up [6]. In middle-aged to older men, insomnia was independently associated with overweight and lack of physical activity [7]. In light of these findings, an interventional study against overweight by increasing physical activity is important in populations with insomnia symptoms.

Several studies have tested using exercise as a nondrug treatment for insomnia [8-11]. Results of these studies suggested that long-term (3 months or longer) exercise could contribute to better sleep quality or eased insomnia symptoms among insomniac populations. Nevertheless, regarding the effects of exercise on insomnia symptoms, the number of randomized-controlled trials with both objective and subjective sleep assessments is very limited. Moreover, although obesity and weight gain have been found to be associated with sleep complaints [6,7], studies about the effects of exercise on overweight populations with insomnia complaints are scarce. To

address these research gaps, we investigated whether a 6-month exercise intervention based on an individual's fitness level could improve objective and subjective assessed sleep among overweight and obese men with chronic insomnia symptoms. We also studied the changes in body weight, fat mass, and daytime behaviors such as physical activity and diet throughout the intervention.

2. Methods

The present two-arm randomized controlled trial forms part of a larger study on the effects of different lifestyle interventions on obesity-related sleep disorders (ISRCTN77172005) [12]. The participant flow is depicted in Fig. 1.

2.1. Participants

The participants were 45 Finnish men aged 30–65 years, who were residents in the city of Jyväskylä and its surrounding communities and who had reported chronic insomnia (lasting for 3 months or longer). Most of the participants (93%) were overweight or obese (BMI \geq 25).

Participation was voluntary. Participants were recruited directly from the outpatient clinic of the Central Finland Central Hospital and public health care centers in the Central Finland Health Care District, or through advertising on the local radio news media and the Internet. The study was approved by the Ethics Committee of the Central Finland Health Care District (7/2011 OTE). Written informed consent was obtained from all participants before the baseline measurements were made, and a copy of the signed consent form was archived.

Individuals reporting chronic insomnia complaints through each recruitment channel were invited for interview at the Laboratory of Sport and Health Sciences, University of Jyväskylä.

During the interview, the sleep questionnaire and the health and behavior questionnaire were collected and reviewed by a physician, and the participant's medical history was examined. The sleep questionnaire comprised a modified version of the Basic Nordic sleep questionnaire (BNSQ) with quantitative criteria for insomnia symptoms (frequencies of difficulty initiating asleep, difficulty maintaining sleep, early-morning awakenings, and nonrestorative sleep) [13], the Epworth Sleepiness Scale (ESS; 0–24 scale for assessing daytime sleepiness) [14], Rimon's Brief Depression Scale (0–21 scale for evaluating depression status) [15], and other items on symptoms of sleep apnea, restless legs syndrome (RLS)/periodic leg movement disorder (PLMD), narcolepsy, cataplexy, and rapid eye movement (REM) behavior disorder.

Insomnia symptoms were classified according to the DSM-IV-TR criteria (without the daytime impairment criterion) from answers to the modified BNSQ. Participants were involved if one or more of the following symptoms had occurred at least 3 nights per week, during the past 3 months: (1) difficulty initiating sleep (sleep onset latency ≥ 30 minutes); (2) difficulty maintaining sleep (awakening during sleep ≥ 3 times/night, or difficulty in falling asleep after nocturnal awakening with total wake after sleep onset ≥ 30 minutes); (3) early-morning awakenings (waking up ≥ 30 minutes earlier than desired in the morning and unable to fall asleep again); and (4) nonrestorative sleep (not feeling rested, or experiencing fatigue upon awakening) [16,17]. The initial participants did not participate further in this study if they did not fulfill the insomnia symptom classification criteria, or if they had a medical history of one or more of the following sleep disorders: moderate or severe apnea (apnea-hypopnea index [AHI] ≥ 15) [18], RLS/PLMD (periodic leg movement arousal index, PLM index > 15), narcolepsy, or REM behavior disorder. Participants who fulfilled the insomnia symptom classification criteria but with diagnosed mild sleep apnea ($5 \leq \text{AHI} < 15$, $n = 2$) were not excluded.

Initial participants who, on the basis of their answers to the sleep questionnaire, were suspected of having sleep apnea, RLS/PLMD, narcolepsy, or REM behavior disorder underwent an overnight polysomnography measurement (SOMNOPlus, SOMNOMedics GmbH, Randersacker, Germany). They were not further involved in this study if they met the diagnostic criteria for any of these disorders.

Based on their medical history or on responses on the health and behavior questionnaire, initial participants with any of the following conditions were also excluded: (1) any medical care during the past 3 years related to: cardiovascular diseases, insulin-dependent diabetes mellitus, Crohn's disease, sarcoidosis, celiac disease, thyroid, liver diseases, chronic diarrhea, ulcerative colitis, rheumatoid arthritis, severe osteoarthritis, systemic lupus erythematosus, or cancer; (2) current diagnosis of major depression; (2) history of other major mental illness or substance abuse; (3) history of cognitive impairment and major neurological disorders; (4) chronic pain conditions; (5) current or regular use of sedatives, hypnotics, or painkillers; (6) shift work (night work); (7) regular leisure-time exercise for more than two times per week and more than 45 minutes per time; or (8) other risks related to participation in the exercise intervention and fitness test.

