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BSc. PHYSIOTHERAPY

The Effectiveness of Aerobic Exercise Treatment for Insomnia: A Literature Review

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ABSTRACT

Background: Insomnia affects an estimated 7.5 to 40% of the general population, and commonly results in severe health and socio-economic functioning deficits. The purpose of this study is to review the literature on the effects of aerobic exercise on insomnia.

Method: The Cochrane library, PubMed, and PEDro databases were searched from 1990 to 2013 for randomised controlled trials published in English. The keywords were: insomnia, aerobic exercise, aerobic training, Pittsburgh Sleep Quality Index, sleep diary and polysomnography. Participants were aged 18 and older, with insomnia complaints, symptoms and/or disorders. Outcome measures were: Sleep quality, sleep onset latency and sleep duration.

Results: Six studies met the inclusion criteria. Data showed that aerobic exercise in insomniac individuals resulted in significant improvements in sleep quality (45-66%); sleep onset latency (27-59%); and sleep duration (13-73%).

Conclusion: There is moderate evidence that aerobic exercise is as an effective treatment alternative for insomnia.

INTRODUCTION

Insomnia refers to the persistent difficulty initiating or maintaining sleep, early morning wakening, and/or sleep dissatisfaction [1]. Moreover, insomnia has been described as a complaint (associated to sleep quantity and sleep quality); a symptom (part of a sleep disorder, or of a mental or organic disorder); or a sleep disorder diagnosis (primary or secondary) [2]. Diagnostic manuals such as The International Classification of Sleep Disorders (ICSD-2) [3], and the International Classification of Diseases (ICD-10) [4], have varying definitions of insomnia (table 1); and consequently differing classification criteria (table 2).

Table 1: Insomnia Definitions

International Classification of Sleep Disorders ICSD-2 [3]	**International Classification of Diseases ICD-10** [4]
• Repeated difficulty with sleep initiation, duration, consolidation, or quality • Occurring despite adequate time and opportunity for sleep. • Resulting in some form of daytime impairment (at least one)	• Unsatisfactory quantity and/or quality of sleepiness • Persists for a considerable period of time • Including difficulty falling asleep, staying asleep, or early awakening.

Table 2: Insomnia classification criteria

International Classification of Sleep Disorders ICSD-2 [3]	**International Classification of Diseases, ICD-10** [4]
• Adjustment (acute) insomnia • Psycho-physiological insomnia • Paradoxical insomnia • Idiopathic insomnia • Insomnia due to mental disorder • Inadequate sleep hygiene • Behavioural insomnia of childhood • Insomnia due to drug or substance • Insomnia not due to substance or known physiological condition, unspecified (non-organic insomnia) • Physiological (organic) insomnia, unspecified	• Organic insomnia • Inorganic insomnia

However, due to the varying definitions used, the prevalence of insomnia in the general population varies widely from 7.5 – 40 %; and prevalent in women than men [5,6]. Risk factors for insomnia include: increasing age; female sex; co-morbid (medical, psychiatric and sleep) disorders; shift work; employment status; regular hypnotic use; previous insomnia complaints and; high level of perceived stress [5-9]. Furthermore, studies have evidenced insomnia to be associated with a number of conditions and diseases, such as: Cardio-metabolic (congestive heart failure, diabetes, hypertension) [10]; musculoskeletal (chronic back or neck pain,

osteoarthritis, rheumatoid arthritis, fibromyalgia, osteoporosis) [11,12]; respiratory (chronic obstructive pulmonary disease, chronic bronchitis, asthma, emphysema) [13]; mental (major depression, anxiety disorders) and other sleep disorders (sleep apnoea, restless leg syndrome) [7,14-16].

Insomnia is commonly linked with daytime functioning deficits, such as: fatigue, depressive mood, irritability or anger, lack of concentration, poor memory, and daytime sleepiness [6]. Consequently, this interference in daytime functioning leads to reduced quality of life, lessened social functioning and decreased workplace performance (lower productivity, work absenteeism and lateness) [1,17-20]. Subsequent development of somatic and psychological disorders, such as: smoking and alcoholism have also been reported in individuals having insomnia [21,22]. Increased risk for suicide, substance use (or relapse), and possible immune dysfunction have equally been described as potential effects associated with insomnia [24].

Treatment is required when insomnia has significant diminishing effects on health and socio-economic functioning. At this time, a number of treatments have been proposed and recommended to treat insomnia. These include: Non-pharmacological and pharmacological therapies (table 3).

Table 3: Insomnia treatment options

Non-Pharmacological Therapies	**Pharmacological Therapies**
• Cognitive Behavioural therapy • Sleep Hygiene • Relaxation therapy • Light therapy • Stimulus control therapy • Exercise	• Hypnotics • Anti-depressants • Herbal and dietary supplements (such as melatonin)

Hypnotic drugs (pharmacotherapy) are first choice treatment of insomnia. However, they pose a risk of harm (withdrawal, dependency and rebound insomnia) after long term use [9,24]. Insomnia equally responds well to cognitive behavioural therapy (CBT), with treatment effects that may be sustained over 6 to 24 months [9,25-27]. Cognitive behavioural therapy involves combinations of the following therapies: cognitive therapy; relaxation therapy; sleep hygiene; sleep restriction; and stimulus control therapy. Additionally, exercise including aerobic exercise is reported to have sleep-enhancing effects; and has been suggested in literature as a low-cost and readily accessible treatment alternative for insomnia [28-30]. However, most studies relating to the effects of exercise on sleep have been performed in healthy sleepers, which may limit the observed effects on sleep [28]. Consequently, the experimental evidence is encouraging but limited.

Nevertheless, the sleep-enhancing effects of exercise have been predicted by three theories on exercise-sleep mechanisms [28]: Thermogenic [31], body restoration [32] and energy conservation theories [33]. The “thermogenic theory” states that there is an interaction between heat loss and sleep mechanisms in the anterior hypothalamus that are activated when temperature is raised following exercise [31]. On the other hand, the “body restoration theory” posits that sleep allows the body to restore and repair damaged tissue, following elevated catabolism produced by physical exertion [32]. The “Energy conservation” theory states

that the primary function of sleep is to conserve energy via a homeostatic mechanism between energy consumption and conservation [33].

