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### Maturitas



# Effect of exercise on sleep quality and insomnia in middle-aged women: A systematic review and meta-analysis of randomized controlled trials



Jacobo Á. Rubio-Arias<sup>a</sup>, Elena Marín-Cascales<sup>a</sup>, Domingo J. Ramos-Campo<sup>a</sup>, Adrian V. Hernandez<sup>b</sup>, Faustino R. Pérez-López<sup>c,\*</sup>

<sup>a</sup> Department of Physical Activity and Sports Sciences, Faculty of Sports and Research Center for High Performance Sport, Catholic University of Murcia (UCAM), Murcia, Spain

<sup>b</sup> School of Medicine, Universidad Peruana de Ciencias Aplicadas (UPC), Lima 9, Peru, University of Connecticut/Hartford Hospital Evidence-based Practice Center, 80 Seymour St, Hartford, CT 06102, USA

<sup>c</sup> Department of Obstetrics and Gynecology, University of Zaragoza Faculty of Medicine and Lozano-Blesa University Hospital, Domingo Miral s/n, Zaragoza 50009, Spain

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#### ABSTRACT

*Objective:* We assessed the effects of programmed exercise (PE) on sleep quality and insomnia in middle-aged women (MAW).

*Methods*: Searches were conducted in five databases from inception through December 15, 2016 for randomized controlled trials (RCTs) evaluating the effects of PE versus a non-exercising control condition on sleep quality, sleep disturbance and/or insomnia in MAW. Interventions had to last at least 8 weeks. Sleep quality was assessed with the Pittsburgh Sleep Quality Index (PSQI) and insomnia with the Insomnia Severity Index (ISI). Random effects models were used for meta-analyses. The effects on outcomes were expressed as mean differences (MDs) and their 95% confidence intervals (CI).

*Results*: Five publications reported data from four RCTs on PE effects during 12–16 weeks on sleep quality (n = 4 studies reporting PSQI results) and/or insomnia (n = 3 studies reporting ISI results), including 660 MAW. Low-moderate levels of exercise significantly lowered the PSQI score (MD = -1.34; 95% CI -2.67, 0.00; p = 0.05) compared with controls. In a subgroup analysis, moderate PE (aerobic exercise) had a positive effect on sleep quality (PSQI score MD = -1.85; 95% CI -3.62, -0.07; p = 0.04), while low levels of physical activity (yoga) did not have a significant effect (MD-0.46, 95% CI -1.79, 0.88, p = 0.50). In three studies (two studies of yoga, one study of aerobic exercise), there was a non-significant reduction in the severity of insomnia measured with the ISI score (MD -1.44, 95% CI -3.28, 0. 44, p = 0.13) compared with controls. Heterogeneity of effects among studies was moderate to high.

*Conclusion:* In middle-aged women, programmed exercise improved sleep quality but had no significant effect on the severity of insomnia.

#### 1. Introduction

Sleep disturbance (insomnia) is quite frequent in the general population, being more prevalent among women [1,2]. Insomnia is not an inherent part of aging, but rather due to multimorbidity, polypharmacy, and socio and laboral factors [3,4]. A 40% to 55% of middle-aged (peri- and postmenopausal) women may show some degree of sleep disturbance according to the menopause status, comorbid conditions, use of psychiatric and concomitant treatments, lifestyle, chronic life events, intimate partner violence and other partner factors, sociodemographic characteristics, and sleep assessment methods [1,3,5–9]. In addition, poor sleep quality and insomnia are

associated, with different magnitudes of the associations, to increased morbidity and mortality in postmenopausal women [10–12]. Despite its importance, insomnia and sleep disorders are under recognized and undertreated. On the other hand, chronic insomnia drug therapy (when used for long periods of time) has several side effects, produces cognitive deficits, and even increases mortality [13–16].

Polysomnography (PSG) has been considered a standard tool to evaluate sleep quality and sleep-related disorders. However, its value remains controversial in assessing insomnia and PSG is not recommended in the evaluation of transient or chronic insomnia [17,18]. Actigraphy data collection has been also used, although it seems that subjective symptoms are more important to assess sleep quality and

\* Corresponding author. E-mail address: faustino.perez@unizar.es (F.R. Pérez-López).

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insomnia [19]. Sleep logs and sleep inventories are simple instruments keeping tract of details about sleep or extensive questionnaires providing information about sleep patterns and alterations, respectively. Several of these clinical questionnaires are commonly used including the Pittsburgh Sleep Quality Index (PSQI) to assess global quality of sleep [8,20], and the Insomnia Severity Index (ISI) to assess insomnia [6,21].

Exercise has been proposed as non-pharmacological alternative to improve sleep quality since there is an inverse relation between sedentarism and quality of life [22]. Exercise has been reported to improve insomnia, anxiety, reduce sleep latency and medication use [23,24]. However, the effect of physical activity or exercise on sleep quality and insomnia is controversial in observational studies of middle-aged women. Therefore, we carried out a systematic review and meta-analysis of randomized control trials (RCTs) to assess the effect of short-term exercise programs on the quality of sleep and insomnia.