2.2. Measurements

All measurements were carried out before randomization and after the intervention period.

2.2.1. Background information

Background information, including age, education, employment, and smoking habits, were elicited at baseline with the health and behavior questionnaire. Age of onset of insomnia and occurrences of insomnia symptoms were elicited with the baseline sleep questionnaire.

2.2.2. Objective sleep measurement

Home-based objective sleep data were collected by an unobtrusive online sleep monitoring system (Beddit pro; Beddit Ltd., Espoo, Finland) for 7 nights both before and after the intervention period. The system includes a piezoelectric bed sensor. Ballistocardiographic signals were sampled by the piezoelectric sensor at 140 Hz and simultaneously uploaded to a Web server through the Internet, where sleep/wake status was classified in 30-second epochs based on heart rate variability, respiration rate variability, and binary actigram [19]. An ambient brightness sensor, included in the system, was placed in the bedroom for determining lights-out time. Two trained research assistants attached all sensors before the measurement. For participants who had a bed partner, sensor attachment was considered to avoid overlapping measurements. Participants were instructed to mention conditions that might have affected the measurements, such as children and pets in the bedroom, in the sleep diary. Measurement was set automatically to start each evening at 18:00 and to end at noon the next day. Participants were instructed to sleep on the sensor for 7 consecutive nights. If this condition could not be fulfilled, participants were instructed to sleep on the sensor for at least 7 nights, including 2 weekend nights, over a 14-night period. Total sleep time (TST), sleep onset latency (SOL, determined as the duration from being present in bed with lights-out to the first 5 minutes of consecutive sleep) [20], wakefulness after sleep onset (WASO), and sleep efficiency (SE) were obtained of each night. Average values across the nights measured were used for analyses. A validation of the sleep/wake in 30-second epochs measured by the piezoelectric system was carried out against 2-night polysomnography

measurement (31 participants with insomnia complaints, aged 51.8 ± 8.4 years, BMI = 30.9 ± 4.8). Correlations in sleep outcomes were obtained as follow: TST (Pearson $r = 0.85$, $p < 0.001$), SOL (Pearson $r = 0.81$, $p < 0.001$), WASO (Kendall tau-b = 0.74 , $p < 0.001$), and SE (Kendall tau-b = 0.68 , $p < 0.001$).

2.2.3. Sleep diary and sleep questionnaire

The 7-night sleep diary was collected on the same days as the objective sleep measurement. Items included time of going to bed, estimated time of falling asleep, number of nocturnal awakenings, final awakening time, morning-rated subjective quality of sleep (1–4 scale, very poor–very good), fatigue upon awakening (1–4 scale, not fatigued at all–very fatigued), nap duration, and other issues related to sleep. The average values for the recorded nights were used for analyses. ESS score, depression score, insomnia symptom frequency, and other subjective sleep assessment results were obtained by the sleep questionnaire.

2.2.4. Physical activity and diet diaries

Behavioral factors at baseline and at the 6-month follow-up were assessed by a physical activity diary and a diet diary, respectively. The 7-day physical activity diary (kept on the same days as the sleep diary collected) recorded the participant's primary living activity at 30-minute intervals over 24 hours. The amount of physical activity was calculated as metabolic equivalent (MET) multiplied by duration in minutes per day (MET min/day) [21]. METs of different activities were referenced to the 2011 Compendium of Physical Activities [21]. For an activity with an intensity level that could not be determined due to lack of detailed information, MET of a general or moderate level of activity was substituted. Physical activities were categorized into exercise and recreational (e.g., dog walking, mushroom picking) activity, livelihood physical activity (e.g.

personal cares, housework, commuting, occupational activities), as well as sedentary behaviors (METs ≤ 1.5 while in a sitting or reclining posture) and sleep [22].

A 3-day diet diary (2 weekdays and 1 weekend day) recorded the type, item and estimated portion of all food and drink intake during each day. Archiving of diet information, calculation of total energy intake, and proportions of energy-yielding nutrients in total energy intake (E%) were carried out with Micro-Nutrica software (The Social Insurance Institution of Finland, Turku, Finland).

2.2.5. Anthropometry and fat mass

All anthropometric measurements were performed after an overnight (12-hour) fast. Height was measured to the nearest 0.5 cm using a fixed wall scale. Weight was determined to the nearest 0.1 kg using a calibrated physician weight scale. BMI was calculated as weight (kg) divided by height² (m²). Neck, chest, waist, and hip circumferences were determined to the nearest 0.1 cm by using a measuring tape according to standardized procedures, and the average value of three measurements was taken for analysis. Blood pressure was measured using an oscillometric monitor in sitting position after a 5-minute rest, and the average value of three measurements was retained. Fat mass was determined using dual energy X-ray densitometry (DXA; Prodigy, GE Lunar, Madison, WI). The anthropometry and fat mass measurements were carried out at the Laboratory of Sport and Health Sciences, University of Jyväskylä.

Comment [KVS3]: AUTHOR: Please verify that the statement “BMI was calculated as weight (kg) divided by height² (m²),” is correct and edited (“per” changed to “divided by”).