The purpose of this literature review is to determine the effectiveness of aerobic exercise treatment for insomnia. Aerobic exercise is generally considered for different patient types across the broad scope of physiotherapy. Therefore, clear experimental evidence can imply that the role of physiotherapy in the management of insomnia could be recognized in the healthcare systems. As such, physiotherapy students, physiotherapists, physiotherapy educational institutions and other health-related programs could refer to the results of this study for treatment practice. Moreover, the economic cost of insomnia related to productivity, work-related accidents, increased absenteeism, insomnia-related alcohol abuse, health-care costs are enormous [20]. Consequently, people suffering from insomnia could derive suited and evidenced treatment benefits from a low-cost and readily accessible aerobic exercise treatment. As a consequence, this could as well have an impact on health insurances, as health policy and regulations could be adapted. Thus, it is the aim of this literature review to propose a well-defined answer to the question: Is aerobic exercise an effective treatment alternative for insomnia?

METHOD

Selection procedure

Selected studies were full text randomized controlled trials (RCTs) published in English, from 1990 to April 2013. The trials were limited to human participants of either gender (male or female); aged 18 and older. Participants with insomnia complaints, symptoms and/or insomnia disorders were eligible for inclusion. However, trial participants with dementia, and sleep disorders other than insomnia were excluded from this review.

Included studies assessed the effects of aerobic exercise (independent variable) on insomnia (dependent variable) using one and/or more of the following outcome measurements: sleep quality; sleep onset latency; and sleep duration. Sleep quality was measured using the subjective sleep quality sub-score of the Pittsburgh Sleep Quality Index, PSQI (appendix I). Sleep onset latency and sleep duration were measured using the PSQI, sleep diary (log) and/or Polysomnography. Furthermore, PSQI sub-scores or time units (minutes/hours) were considered as measurable units for both sleep onset latency and sleep duration.

Studies that assessed the effects of different aerobic exercise types and intensities were considered for this study. The type of comparators were not limited to “no intervention” control groups; but included other exercise forms and leisure activities. Moreover, no restrictions on the frequency and duration of both interventions and comparators were set forth.

Search strategy

The Cochrane Library, PubMed and Physiotherapy Evidence Database – PEDro databases were searched to find articles for potential inclusion in this review. Additional articles were found by getting hold of experts, examining reference lists from relevant studies, and searching appropriate internet resources through Google. The search for literature on the databases was performed using different combinations of keywords (table 4), and the Boolean Operators “and” and “or”.

Table 4: Keywords

Insomnia	Aerobic exercise Aerobic training	PSQI Polysomnography Sleep diary

The following Boolean searches were made: “(insomnia) and (aerobic exercise)”; “(insomnia) and (aerobic exercise or aerobic training)”; “(insomnia) and (aerobic exercise or aerobic training) and (PSQI or polysomnography or sleep diary)”.

Assessment of methodological quality

Methodological quality was verified using the Physiotherapy Evidence Database PEDro Score- a reliable and valid measure of the methodological quality of RCTs [34,35]. Moreover, the PEDro scale includes other important criteria in methodological quality assessment, such as concealed allocation, adequacy of follow-up and intention-to-treat analysis [36].

The PEDro score for each article was looked up on the PEDro database. The maximum score of a study on the PEDro scale is 10. Therefore, RCTs scoring 9-10 on the PEDro scale were considered “excellent” quality. RCTs with PEDro scores between 6 and 8 were considered “good” quality, while those scoring 4 or 5 were “fair” quality. RCTs with PEDro scores less than 4 were considered “low” quality, and excluded from this review. Where the PEDro score for an article was unavailable on the PEDro database, the article was assessed using the PEDro scale and same decision rules specified by PEDro (appendix II).

Data analysis

The titles and abstracts of all potentially eligible articles were assessed using the inclusion and exclusion criteria. When a clear conclusion could not be made based on the titles and/or abstracts alone, the full text articles were obtained for detailed analysis and further screened against the inclusion criteria.

Where an article was identified as eligible, data relevant to the study details and design; participant details; intervention and comparators; outcome measures; and results, were extracted as appropriate, into a data extraction form. The study details and design included: author name, publication year, and location. Participant details covered sample size, female percentage, mean age, and insomnia history. Intervention and comparators comprised details on exercise type, frequency and duration. Outcome measures included: PSQI, sleep diary and/or Polysomnography measurements of sleep quality, sleep onset latency and/or sleep duration. The results (extraction table) reported significant findings of the aerobic exercise interventions only.

Two authors (of different articles) were contacted by email and asked to provide additional information and/or missing data regarding the descriptive statistics of the participants. One of the authors provided the percentages of females and the mean ages for both male and female participants in the intervention and control groups. The other author provided supplementary information on the insomnia history of the participants.

Best evidence synthesis

A modified five levels of evidence system [37] (appendix III), based on the levels of evidence adapted by Sackett et al [38], was used to summarize the findings of this review. Each level of evidence took into account the PEDro scores of the RCTs. Following similar classification criteria [37], two or more higher RCTs with PEDro scores equal to or greater than 6 was classified as level 1a evidence (strong). A single higher RCT with a PEDro score equal to or greater than 6 was classified as level 1b evidence (moderate). A lower RCT with PEDro scores less than 6 was classified as level 2 evidence (weak).

RESULTS

264 articles were initially found using the search method earlier described in this literature review. After screening titles and abstracts, 11 potentially relevant articles were identified for full text evaluation (figure 1).