#### 2. Methods

#### 2.1. Data sources and searches

A comprehensive literature search was performed using PubMed-Medline, Web of Sciences and the Cochrane Library from database inception through December 10, 2016. The database searches were performed independently by three authors (JARA; DJRC and EMC). The following combination terms was used: "peri-menopausal" or "perimenopausal" or "pre-menopausal" or "premenopausal" or "postmenopausal" or 'post-menopausal'. The Boolean operator "AND" was used to combine these descriptors with: "sleep" or "insomnia" or "sleep disturbance" and "exercise" or "physical activity" or "training" or "yoga" or "sport".

#### 2.2. Inclusion and exclusion criteria

The following specific inclusion criteria were considered: (1) RCTs examining the effect of programmed regular physical activity or exercise lasting at least 8 weeks on a self-reported of sleep quality tool using the Pittsburgh Sleep Quality Index (PSQI) and/or insomnia severity using the Insomnia Severity Index (ISI); (2) the presence of a control group; (3) based on physical activity in late pre-, peri- and/or postmenopausal women; (4) studies in English language; (5) Studies provided information of outcomes both at baseline and follow-up.

Studies were excluded if: (1) used a sample population with pathologies or if they were young premenopausal women; (2) were observational studies; (3) did not provide or specify numerical data on the specified tools; (4) examined acute effects of interventions; (5) people with pathologies and testing with food supplements, nutritional or pharmacological aids; (6) studies examining atypical sleep regimens, such as studies with shift workers or utilizing experimentally-induced insomnia; (7) studies of populations with medical and psychiatric conditions other than sleep disturbance.

#### 2.3. Outcomes

Outcomes were the PSQI and the ISI. The self-reported PSQI assesses quality of sleep during the previous weeks and includes nine items describing seven sleep components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleep medications, and daytime dysfunction. Each item can be scored from 0 (no difficulty or absent) to 3 (severe difficulty), and results are summed providing a global PSQI score from 0 to 21. A global PSQI score of 5 or higher is indicative of poor sleep quality [8,20].

The self-applicable ISI is a tool that assesses perceived severity of insomnia during the previous weeks and includes seven questions in relation with the satisfaction experienced, the degree of functional impairment during the day, perception of decline and the concerns related to the sleep problem. Each item is rated on a Likert scale (from zero to four) to set a score from zero to 28. The higher scores indicate very severe insomnia, and a cutoff point of ten has been proposed as optimal for detecting cases of insomnia in the population. A global ISI score of 8 or higher correspond to some degree of insomnia, being moderate insomnia with score 15–21 and severe insomnia with score 22–28 [6.21].

#### 2.4. Study selection and data extraction

Retrieved articles were reviewed independently by three authors (JARA; DJRC and EMC), to choose potentially relevant articles; all disagreements on inclusion/exclusion were discussed and resolved by consensus. References of potentially relevant articles were also searched to find additional studies, and authors of selected studies were contacted for non-reported information. Three reviewers (JARA; DJRC and EMC) independently extracted data from included studies. The following information was extracted: site and country of the study, type of exercise, number of women included, menopause status, age, body mass index (BMI), clinical characteristics, and hormone therapy. The information about characteristics of exercise programs included exercise intensity, frequency (sessions/week), session length (minutes/week), study duration in weeks, total number of sessions and the baseline mean PSQI and ISI scores.

#### 2.5. Risk of bias assessment (study quality)

The methodological quality of selected RCTs was assessed with the Cochrane risk of bias tool (Higgins et al.) [25]. This tools evaluates the following aspects: randomness of the allocation sequence (selection bias); concealment of the allocation sequence (selection bias); blinding of participants and personnel and blinding to outcome assessment (performance and detection bias, respectively); incomplete outcome data (attrition bias); selective outcome reporting (reporting bias); and any other biases. For each RCT, each item was described as having either a low risk of bias, a high risk of bias, or an unclear risk of bias. RCTs with high risk of bias for items of randomization or blinding were considered being a high risk of bias. Risk of bias was assessed independently by two authors (J.A.R.A. and E.M.C.) using the Cochrane risk of bias tool [25].

#### 2.6. Data synthesis and statistical analysis

Our systematic review and meta-analysis follow the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al.) [26]. A random effects meta-analysis was conducted to determine summary effect of physical activity on quality of sleep (PSQI score) and insomnia (ISI score). Effects on outcomes between exercise and control arms were expressed as mean differences (MDs) and their 95% confidence intervals (CI). Differences within arms were calculated as MDs between the follow-up and baseline times. If enough information was available, we planned to perform subgroup analyses by comparing yoga intervention versus more intense exercise types.

We evaluated statistical heterogeneity using the Cochran chi-square, the  $I^2$  statistic, and the between-study variance using the tau-square (*Tau*<sup>2</sup>) (Higgins 2003, 2008) [27,28].  $I^2$  values of 30–60% represented a moderate level of heterogeneity. A p value < 0.1 for the chi-square was defined as indicating the presence of heterogeneity; a *Tau*<sup>2</sup> > 1 suggests the presence of substantial statistical heterogeneity. Publication bias was considered with the funnel plot and tested with the Egger test of funnel plot asymmetry if a minimum of 10 studies were available, and  $p \le 0.05$  was considered to be statistically significant (Egger et al.) [29].

For statistical analyses we used the Review Manager software (RevMan 5.2; Cochrane Collaboration, Oxford, UK) [30] and Compre-

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