Comment [KVS4]: AUTHOR: Please advise whether “dual energy X-ray densitometry” may be changed to “dual energy X-ray absorptiometry,” which is the usual expansion of “DXA.”

2.2.6. Fitness test

The 2-kilometer walk test (UKK Institute, Tampere, Finland) was used to determine fitness level. Participants were instructed to walk 2 kilometers as fast as possible at a steady pace. Walk time duration and heart rate immediately on finishing the walk were measured for estimation of

maximal aerobic power (estimated VO_{2max}). The fitness index was calculated based on walk time duration, heart rate immediately on finishing the walk, BMI, age, and gender as follows: $420 - [\text{Walking time (min)} \times 11.6 + \text{Walking time (s)} \times 0.2 + \text{Heart rate (beats/min)} \times 0.56 + \text{BMI (kg/m}^2) \times 2.6 - \text{Age (y)} \times 0.2]$.²³ A fitness index of less than 70 was defined as low, 70–89 as medium, and greater than 89 as high, respectively [23]. An exercise watch with a heart rate monitoring belt (M5; Suunto Ltd., Vantaa, Finland) was used to determine heart rate. The tests were carried out at on an outdoor athletic field. The test was safe for the overweight and obese adults who met our inclusion criteria [24].

2.3. Randomization

After the baseline measurements, participants were randomized into the 6-month exercise intervention, 6-month diet intervention, or control group according to a case-matched computer-generated randomization, stratified for age and BMI [12]. This study reports comparisons between the exercise and control groups only.

2.4. Exercise intervention

The progressive exercise program was made according to each fitness level (level 1: low fitness class; level 2: medium fitness class; level 3: high fitness class) determined by the fitness test at baseline. Exercise was prescribed according to the recommendations of the American College of Sports Medicine [25,26]. The lower the participant's baseline fitness class, the lower the exercise frequency per week and shorter time duration per session introduced at the beginning (Fig. 2). Nordic walking or other optional aerobic exercise was performed 30 to 60 minutes per session, one to five sessions per week, at the intensity level of 60%–75% of estimated maximum heart rate. An intermediate fitness test (2-kilometer walk test) was carried out at week 13, to adjust the

exercise duration individually. Two experienced exercise trainers were responsible for the instruction and supervision of the 6-month (26-week) exercise intervention. The participants were instructed to attend the supervised exercise session at least once a week. In the other sessions, the participants exercised independently. Before each exercise week, the trainer informed the participant of the duration and intensity (heart rate interval) of each exercise session. All of the independent and supervised exercise sessions were to be finished at least 3 hours before the bedtime. Participants were instructed to do stretching exercises before the exercise session and to finish with relaxation.

Each participant was instructed to wear a sport watch with a heart rate monitoring belt (M5; Suunto Ltd., Vantaa, Finland) in all exercise sessions. Real-time heart rate was displayed on the watch, and thus the participant could maintain exercise intensity (heart rate) within the recommended range. The duration and average heart rate of each session were saved in the watch. Participants were instructed to upload these data from the watch to a website service (Movescount; Suunto Ltd., Vantaa, Finland) every 2 weeks. Each participant had one account for the service, which was accessible only by that participant and the trainers. A teaching session on use of the heart rate monitor and data uploading, followed by a manipulation test, was held before the intervention. All participants were able to use the device and to upload data correctly.

2.5. Control group

Control participants were instructed to maintain their habitual, prerecruitment lifestyle for 6 months. They were invited to a lecture explaining the purpose of the group. After the 6-month study period, they were given an opportunity to participate in the exercise plus diet intervention program for 3 months.

2.6. Statistical analysis

Data were input into the computers for analyses by a research assistant who did not participate in data collection, or in writing this paper. Group information was hidden in data input. All analyses followed the intent-to-treat principle. For participants with missing or incomplete values at 6 months, the last observed values were used. All analyses were performed with IBM SPSS statistics version 20 (SPSS, Inc., Chicago, IL). The Shapiro-Wilk W-test, and Levene test were used to examine the normality and homogeneity, respectively. Skewed data (objective and subjective SOL; objective WASO; objective SE; Rimon depression score; alcohol E%) were transformed by natural logarithm before further analysis. Baseline differences between groups were evaluated by one-way analysis of variance (ANOVA), or Pearson Chi-square test. Time-by-group changes in sleep outcomes and possible mediators were evaluated by analysis of covariance (ANCOVA) on postintervention values, controlling for baseline values. Within-group pre-post intervention differences within group were evaluated by repeated-measures ANOVA. F values and their error degrees of freedom were given in the ANCOVA and repeated-measures ANOVA results, along with their statistical significance. Measures of effect size in the ANCOVA and repeated-measures ANOVA were shown in partial η^2 . Partial η^2 values that reached 0.01, 0.06, and 0.14 were regarded as small, medium, and large effects sizes, respectively [27]. All tests were two-tailed, and a P value of less than 0.05 was set as significant.

3. Results

Descriptive characteristics of the participants at baseline are shown in Table 1. Retention rates between the two groups were comparable (exercise = 21/24, control = 19/21, $p = 0.889$; Pearson Chi-square test).