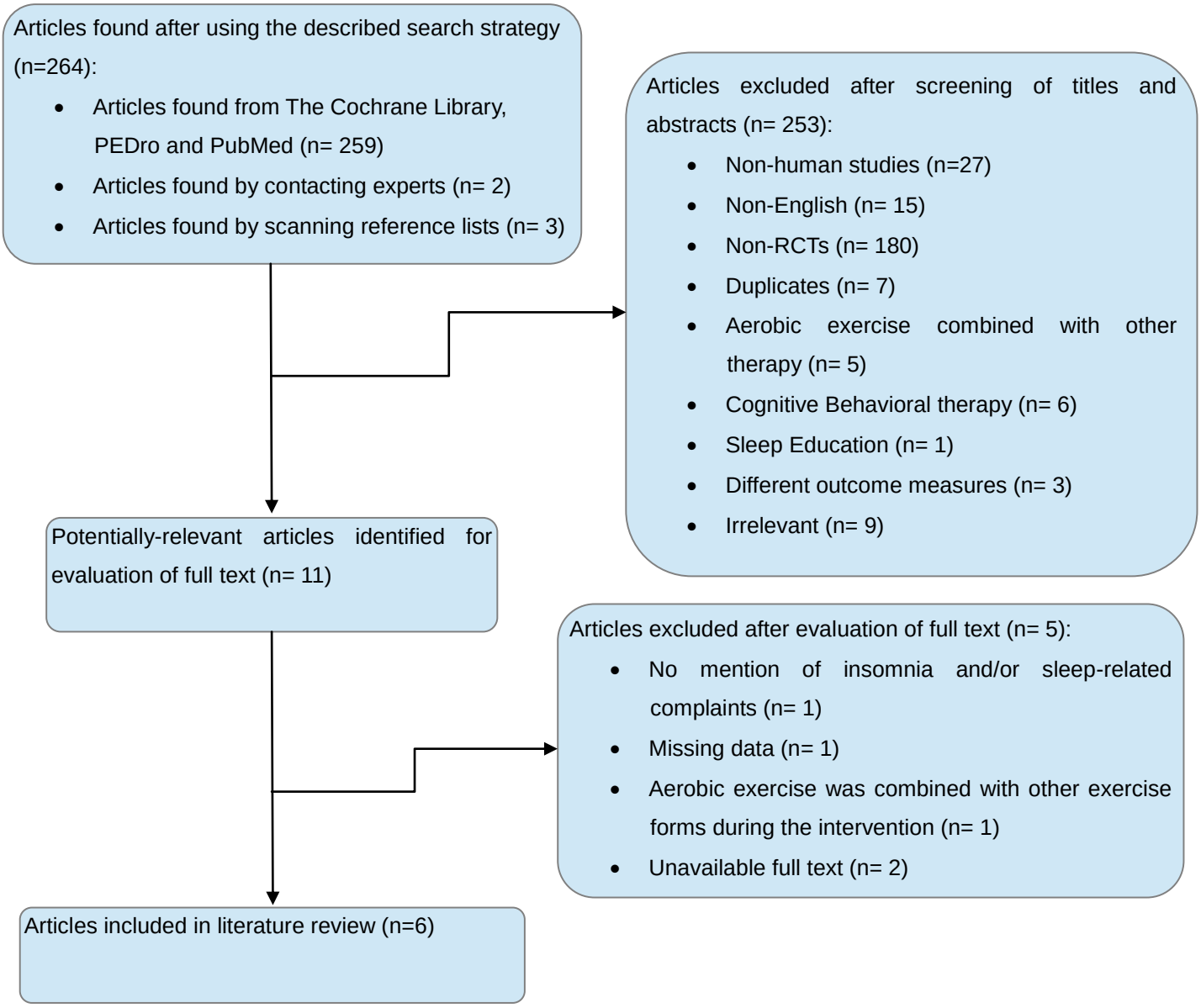

Figure 1: Identification and selection of articles

Five articles were subsequently excluded after evaluation of the full text. Six articles were included in this review, and a summary of the trials is presented in Table 5 (and appendix IV). The six included studies consisted a total of 308 participants; predominately female (n= 228, 74%), and the mean age ranged from 18.3 to 75.4 years. Three studies comprised of elderly participants, with mean ages: 75.38 ± 11 years [39]; 61.6 ± 4.3 years [41]; and 71.75 ± 8.13 years [43]. Two studies comprised of middle-aged participants, with mean ages: 44.4 ± 8 years [40]; and 45.0 ± 1.9 years [42]. One study comprised of adolescents with mean age, 18.3 ± 0.89 years [44].

Table 5: A summary of the six included RCTs.

Study Details & Design	Participant Details	Interventions/Comparators	Outcomes Measures	Results
Li *et al.* 2004, [39] USA **Study Design:** RCT **Setting:** General Community	**# Participants:** 118 (96 females). Mean age: 75.38 ± 11 yrs **Intervention:** 62 (52 females). Mean age: 75.30 **±** 7.8 yrs **Comparator:** 56 (44 females). Mean age: 75.45 ± 7.8 yrs **Insomnia Details:** Moderate sleep complaints	**Volume:** 60 min; 3x/wk; 24 weeks **Intervention:** Yang style Tai chi **Comparator:** Low-impact (controlled breathing, stretching & relaxation)	**PSQI** - SQ, sub-score - SOL, mins - TST, hr	↑ **PSQI-SQ** ↓ **PSQI-SOL** ↑ **PSQI-TST**
Passos *et al.* 2010, [40] Brazil **Study Design:** RCT **Setting:** General Community	**# Participants:** 48 (38 females). Mean Age: 44.4 ± 8 yrs **Intervention:** 12 (10 females). Mean age: 42..7 **±** 7 yrs **Comparator # 1:** 12 (9 females). Mean age: 42.2 ± 9 yrs **Comparator # 2:** 12 (10 females). Mean age: 42.4 ± 9 yrs **Comparator # 3:** 12 (9 females). Mean age: 45.2 ± 8 yrs **Insomnia Details:** Chronic insomnia (≥ 6 months)	**Volume:** One session/1-2 days **Intervention:** MAE (Treadmill) **Comparator 1:** HAE (Treadmill) **Comparator 2:** MRE **Comparator 3:** No intervention	**PSG & Sleep Diary** - TST, hr - SOL, min	↓ **Sleep Dairy - SOL** ↑ **Sleep Dairy - TST** ↓ **PSG-SOL** ↑ **PSG-TST**
Reid et *al.* 2010, [41] USA **Study Design:** RCT **Setting:** General Community	**# Participants:** 17 (16 females). Mean age: 61.6 ± 4.3 yrs **Intervention:** 10 (10 females). Mean age: 62.0 ± 4.5 yrs **Comparator:** 7 (6 females). Mean age: 63.5 ± 4.3 yrs **Insomnia Details:** Primary insomnia (≥ 3 months)	**Volume:** 10→40 min; 4x/wk; 16 weeks **Intervention:** MAE (Walking, stationary bike, and treadmill) **Comparator:** No intervention	**PSQI** - SOL, sub-score - TST, sub-score - SQ, sub-score	↓ **PSQI-SOL** ↑ **PSQI-TST**
Passos *et al.* 2011, [42] Brazil **Study Design:** RCT **Setting:** General Community	**# Participants:** 19 (15 females). Mean age: 45.0 ± 1.9 yrs **Intervention # 1:** 10 (8 females). Mean age: 42.3 ± 2.6 yrs **Intervention # 2:** 9 (7 females). Mean age: 48.0 ± 2.5 yrs **Insomnia Details:** Chronic insomnia (≥ 6 months)	**Volume:** 50 min; 3x/wk; 24 weeks **Intervention # 1:** Morning MAE **Intervention # 2:** Late-afternoon MAE **Both interventions:** Treadmill	**PSG & Sleep Diary** - SOL, min - TST, min	↓ **PSG-SOL** ↓ **Sleep Dairy-SOL**
Chen *et al.* 2012, [43] Taiwan **Study Design:** RCT **Setting:** General Community	**# Participants:** 55 (36 females). Mean age: 71.75 ± 8.13 yrs **Intervention:** 27 (17 females). Mean age: 70.48 ± 7.90 yrs **Comparator:** 28 (19 females). Mean age: 72.96 ± 8.30 yrs **Insomnia Details:** moderate sleep complaints	**Volume:** 30 min; 3x/wk; 12 weeks. **Intervention:** Baduajin exercise **Comparator:** No intervention.	**PSQI** - SQ, sub-score - SOL, sub-score - TST, sub-score	↑ **PSQI-SQ** ↓ **PSQI-SOL** ↑ **PSQI-TST**
Kalak *et al.* 2012, [44] Switzerland **Study Design:** RCT **Setting:** General Community	**# Participants:** 51 (27 females). Mean age: 18.3 ± 0.89 yrs **Intervention:** 27 (14 females). Mean age: 18.1 ± 0.85 yrs **Comparator:** 24 (13 females). Mean age: 18.1 ± 0.90 yrs **Insomnia Details:** Sub-threshold insomnia with mean insomnia severity ≈ 13.8 (according to the Insomnia severity scale).	**Volume:** 30-37 min; 5x/wk; 3 weeks **Intervention:** MAE (running) **Comparator:** No intervention	**PSG** - SOL, min - TST, hr	↓ **PSG-SOL**

MAE = Moderate-intensity aerobic exercise; HAE = High-intensity aerobic exercise; MRE = Moderate-intensity resistance exercise; SQ = Sleep Quality; SOL = Sleep onset latency; TST = Sleep duration; PSG = Polysomnography; PSQI = Pittsburgh Sleep Quality Index.

Several types of insomnia were described in the six studies: moderate sleep complaints [39,43]; chronic insomnia (≥ 6 months) [40,42]; primary insomnia (≥ 3 months) [41]; and sub-threshold insomnia [44].

The aerobic exercise interventions included: tai chi (yang style) [39]; treadmill exercising [40,42]; baduan jin [43]; running [44] and; a combination of walking, stationary bike and treadmill exercises [41]. The aerobic exercise interventions in the included studies were mostly moderate in intensity; however, high intensity aerobic exercise was used as a comparator in a study conducted by Passos et al. [40]. The comparators in the included studies either received “no intervention” [40,41,44], low-impact exercise [39], resistance exercise [40], or made use of different moderating variables, such as time of the day [42]. In addition, five studies [39,41-44] were long-term, lasting 3 weeks to 6 months; with averagely 3 to 5 sessions (of 30-60 minutes) per week. However, Passos et al. [40] evaluated the effects of acute aerobic exercise on chronic insomnia in a trial that lasted one session.

The included studies showed dropout rates of 1.8% to 66%; excluding the Passos et al. [40] 1 exercise session study that reported a zero dropout rate. Li et al. [39], dropout rate of 66%; Reid et al. [41], dropout rate of 22%; Passos et al. [42], dropout rate of 36.6%; Chen et al. [43], dropout rate of 1.8%; and Kalak et al. [44], dropout rate of 8.9%.

The PEDro score for Kalak et al. [44] was unavailable on PEDro, and therefore was assessed using the PEDro scale. The PEDro scores and methodological characteristics of the six included articles are summed in table 6. The mean total PEDro score of the included studies is 5, with a range from 4 to 6. Following the pre-determined levels of quality for the PEDro scores, two articles [39,44] and four articles [40-43] were classified as "good" and "fair" quality respectively. Furthermore, the second most satisfied criteria were “between-group comparisons” (5 of 6 articles) [39,41-44]. The concealed allocation criterion was satisfied by 2 articles [39,44]; blind assessors criterion by 2 articles [40,42]; and the adequate follow-up criterion, as well by 2 articles [43,44]. Intention-to-treat analysis was satisfied by only one article [39], and no article met the “blind subject” and “blind therapist” criteria.

Table 6: PEDro scores and methodological quality characteristics of the six included RCTs.

Articles	**Eligibility criteria**	**Random allocation**	**Concealed allocation**	**Baseline comparability**	**Blind subjects**	**Blind therapists**	**Blind Assessors**	**Adequate follow-up**	**Intention-to-treat analysis**	**Between-group comparisons**	**Point estimates & variability**	**PEDro Score**	**Quality**
Li *et al.* 2004. [39]	Yes	Yes	Yes	Yes	No	No	No	No	Yes	Yes	Yes	6	Good
Passos *et al.* 2010. [40]	No	Yes	No	Yes	No	No	Yes	No	No	No	Yes	4	Fair
Reid *et al.* 2010. [41]	Yes	Yes	No	Yes	No	No	No	No	No	Yes	Yes	4	Fair
Passos *et al.* 2011. [42]	Yes	Yes	No	Yes	No	No	Yes	No	No	Yes	Yes	5	Fair
Chen *et al.* 2012. [43]	Yes	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	5	Fair
Kalak *et al.* 2012. [44]	Yes	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Yes	6	Good

Effect of aerobic exercise on sleep quality

Two of the six studies [39,42] reported significant improvements in sleep quality on the PSQI- subjective sleep quality sub-scale. One study reported non-significant improvement in sleep quality [41], whereas three studies did not use the PSQI [40,42,44].

Li et al. [39] reported significant pre- to post-intervention improvement (66%) in sleep quality in the tai chi exercise group compared to low-impact exercise after a 24-week intervention (from 1.39 [SD 0.84] to 0.47 [SD 0.59] PSQI sub-score; P‹ 0.001).

Chen et al. [43] observed significant improvement (45%) in sleep quality in the baduan jin exercise group after the 12-week intervention (from 2.44 [SD 0.58] to 1.33 [SD 0.48] PSQI sub-score; P‹ 0.001). Moreover, the exercise group showed a significantly improved mean score over the control group in subjective sleep quality (β= -0.37, P‹ 0.001) after 8 weeks of the exercise program.