3.1. Compliance with exercise program

On average, the participants in the exercise group who attended the 6-month follow-up measurements engaged in 3.0 (standard deviation [SD] 1.6) exercise sessions per week at 54.5 (14.2) minutes per session. The average total exercise duration during intervention per exerciser was 3797.4 (1314.3) minutes, and the average compliance rate (Total exercise duration / Total prescribed exercise duration \times 100 %) was 113.5% (41.6%). The average heart rate during exercise was 68.7% (5.6%) of the individual's estimated maximum heart rate. Among these participants, four had a compliance rate of less than 80% (range 54%–60 %). In addition, three participants dropped out of the exercise intervention. One participant did not perform any exercise, and the other two discontinued after 11 and 26 exercise sessions, respectively.

3.2. Objective sleep measurement outcomes

On average, for the exercise group, 6.6 (SD 0.8), and 6.7 (0.8) nights of objective sleep data at baseline and 6 months, respectively, were available for analysis; for the control group, the corresponding numbers were 6.8 (0.6), and 6.6 (0.7). Nights marked by participants with significant disturbance of the measurement process (such as when pet slept in bed) were excluded. The results of the objective sleep measurements are given in Table 2. Compared to the control group, the exercise group showed lower SOL at 6 months ($F_{1,42} = 7.365$, $p = 0.010$, partial $\eta^2 = 0.149$). Final awakening time in control group was later compared to the exercise group ($F_{1,42} = 5.675$, $p = 0.022$, partial $\eta^2 = 0.122$). Moreover, although without time-by-group difference, WASO was lowered ($F_{1,23} = 9.969$, $p = 0.004$, partial $\eta^2 = 0.302$), and SE improved ($F_{1,23} = 18.580$, $p < 0.001$, partial $\eta^2 = 0.447$) within exercise group after intervention.

3.3. Sleep diary outcomes

Sleep diary outcomes are shown in Table 2. No time-by-group difference was detected. Within the exercise group, fewer nocturnal awakenings ($F_{1,23} = 8.036$, $p = 0.010$, partial $\eta^2 = 0.268$), improved morning-rated sleep quality ($F_{1,23} = 4.684$, $p = 0.042$, partial $\eta^2 = 0.176$), and eased fatigue upon awakening ($F_{1,23} = 4.425$, $p = 0.047$, partial $\eta^2 = 0.167$) were reported after the intervention.

3.4. Sleep questionnaire outcomes

Compared to the control group, the exercise group showed a lower frequency of difficulty initiating sleep ($F_{1,42} = 5.761$, $p = 0.021$, partial $\eta^2 = 0.121$, Table 3), and a lower depression score ($F_{1,42} = 4.098$, $p = 0.049$, partial $\eta^2 = 0.089$) at 6 months. The ESS score ($F_{1,23} = 7.870$, $p = 0.010$, partial $\eta^2 = 0.255$) was reduced within the exercise group; however the reduction was not significant when compared to the controls.

3.5. Habitual amount of physical activity and diet

No time-by-group difference was detected in outcomes of physical activity and diet (Table 4). The exercise group showed increased amounts of exercise and recreational physical activity after the intervention ($F_{1,23} = 6.432$, $p = 0.019$, partial $\eta^2 = 0.226$). The amount of other physical activities and sedentary behavior were maintained in both groups. Except for an increased rate of protein-derived energy within the control group ($F_{1,20} = 6.333$, $p = 0.021$, partial $\eta^2 = 0.250$), proportions of macronutrients, total energy intake, and alcohol intake remained unchanged in both groups. In addition, coffee consumption was reduced in the control group, compared to that in the exercise group ($F_{1,42} = 5.028$, $p = 0.031$, partial $\eta^2 = 0.112$).

Comment [KVS5]: AUTHOR: Please verify that the phrase "proportions of macronutrients, total energy intake, and alcohol intake remained unchanged in both groups" is correct as edited ("were remained" changed to "remained unchanged").

3.6. Changes in anthropometry, fat mass, and physical fitness

No time-by-group difference was found in anthropometry, fat mass, and fitness level (Table 5). However, body weight ($F_{1,20} = 11.234, p = 0.003, \text{partial } \eta^2 = 0.360$) and circumference of the neck ($F_{1,20} = 13.659, p = 0.001, \text{partial } \eta^2 = 0.406$), chest ($F_{1,20} = 17.428, p < 0.001, \text{partial } \eta^2 = 0.466$), and waist ($F_{1,20} = 11.348, p = 0.003, \text{partial } \eta^2 = 0.362$) increased within the control group. The exercise group showed increased estimated $\text{VO}_{2\text{max}}$ ($F_{1,23} = 13.684, p = 0.001, \text{partial } \eta^2 = 0.383$) and a higher fitness index ($F_{1,23} = 13.623, p = 0.001, \text{partial } \eta^2 = 0.382$) across the intervention.

4. Discussion

The results of this study indicate that a 6-month aerobic exercise program is effective in improving sleep among overweight and obese men with chronic insomnia symptoms. In particular, in the exercise group compared to the control group, the exercise intervention significantly shortened objective SOL, reduced frequency of difficulty initiating sleep, and eased depressive status.