Reid et al. [41] reported non-significant improvement in sleep quality (PSQI subjective sleep quality sub-score) in the exercise group compared to the non-physical activity group (from 1.90 [SD 1.27] to 0.08 [SD 0.63]; P = 0.127). However, there was a significant effect for time on subjective sleep quality on the PSQI ($F(1,15)= 26.09$; $P < 0.001$).

Passos et al. [40], Passos et al [42], and Kalak et al. [44] did not use the PSQI.

Effect of aerobic exercise on sleep onset latency

All six included studies reported significant results in sleep onset latency on the PSQI, sleep diary and/or polysomnography.

Li et al. [39] reported significant pre—to post-intervention improvement (59%) in sleep onset latency in tai chi participants compared to low-impact exercise participants (from 39.65 [SD 28.45] to 16.21 [SD 0.95] minutes; P= 0.001).

Passos et al. [40] reported significant improvements of 39% and 55% in sleep diary (from 80.8 [SD 45] to 49 ± [SD 32] minutes; P‹ 0.05) and polysomnography (37.6 [SD 31] to 16.8 [SD 16] minutes; P‹ 0.05) respectively, in the moderate-intensity aerobic exercise group.

Reid et al. [41] reported significant results in sleep onset latency, of approximately 37% on the PSQI sleep onset latency subscale (from 1.6 [SD 1.27] to 1.0 [SD 0.94] PSQI sub-score; P= 0.049) in the physical activity group.

Passos et al. [42] reported significant results (49%) in polysomnography sleep onset latency (from 17.1 [SD 2.6] to 8.7 [SD 1.4] minutes; $P < 0.01$) following aerobic exercise training on chronic primary insomnia. Similarly, data from sleep diaries equally revealed a significant improvement of approximately 54% in sleep onset latency (from 76.2 [SD 21.5] to 35.2 [SD 12.1] minutes; $P < 0.01$).

Chen et al. [43] equally reported significant improvement (35%) in sleep onset latency (PSQI) in the badjuan jin group compared with the control group after 12 weeks of intervention (from 2.74 [SD 0.53] to 1.78 [SD 0.42] PSQI sub-score; P‹ 0.001).

Kalak et al. [44] reported a significant improvement (27%) in polysomnography sleep onset latency (minutes) in the running group compared with the control group (no intervention) after a 3-week period (from 10.17 [SD 5.33] to 7.42 [SD 4.73] minutes; P‹ 0.05).

Effect of aerobic exercise on sleep duration

Four studies [39-41,43] described significant results on sleep duration following aerobic exercise interventions. However, two studies [42,44] showed non-significant results.

Li et al. [39] reported pre- to post-intervention significant improvement (13%) in sleep duration (hours) in tai chi participants compared to low-impact exercise participants (from 6.28 [SD 1.27] to 7.45 [SD 0.9] hours; P= 0.005).

Passos et al. [40] equally reported significant improvements in sleep duration of 18% and 26% in polysomnography (from 4.9 [SD 1] to 5.8 [SD 1] hours; P‹ 0.05) and sleep diary (from 3.9 [SD 1] to 4.9 [SD 1] hours; P‹ 0.05) respectively, in the moderate-intensity aerobic exercise group.

Reid et al. [41] reported significant pre- to post-intervention improvement (45%) in sleep duration (PSQI sub-score) in the aerobic exercise group compared with the control group after 16 weeks (from 2 [SD 0.67] to 1.1 [SD 0.740] PSQI sub-score; P= 0.04).

The study conducted by Chen et al. [43] observed significant improvement (73%) in sleep duration (PSQI sub-score) in the baduan jin group compared with the control group after 12-week intervention (from 1.22 [SD 0.58] to 0.33 [SD 0.48] PSQI sub-score; P‹ 0.001).

There were no significant time or group x time effects found for sleep duration in the studies conducted by Passos et al. [42] and Kalak et al. [44].

Best evidence synthesis

There is level 1a evidence (strong) that aerobic exercise significantly improves sleep onset latency in individuals having insomnia. This evidence includes two RCTs [39,44] with PEDro scores equal to 6; two RCTs [42,43] with PEDro scores equal to 5; and two more RCTs [40,41] with PEDro scores equal to 4.

There is level 1b evidence (moderate) that aerobic exercise significantly improves sleep quality in individuals having insomnia. This evidence includes one RCT [39] with a PEDro score equal to 6, and one more RCT [43] with a PEDro score equal to 5.

Similarly, there is level 1b evidence (moderate) that aerobic exercise significantly and equally improves sleep duration in individuals having insomnia. This evidence includes one RCT [39] with a PEDro score equal to 6; one RCT [43] with a PEDro score equal to 5; and two RCTs [40,41] with PEDro scores equal to 4. An overview of a best evidence synthesis is presented in table 7.

Table 7: An overview of best evidence synthesis

Outcome measure	**RCT and PEDro score**	**Level of evidence**
Sleep quality	Li et al. [39]; PEDro score = 6 Chen et al. [43]; PEDro score = 5	Level 1b (moderate); a single higher RCT with PEDro score ≥ 6
Sleep onset latency	Li et al. [39]; PEDro score = 6 Passos et al. [40]; PEDro score = 4 Reid et al. [41]; PEDro score = 4 Passos et al. [42]; PEDro score = 5 Chen et al. [43]; PEDro score = 5 Kalak et al. [44]; PEDro score = 6	Level 1a (strong); two higher RCTs with PEDro score score ≥ 6
Sleep duration	Li et al. [39]; PEDro score = 6 Passos et al. [40]; PEDro score = 4 Reid et al. [41]; PEDro score = 4 Chen et al. [43]; PEDro score = 5	Level 1b (moderate); a single higher RCT with PEDro score ≥ 6

DISCUSSION

Study objective

The purpose of this study was to determine if aerobic exercise is an effective treatment alternative for insomnia. A literature search to identify RCTs investigating the effects of aerobic exercise on insomnia yielded six studies that met the inclusion criteria for the present study. Following analysis of these six studies, the results indicate that aerobic exercise has significant positive effects on insomnia. This suggestion, however, is founded on evidence that aerobic exercise improves sleep quality, reduces sleep onset latency, and increases sleep duration in individuals having insomnia complaints, symptoms and/or disorders.

Interpretation of results

Results (moderate evidence) demonstrated by Chen et al. [43] and Li et al. [39], indicate that aerobic exercise training results in significant increases in subjective sleep quality (45-66%,mean= 55.5%). These results were observed following 12-24 weeks of aerobic exercise interventions (3 sessions per week of 30-60 minutes).

Similarly, the results (strong evidence) indicate that aerobic exercise decreases sleep onset latency. This is supported by significant improvements in polysomnography and self-reported (PSQI/sleep diary) sleep onset latency documented by all six included studies. The percentages of significant improvements in self-reported sleep onset latency from five studies [39-43] ranged from 35% to 59% (mean= 44.8%). Polysomnography percentages of significant improvements from two studies [40,44] ranged from 27% to 49% (mean= 38%). These results were observed following a single session and long-term aerobic exercise interventions, which lasted approximately 1 hour [40], and 3 to 24 weeks [39,41-43], respectively. Long-term aerobic exercise interventions comprised of 3 to 5 training sessions per week lasting an average of 30 to 60 minutes.

The results (moderate) equally indicate that aerobic exercise significantly increases sleep duration as well, following a single session (1 hour) [40] and long-term aerobic training of 12 to 24 weeks [39,41,43]. The percentages of significant improvements in self-reported and polysomnography sleep duration from four studies [39-41,43] ranged from 13% to 73% (mean= 37.3%) and 26%, respectively.

The results demonstrated in the present study indicate that the different aerobic exercise types described in the six included studies, improve sleep onset latency in individuals having insomnia. However, the most significant improvement (73%) in outcome measures following aerobic training was observed in Chen et al. [43] after 12 weeks.

Reid et al. [41] further demonstrates that aerobic exercise is required to improve sleep despite the use of sleep hygiene. This finding is founded on the significant improvements observed in sleep onset latency and sleep duration following sleep hygiene and aerobic training (16 weeks). The sleep effects may have been as a result of the sleep hygiene, but the, the effects of aerobic exercise on insomnia was ascertained as the control group with the same sleep hygiene alone showed no improvements in sleep. Furthermore, Passos et al. [40] showed that acute aerobic exercise can have positive effects on chronic primary insomnia (with significant improvements in sleep onset latency and sleep duration).

Even though two quality studies [39,43] reported significant improvements in sleep quality based on the PSQI-subjective sleep quality sub-score, significant improvement (P-0.02) in sleep dairy measures of sleep quality was observed in Passos et al. [42]. Moreover, insomnia severity index scores (subjective sleep) of healthy adolescents with sub-threshold insomnia decreased significantly over time in the study conducted Kalak et al [44]

Description of the different aerobic exercises

Tai chi and baduan jin have increasingly been described as low- moderate intensity aerobic exercises [45-47]. In addition to the mind-body feature, tai chi and baduan jin can be performed in standing and/or seated position. The tai chi exercise in Li et al. [39] was a simplified Yang style, 8-form easy tai chi that emphasized multi-directional weight-shifting, awareness of body alignment, multi-segmental (arms, legs, trunk) movement coordination, and regulated breathing. Similarly, baduan jin in Chen et al. [43] was equally simplified and shortened from the original Baduan jin exercise. Baduan jin is characterized by 8 sections of simple, slow, relaxing movements, and is reported to be less physical and cognitive demanding [46]

Unlike tai chi [39] and baduan jin exercises [43], the treadmill exercises in Passos et al [40] and Passos et al [42] were performed at moderate-intensity based on first ventilatory threshold. Exercising at first ventilatory threshold may have been difficult; particularly with the sedentary trial populations (regular exercise less than 2 times per week) [40-42]. Therefore, it is plausible that at this intensity, fatigue was elicited; thereby impacting exercise performance, and sleep response successively. Similarly, the running in Kalak et al. [44], and the combined walking, stationary bike and treadmill exercises in Reid et al [41] were also performed at similar moderate intensities.

Quality assessment

The quality level of evidence for the present study was strongly based on the methodological quality of the included studies. The included studies were mostly rated as “good” [39,44] and fair quality [40-43] according to the PEDro scores (mean total PEDro score of 5, and range from 4 to 6).

There were no significant differences between groups at baseline in the included studies, and the sample sizes ranged from 17 [41] to 118 participants [39] mean sample size, 51. Likewise, the effects of aerobic exercise on insomnia were described as a difference in group outcomes [39-41, 43,44] and/or as the outcome in all groups [42].

Comparison with other research

Current clinical practices for the treatment of insomnia include drug therapy and cognitive behavioural therapy. There exist at this time no standard clinical guidelines on exercise treatment of insomnia. Nevertheless, this review shows significant positive effects of aerobic exercise on insomnia. Likewise, exercise has been endorsed by the American Sleep Disorders Association [48,49], and recommended in literature [28-30] as a treatment alternative to improve sleep.

The significant improvements in sleep quality; sleep onset latency; and sleep duration demonstrated in this review are consistent with previous review main findings made by Driver et al [28], and Passos et al. [30] on the effects of exercise on sleep. Driver et al. [28] remarked that long-term exercise (including aerobic) appears to decrease sleep onset latency, and increase sleep duration and slow-wave sleep (more sleep of deeper quality). Passos et al. [30] also concluded that exercise (including aerobic) is effective to decrease sleep complaints and to treat chronic insomnia.

Furthermore, thermogenic [31], body restoration [32] and energy conservation theories [33] indicate that exercise, unlike any other stimuli, stimulates more elevation of body temperature, tissue breakdown, or energy consumption, respectively; to produce a sleep response. It is, therefore, plausible to say that improved sleep, and/or an increased need to sleep was expected following elevated core body and brain temperature; destructive metabolism produced by physical exertion; and/or energy consumption in aerobic exercise. However, exercise-sleep mechanisms described in thermogenic [31], body restoration [32] and energy conservation theories [33] are beyond the scope of the present study.

Strengths and limitations

The present study focuses on sleepers having insomnia (complaints, symptoms, disorders) as study participants. The age group and geographic diversity of the included study participants equally form a strong characteristic of this review. As such, it is plausible to say that the results of this study can be applied more generally and widely to the general population. Moreover, the significant effects of different types of aerobic exercise on insomnia are described; thereby, providing evidence for not just a single type of aerobic exercise. In addition to the clearly defined search procedure, the methodological quality assessment and evidence synthesis processes constitute an added strength of the present study.