Epidemiological studies have suggested that sedentary lifestyle and physical inactivity are associated with insomnia in the general population [7,28]. Recent investigations have also shown that adults who have better sleep quality or who are free of insomnia engaged in a greater amount of habitual exercise, compared to their counterparts with worse sleep quality or insomnia [29,30]. In addition, exercise intervention targeted to insomnia patients or persons with insomnia complaints successfully improved sleep quality in these populations [9–11,31,32]. However, few lifestyle interventional studies among populations with insomnia symptoms have included

objective sleep measurements. In one study focused on sedentary adults with diagnosed chronic insomnia, a 6-month moderate aerobic exercise program (50 min/session, 3 sessions/wk) led to decreased polysomnographic SOL, WASO, and improved SE [9]. Despite the difference in insomnia classification, similar results were found in our study, such as the shortened SOL in exercise group compared to that in the controls. Several methodological differences between our study and the previous one are worth noting. First, in the previous study, polysomnographic sleep was measured for 1 night. In our study, objective sleep measurements were carried out for 7 nights, which considerably lowered the risk of measurement bias caused by high nightly variability in sleep among insomnia patients [9]. Second, unlike the previous study, in which the polysomnographic measurements were carried out in a sleep laboratory, the objective sleep outcomes in our study were obtained from home-based sleep measurements, and thus sleep was not affected by a change of environment. Third, because of the lack of a control condition, the improvements of sleep parameters reported in the previous study were based on within-group comparison only. Some of these findings were strengthened by the time-by-group differences exhibited in our study. Furthermore, in the previous study, exercise was performed in groups and was of fixed duration. In our study, exercise was performed mostly independently, and duration was adjusted according to the individual's fitness level. This individualized exercise plan might have contributed to the better exercise retention in our study (21/24 to 19/30) [9]. Thus, we conclude that personalized aerobic exercise with proper supervision, which results in greater participant retention, can also improve objective sleep quality among overweight and obese men with insomnia symptoms.

In most previous exercise intervention studies in individuals with insomnia, sleep outcomes have been self-reported. Among older adults (≥ 55 years of age) with mild to moderate sleep

complaints, a 12-month aerobic exercise program (35–40 min/day, 5 days/wk) significantly reduced diary-based SOL.³¹ However, in our study, despite a shortened SOL observed in the objective sleep data, diary-assessed SOL was not significantly reduced during the exercise intervention. This might be due to the overestimation of habitual SOL among insomniacs, as mentioned in previous studies [33,34]. Nevertheless, according to the sleep questionnaire results, the exercisers showed reduced frequency of difficulty initiating sleep. Consequently, the objective SOL results and the subjective frequency of difficulty falling asleep suggested an easing of this symptom during the 6-month exercise intervention.

Our findings in objective SOL and self-rated frequency of difficulty initiating sleep were consistent with each other. On the other hand, sleep outcomes related to difficulty maintaining sleep, early morning awakenings, and nonrestorative sleep did not exhibit time-by-group differences. These may suggest that the main effect of regular exercise on insomnia symptoms is on improving the sleep onset process. The improvement on sleep initiating, but not other insomnia symptoms after a long-term exercise intervention, was reported in a similar study [35]. It is worth noting that compared to other insomnia symptoms, multiple health outcomes have been specifically linked to the difficulty of initiating sleep [36,37]. A study also reported that this symptom is associated with mortality among men [38]. Therefore, regarding this issue, our study results may suggest a dampening of physiologic hyperarousal. We speculate that energy balance played an important role behind the effect of exercise on sleep initiation. One commonly mentioned theory regarding the function of sleep is to achieve greater energy conservation beyond rested wakefulness [39]. Under this logic flow, among individuals with chronic insomnia symptoms who may be constantly sleep deprived, exercise-derived energy expenditure may trigger sleep initiation for energy saving [40]. This speculation was further supported by results

from our diet diary, as the total energy intakes and dietary patterns of the exercise group were maintained during the intervention. Nevertheless, current understanding of the associations among regular exercise, energy balance, and chronic insomnia symptoms are vague; thus, studies with accurate measurement of energy balance in this population are encouraged, to verify such a hypothesis.

Regardless of the improvement in sleep outcomes among the exercise group, we did not observe a reduction in body weight or BMI at the end of the intervention. Similar results were reported by a study that implemented an aerobic exercise program among overweight and obese adults with sleep apnea [41]. In contrast to the previous study, we found no reduction in fat mass through the exercise intervention either. As energy intake did not change during the intervention, we speculate that either there was significant underreporting in dietary intake [42] or that the 6-month aerobic exercise in the amount prescribed in our study was not sufficient to induce a reduction in weight or fat mass. Nonetheless, these results suggest that regular aerobic exercise alleviates symptoms of insomnia such as difficulty initiating sleep, irrespective of a loss in weight or fat mass. On the other hand, the control group showed weight gain and increased waist circumference during the study period. This may indicate that the symptoms of chronic insomnia may boost the development of obesity, especially central obesity. Further studies are needed to test whether this association also exists among populations with insomnia.

Another interesting point is that although participants in the exercise group in our study performed even a larger amount of exercise than the prescribed dose, they showed neither better physical fitness nor greater habitual recreational physical activity than the controls throughout the intervention. These findings may reflect two issues. First, sleep disturbances caused by chronic insomnia symptoms impair exercise capability such as that needed to achieve or

maintain physical fitness [43], and regular exercise at the prescribed dose may not significantly improve fitness, at least among overweight or obese insomniac population. Second, even when sleep is significantly improved as a result of regular aerobic exercise, a higher level of habitual physical activity is difficult to achieve in this population.