This review is not without its limitations. The literature search was limited to RCTs published in English language; consequently, some RCTs published in languages other than English may have been missed. Similarly, more RCTs may have been sourced, should unpublished literature been included in the search. Other study designs such as, cohorts studies, may as well have been used in this review; either as an additional source of research data, or to complement data provided by the RCTs. Most studies investigating the effects of exercise on sleep have been performed in healthy sleepers [28]; consequently, studies on the effects of aerobic exercise on insomnia were limited. In addition, none of the included studies compared the effects of aerobic exercise intervention on insomnia to hypnotic drugs or cognitive behavioural therapy.

Furthermore, the sample sizes in the included RCTs were relatively small, and had lesser proportion of males compared to females as study participants (a total of 80 males to 228 females in all included studies). This finding, however, appears to support epidemiological studies [5,6]; that insomnia is more prevalent in women than men.

Relatively high dropout rates were equally observed. Nevertheless, the dropout rates resulted from health problems unrelated to intervention [39,42,44]; participant non-compliance [41]; personal reasons (time commitment, inconvenience, relocation) [39,42,43]; and/or as a result of participants wanting to be part of the exercise group [41]. The absence of blind assessors [39,41,43,44], adequate follow-up [39-42], and intention-to-treat analysis [40-43] surely impacted the levels of evidence for the present study.

Future research

The evidence that aerobic exercise treats insomnia is compelling and encouraging. However, there is a need for further and higher quality RCTs backed by solid methodology. Adequate blinding of assessors, adequate follow-up and intention-to-treat analysis are crucial for the methodological quality of future RCTs. The sample sizes should be bigger and the trials continued for longer (> 6 months). Population samples should equally include more males and adolescents. Considering physiological differences in male and female, controlled studies on gender differences in the response of insomnia to aerobic exercise should be a subject of future research. Similarly, future RCTs should compare the effects of aerobic exercise on insomnia to current insomnia treatments, such as hypnotic drugs and/or cognitive behavioural therapy.

Implications

It is essential, however, to mention that the results reported in this review meet the goals of insomnia treatment [9] that include: improvement in sleep quantity, sleep onset latency and sleep duration. The outcome of the present study is clinically meaningful, and thereby endorses aerobic exercise as an effective treatment for insomnia. Thus, individuals suffering from insomnia can derive effective and affordable aerobic exercise treatment without use of medication. Individuals with insomnia can equally derive additional health benefits of aerobic exercising, such as: improved heart, lung and metabolic function; improved perception of muscle tone [50]; and improved psycho-social functioning [51].

Altogether, exercise intensity, type of aerobic exercise, and the timing in relation to sleep are important contributing factors to the sleep response [28]. Therefore, it is recommended to assess aerobic fitness with either maximal or submaximal tests in order to determine the optimal intensity level for aerobic training. Supervised exercise is equally recommended at the start of the treatment to instruct the proper techniques, and match the most appropriate exercise type(s) and/or intensity to a person. Patient compliance to a prescribed aerobic exercise treatment should as well be encouraged to prevent dropouts. Negotiating a treatment plan; adequate patient education; and social support (through group therapy), are just one of the several ways of promoting patient compliance to exercise prescription.

Aerobic exercise training should be performed within 4 to 11 hours of bedtime. This is, however, consistent with sleep hygiene recommendations that suggest exercising in the morning and or late afternoon [50,51]. The exercise intensity (low to moderate); time per session (30-60 minutes); and number of sessions per week (3-5 times), should be tailored to suit the age, activity level, co-morbid conditions and individual preferences of the individual. However, precautionary measures should be taken to avoid over-training syndrome. Over-training syndrome is evidenced to induce increased fatigue and more disturbed sleep [54]

There is a catalogue of different types of aerobic exercises to select from when considering treatment for insomnia. An effective aerobic exercise treatment program for insomnia should include at least two or more of the following: treadmill; stationary; walking; and/or running; style tai chi; and/or baduan jin. Tai chi and baduan jin are particularly suitable for older adults, but can be performed by other age-groups. Interestingly, tai chi and baduan jin can also be performed in seated positions, thus, it surely is suitable for “wheelchair-bound” persons having insomnia. Treadmill, bike (stationary), and running are equally appropriate for the different genders and age groups, but then, may not be convenient for the elderly population.

CONCLUSION

Aerobic exercise is as an effective treatment alternative for insomnia; with significant improvements in sleep quality, sleep onset latency and sleep duration. The evidence demonstrated in this review is very compelling (moderate); however, there is need for further research studies. Large randomised controlled trials backed by strong methodology are necessary to further establish the effects of aerobic exercise in the treatment of insomnia.

Notwithstanding, several practical implications and recommendations can be brought forward as a result of this study. The results of the present study propose clinical prescription of aerobic exercise in the treatment of insomnia. This is applicable to insomniac individuals having poor sleep quality, prolonged sleep onset latency, and/or reduced sleep duration. Consequently, aerobic exercise can be used in physiotherapy to treat patients with insomnia (primary, secondary and/or comorbid). However, as physiotherapists, it is equally essential to recognize and treat co-morbid conditions that commonly occur with insomnia. Notwithstanding, proper sleep hygiene recommendations should be observed.

Cost-effective aerobic exercise treatment for insomnia will surely cut down the economic costs of insomnia by: improving productivity, reducing work-related accidents, decreasing absenteeism, and reducing insomnia-related alcohol abuse.

In conclusion, aerobic exercise is a low-priced, and more importantly, an effective treatment alternative for insomnia.

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APPENDIX

1. Appendix I: Pittsburgh Sleep Quality Index (PSQI) instrument
2. Appendix II: PEDro scale and decision rules
3. Appendix III: Best evidence synthesis grading scheme
4. Appendix IV: Extraction tables of the six included studies
5. Appendix V: Approval project plan

Subject's Initials_____ID#_____Date_____Time_____AM PM

PITTSBURGH SLEEP QUALITY INDEX

INSTRUCTIONS:
The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night?

   BED TIME _____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

   NUMBER OF MINUTES _____

3. During the past month, what time have you usually gotten up in the morning?

   GETTING UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)

   HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you . . .

a) Cannot get to sleep within 30 minutes

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

b) Wake up in the middle of the night or early morning

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

c) Have to get up to use the bathroom

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

d) Cannot breathe comfortably

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

e) Cough or snore loudly

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

f) Feel too cold

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

g) Feel too hot

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

h) Had bad dreams

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

i) Have pain

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

j) Other reason(s), please describe_____

_____

How often during the past month have you had trouble sleeping because of this?