Comment [KVS6]: AUTHOR: Please verify that the phrase "First, sleep disturbances caused by chronic insomnia symptoms impair exercise capability such as that needed to achieve or maintain physical fitness" is correct as edited (changed from "First, sleep disturbances caused by chronic insomnia symptoms impair exercise capability such as physical fitness").

In our intervention, we instructed the participants to finish their physical exercise at least 3 hours before going to bed. This was based on the view that intensive exercise close to bedtime may have negative effects on sleep [20]. However, the results of a recent study challenged this notion [44], and hence more studies are needed to determine whether evening exercise can also benefit sleep among individuals with insomnia or sleep complaints.

Currently, cognitive behavioral therapy (CBT) is considered the treatment of choice for chronic insomnia [18,45]. In this study, we did not use any formal CBT programs, and thus we could not compare the effects of individualized aerobic exercise and CBT on insomnia symptoms. We hypothesize, however, that adding exercise training to CBT programs may give better results than CBT without exercise. Future studies could usefully compare the effectiveness of CBT, exercise, and CBT plus exercise in treating chronic insomnia among sedentary populations.

Our study was among the first that aimed to determine the effects of aerobic exercise on home-based objective and subjective sleep quality in persons with insomnia symptoms. This study was also one of the few interventional studies focused on the overweight and obese insomniac population. In addition to the standard anthropometry measurement, we used DXA for a precise assessment of fat mass. However, this study also has certain limitations. First, the sample size did not allow us to stratify our participants into different groups according to insomnia subtypes/symptoms. Second, we did not include women in our study; thus, whether the exercise

program would also improve sleep among overweight and obese women with chronic insomnia remains uncertain. Third, objective sleep measurement was carried out by a low-validated technology (lack of published validation study). Furthermore, we were not able to blind participants to the intervention, and hence the Hawthorne effect might have altered the behavior of some of the controls. Although we did not detect changes in major behavioral factors at 6 months in the control group, we nevertheless suggest the inclusion of intermediate follow-ups on behavioral factors in future studies. Finally, the inclusion of patients with mild apnea in our study and the possible underestimation of apnea patients induced heterogeneity of the study population.

5. Conclusions

This study showed that among overweight and obese middle-aged men with chronic insomnia symptoms, a 6-month exercise intervention was effective in improving both objective and subjective home-based sleep quality, and especially in alleviating difficulty of initiating sleep. These improvements were observed regardless of change in body weight or fat mass.

Conflict of interest

This was not an industry-supported study. The authors declare no conflict of interest.

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Comment [KVS7]: AUTHOR: Please list first six authors before “et al.” in reference 1 and all other references in which “et al.” is used, in keeping with journal style.

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Figure 1 – Participant flow of the study

Fig. 2. Exercise plan made after baseline measurement for fitness level 1.

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Table 1. Baseline characteristics of exercise and control groups.

Characteristic	Exercise group (n = 24)	Control group (n = 21)
	Mean (95% CI)	Mean (95% CI)
Age (y)	51.2 (46.6–55.8)	52.6 (48.0–57.2)
Age at first insomnia complaint (y)	40.9 (35.5–46.3)	39.8 (33.7–46.0)
Height (cm)	177.4 (174.7–180.1)	178.3 (175.6–180.9)
Weight (kg)	92.3 (86.2–98.5)	93.0 (85.2–100.9)
Body mass index (kg/m ²)	29.3 (27.6–31.0)	29.2 (27.2–31.2)
Systolic blood pressure (mm Hg)	140.0 (132.4–147.7)	140.7 (135.2–146.3)
Diastolic blood pressure (mm Hg)	90.0 (85.7–94.4)	91.4 (86.7–96.1)
Occurrences	Percentage	Percentage
Difficulty initiating sleep	50.0	42.9
Difficulty maintaining sleep	54.2	76.2
Early morning awakening	33.3	23.8
Non-restorative sleep	50.0	42.9
Diagnosed mild apnea	8.3	0.0
Smokers (smoking currently)	29.2	19.0
At least tertiary degree education	91.7	95.2
Employed	82.6	71.4

Comment [KVS9]: AUTHOR: Please clarify "tertiary degree education."

Abbreviations: CI, confidence interval.

Table 2. Sleep outcomes by 7-night objective measurement and sleep diary in exercise and control group.

	Exercise group			Control group			Time by group
	Baseline	6 Months	<i>p</i>	Baseline	6 Months	<i>p</i>	<i>p</i> ^a
Objective sleep measurement							
Total sleep time (min)	376.8 (353.7–399.8)	390.1 (364.8–415.3)	0.254	393.3 (370.9–415.8)	412.8 (390.4–435.2)	0.071	0.353
Sleep onset latency (min) ^b	23.9 (14.0–42.2)	13.7 (6.7–22.6)	<0.001	18.1 (12.1–32.9)	20.7 (8.8–33.4)	0.729	0.010
Wake after sleep onset (min) ^b	48.3 (43.9–62.2)	39.1 (35.9–52.3)	0.004	44.8 (37.2–49.4)	38.7 (34.4–49.3)	0.199	0.326
Sleep efficiency (%) ^b	81.7 (78.3–86.7)	87.1 (83.1–89.3)	<0.001	85.9 (82.1–88.4)	86.6 (83.4–89.8)	0.215	0.110
Sleep initiating time (hh:mm) ^c	23:16 (22:54–23:38)	23:17 (22:53–23:40)	0.357	23:17 (22:53–23:41)	23:16 (22:49–23:41)	0.841	0.568
Final awakening time (hh:mm)	6:55 (6:29–7:20)	6:40 (6:12–7:08)	0.154	6:59 (6:36–7:23)	7:20 (6:54–7:42)	0.153	0.022
Sleep diary							
Sleep onset latency (min) ^b	30.0 (12.0–60.0)	21.0 (12.0–40.0)	0.206	21.5 (17.3–41.8)	25.0 (15.0–42.5)	0.463	0.496
Nocturnal awakenings	2.6 (1.8–3.3)	1.9 (1.4–2.4)	0.010	2.6 (1.8–3.4)	2.3 (1.8–2.8)	0.293	0.133

(times/night)							
Nocturia (times/night)	0.8 (0.5– 1.1)	0.7 (0.4– 1.0)	0.206	0.7 (0.4– 0.9)	0.5 (0.3– 0.8)	0.080	0.783
Morning-rated sleep quality (1–4, very poor– excellent)	2.5 (2.3– 2.7)	2.7 (2.5– 2.9)	0.042	2.4 (2.2– 2.5)	2.4 (2.2– 2.6)	0.785	0.094
Fatigue upon awakening (1–4, not at all– very much)	2.2 (2.0– 2.4)	1.9 (1.7– 2.1)	0.047	1.9 (1.6– 2.1)	2.0 (1.8– 2.2)	0.300	0.269
Nap (min/day) ^d	18.3 (5.4– 31.2)	22.9 (12.5– 33.3)	0.574	12.5 (4.4– 20.6)	11.9 (2.2– 21.6)	0.885	0.147

Data are shown as mean (95% confidence interval) unless otherwise specified.

^a Analysis of covariance controlling for baseline values.

^b Comparisons under natural log transformed data; values are shown as the median and 25th through 75th percentiles.

^c Time when lying in bed with light off.

^d Exercise group, $n = 17$; control group, $n = 12$.

Table 3. Sleep outcomes by sleep questionnaire in exercise and control groups.

	Exercise			Control			Time by group
	Baseline	6 Months	<i>p</i>	Baseline	6 Months	<i>p</i>	<i>p</i> ^a
Difficulty initiating sleep (1–5) ^b	2.8 (2.2–3.3)	2.2 (1.7–2.6)	0.002	2.8 (2.2–3.3)	2.7 (2.1–3.2)	0.540	0.021
Early morning awakenings (1–5) ^b	2.7 (2.2–3.3)	2.6 (2.1–3.1)	0.575	3.0 (2.5–3.5)	3.1 (2.5–3.7)	0.452	0.216
Sleep less than 5h in last month (1–6) ^c	2.8 (2.2–3.5)	2.5 (1.8–3.1)	0.233	3.0 (2.3–3.6)	2.8 (2.2–3.3)	0.384	0.473
Habitual sleep duration (h)	6.8 (6.2–7.3)	6.9 (6.4–7.4)	0.465	6.7 (6.2–7.2)	6.6 (6.1–7.1)	0.545	0.272
Desired sleep duration (h)	8.2 (7.8–8.6)	8.0 (7.7–8.3)	0.350	8.1 (7.6–8.5)	7.9 (7.5–8.3)	0.117	0.668
Ease in getting up in the morning (1–4) ^d	2.6 (2.2–3.0)	2.8 (2.5–3.2)	0.056	2.9 (2.5–3.2)	2.8 (2.5–3.2)	0.666	0.157
Epworth Sleepiness Scale score	8.4 (7.0–9.8)	6.8 (5.5–8.1)	0.010	8.3 (6.2–10.5)	7.4 (5.2–9.7)	0.056	0.348
Rimon’s Brief Depression Scale score ^e	4.0 (2.0–7.8)	2.5 (0.0–4.0)	0.003	4.0 (3.0–7.5)	3.0 (2.5–5.5)	0.187	0.049

Data are shown as mean (95% confidence interval) unless otherwise specified.

^a Analysis of covariance controlling for baseline values.

^b 1 = Never/less than once per month; 2 = less than once per week; 3 = 1–2 days per week; 4 = 3–5 days per week; 5 = daily or almost daily.

^c 1 = 0 Night; 2 = 1–5 nights; 3 = 6–10 nights; 4 = 11–15 nights; 5 = 16–20 nights; 6 = more than 20 nights.

^d 1 = Not easy at all (difficult); 2 = not very easy (a bit difficult); 3 = quite easy; 4 = very easy.

^e Comparisons under natural log transformed data; values are shown as the median and 25th through 75th percentiles.

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Table 4. Energy expenditure and diet characteristics, based on 7-day physical activity diary and 3-day diet diary in exercise and control groups.

	Exercise group			Control group			Time by group p^a
	Baseline	6 Months	p	Baseline	6 Months	p	
Energy expenditures							
Total energy expenditure (MET min/day)	2349.9 (2252.6–2447.1)	2335.5 (2233.8–2437.3)	0.798	2341.1 (2224.0–2458.1)	2322.6 (2210.0–2435.3)	0.796	0.882
Exercise and recreational physical activity (MET min/day)	231.9 (118.8–343.2)	291.3 (218.0–364.5)	0.019	249.5 (145.2–353.8)	254.3 (151.9–356.7)	0.800	0.097
Livelihood physical activity (MET min/day)	820.8 (633.6–1008.1)	737.9 (526.8–948.9)	0.350	803.0 (631.5–974.5)	751.6 (548.6–954.6)	0.627	0.849
Sedentary behaviors (MET min/day)	863.3 (745.9–980.7)	836.1 (735.9–936.4)	0.601	824.6 (737.1–912.1)	845.0 (758.3–931.7)	0.608	0.625
Diet							
Total energy intake (Kcal/day)	2293.7 (2016.6–2570.8)	2100.5 (1800.7–2400.3)	0.090	2151.5 (1922.8–2380.1)	1977.1 (1770.8–2183.3)	0.075	0.850
Carbohydrates (E%)	40.3 (36.6–44.0)	42.8 (39.1–46.5)	0.080	39.7 (37.1–42.3)	40.1 (36.3–44.0)	0.809	0.256
Fat (E%)	37.4 (34.1–40.7)	36.4 (33.3–39.5)	0.342	38.2 (35.2–41.2)	36.6 (33.6–39.6)	0.369	0.886
Protein (E%)	17.4	17.8	0.558	17.5	19.0	0.021	0.145

	(15.9– 18.9)	(16.4– 19.1)		(16.2– 18.9)	(17.6– 20.3)		
Coffee (mL/day)	426.9 (335.5– 518.3)	440.9 (362.9– 519.0)	0.698	428.0 (314.1– 541.9)	341.0 (239.4– 442.7)	0.035	0.031
Alcohol (E%) ^{b,c}	4.5 (1.9– 6.6)	2.1 (0.6– 7.4)	0.066	3.0 (1.0– 7.5)	4.4 (1.0– 8.6)	0.863	0.155

Data are shown as mean (95% confidence interval) unless otherwise specified.

^a Analysis of covariance controlling for baseline values.

^b Comparisons under natural log transformed data; values are shown as median and 25th through 75th percentiles.

^c Exercise group, $n = 18$; control group, $n = 15$.

Table 5. Anthropometry, fat mass, and fitness levels at baseline and 6 months in exercise and control groups.

	Exercise group			Control group			Time by group
	Baseline	6 Months	<i>p</i>	Baseline	6 Months	<i>p</i>	<i>p</i> ^a
Weight (kg)	92.3 (86.2– 98.5)	92.5 (86.6– 98.4)	0.714	93.1 (85.2– 100.9)	94.4 (86.3– 102.5)	0.003	0.083
Body mass index (kg/m ²)	29.3 (27.6– 31.0)	29.4 (27.7– 31.0)	0.615	29.2 (27.2– 31.2)	29.4 (27.3– 31.5)	0.247	0.558
Neck circumference (cm)	41.9 (40.7– 43.1)	42.1 (41.0– 43.2)	0.315	41.9 (40.6– 43.3)	42.6 (41.2– 44.0)	0.001	0.068
Chest circumference (cm)	107.9 (104.2– 111.6)	109.2 (105.5– 112.9)	0.025	107.7 (102.6– 112.9)	109.5 (104.5– 114.5)	<0.001	0.485
Waist circumference (cm)	104.4 (99.7– 109.1)	105.1 (100.8– 109.5)	0.131	105.0 (99.9– 110.1)	106.7 (101.3– 112.2)	0.003	0.177
Hip circumference (cm)	103.0 (99.1– 106.9)	102.5 (98.9– 106.1)	0.641	102.7 (98.6– 106.7)	104.0 (100.0– 108.1)	0.101	0.174
Total body fat (% of body mass)	28.8 (25.9– 31.7)	28.7 (26.0– 31.5)	0.892	29.4 (27.3– 31.6)	30.0 (27.6– 32.3)	0.050	0.171
Trunk body fat (% of body mass)	18.2 (16.2– 20.3)	18.4 (16.4– 20.3)	0.669	18.4 (16.7– 20.1)	18.8 (17.1– 20.5)	0.107	0.452

Estimated	29.3	31.4		30.9	30.4		
VO _{2max}	(25.3–	(27.4–	0.001	(27.1–	(26.5–	0.723	0.114
(mL/min/kg)	33.4)	35.4)		34.8)	34.3)		
	73.4	78.6		78.5	80.6		
Fitness index	(63.2–	(68.6–	0.001	(69.2–	(72.0–	0.421	0.379
	83.6)	88.6)		87.8)	89.3)		

Data are shown as mean (95% confidence interval) unless otherwise specified.

No between-group differences were detected by one-way analysis of variance or Pearson Chi-square test.

^a Analysis of covariance controlling for baseline values.