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

6. During the past month, how would you rate your sleep quality overall?

Very good _____

Fairly good _____

Fairly bad _____

Very bad _____

7. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all _____

Only a very slight problem _____

Somewhat of a problem _____

A very big problem _____

10. Do you have a bed partner or room mate?

No bed partner or room mate _____

Partner/room mate in other room _____

Partner in same room, but not same bed _____

Partner in same bed _____

If you have a room mate or bed partner, ask him/her how often in the past month you have had . . .

a) Loud snoring

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

b) Long pauses between breaths while asleep

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

c) Legs twitching or jerking while you sleep

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

d) Episodes of disorientation or confusion during sleep

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

e) Other restlessness while you sleep; please describe_____

_____

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: Psychiatry Research, 28:193-213, 1989.

PEDro Scale

1.	eligibility criteria were specified	no ❑ yes ❑ where:
2.	subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no ❑ yes ❑ where:
3.	allocation was concealed	no ❑ yes ❑ where:
4.	the groups were similar at baseline regarding the most important prognostic indicators	no ❑ yes ❑ where:
5.	there was blinding of all subjects	no ❑ yes ❑ where:
6.	there was blinding of all therapists who administered the therapy	no ❑ yes ❑ where:
7.	there was blinding of all assessors who measured at least one key outcome	no ❑ yes ❑ where:
8.	measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	no ❑ yes ❑ where:
9.	all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no ❑ yes ❑ where:
10.	the results of between-group statistical comparisons are reported for at least one key outcome	no ❑ yes ❑ where:
11.	the study provides both point measures and measures of variability for at least one key outcome	no ❑ yes ❑ where:

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (*Verhagen AP et al (1998). The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41*). The list is based on "expert consensus" not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to "weight" scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (ie RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or "generalisability" or "applicability" of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the "validity" of a study's conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the "quality" of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Notes on administration of the PEDro scale:

All criteria	**Points are only awarded when a criterion is clearly satisfied**. If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
Criterion 1	This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
Criterion 2	A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
Criterion 3	*Concealed allocation* means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site".
Criterion 4	At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.
Criteria 4, 7-11	*Key outcomes* are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
Criterion 5-7	*Blinding* means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
Criterion 8	This criterion is only satisfied if the report explicitly states *both* the number of subjects initially allocated to groups *and* the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
Criterion 9	An *intention to treat* analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
Criterion 10	A *between-group* statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group × time interaction). The comparison may be in the form hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
Criterion 11	A *point measure* is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. *Measures of variability* include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.

Appendix III

Modified Five Levels of Evidence adopted from Sackett et al. 2010 by SCIRE

Level	Research Design	Description
Level 1a	Randomised controlled trial (RCT)	More than 1 Higher RCT: Randomized Controlled Trial, PEDro score ≥ 6. Includes within subjects comparison with randomized conditions and cross-over designs
Level 1b	RCT	1 Higher Randomized Controlled Trial, PEDro score ≥ 6.
Level 2	RCT	Lower RCT, PEDro score < 6.
	Prospective controlled trial	Prospective controlled trial (not randomized)
	Cohort	Prospective longitudinal study using at least 2 similar groups with one exposed to a particular condition.
Level 3	Case Control	A retrospective study comparing conditions, including historical controls.
Level 4	Pre-post	A prospective trial with a baseline measure, intervention, and a post-test using a single group of subjects.
	Post-test	A prospective post-test with two or more groups (intervention followed by post-test and no re-test or baseline measurement) using a single group of subjects.
	Case Series	A retrospective study usually collecting variables from a chart review.
Level 5	Observational	Study using cross-sectional analysis to interpret relations.
	Clinical Consensus	Expert opinion without explicit critical appraisal, or based on physiology, biomechanics or "first principles"
	Case Report	Pre-post or case series involving one subject

*SCIRE: The Spinal Cord Injury Rehabilitation Evidence project.

Appendix IV

Data Extraction

Li et al. [39]: Tai Chi and Self-Rated Quality of Sleep and Daytime Sleepiness in Older Adults: A Randomized Controlled Trial

Study Details & Design	Participant Details	Interventions/Comparators	Outcomes Measures	Results
Li F *et al.* 2004, [39] USA **Type of publication:** Full publication **Study Design:** RCT **Setting:** General Community **Duration of Recruitment:** NR	**Inclusion & Exclusion criteria:** (a) aged 60 and older; (b) being inactive, (absence of involvement in any structured or regular exercise activities during the previous 3 months); (c) being healthy to the extent that participation in exercise testing and an exercise program would not exacerbate any existing disease conditions; (d) physician approval for participation; (e) willingness to be randomly assigned to intervention condition and participate on a weekly basis for the 24-week intervention; (f) free of a clinically diagnosed or clinically significant sleep disorder (e.g., sleep apnea) or a medical or psychiatric condition (e.g., chronic pain, clinical depression) responsible for sleep complaints; (g) use of prescription sleep medication no more than once a week for duration of the study; (h) no use of other psychotropic medication; (i) not a current recipient of sleep disorder treatment; (j) no indication of significant cognitive impairment as indicated by a cutoff score of 3 on the Pfeiffer Mental Status Questionnaire;37 (k) consumption of no more than seven alcoholic beverages per week or use of alcohol close to bedtime or smoking more than 10 cigarettes per day; and (l) moderate sleep complaints, defined as ratings of 3 or higher on two of three sleep items drawn from the Sleep Questionnaire and Assessment of Wakefulness38 or a	**Intervention:** Tai Chi exercise (emphasizing movement coordination and regulated breathing). 1-hour session, three times per week, for 24 consecutive weeks. *No. recruited:* 62 *No. Analyzed:* 62 *Mean Age ± SD:* 75.30 ± 7.8 yrs *# Female (%) :* 52 (84) **Comparator:** Low-impact exercise, incl: seated exercise with controlled breathing, stretching and relaxtion. 1-hour session, three times per week, for 24 consecutive weeks. *No. recruited:* 56 *No. Analyzed: 56* *Mean Age ± SD:* 75.45 ± 7.8 yrs *# Female (%) :* 44 (79)	**1. Pittsburgh Sleep Quality Index (PQSI)** - Sleep quality (sub-score) - Sleep onset Latency, SOL (min) - Sleep duration, TST (hr)	**TAI CHAI** ↑ **Sleep Quality:** *Baseline:* 1.39 ± 0.84 *Post-test:* 0.47 ± 0.59 *Change:* - 0.92 ± 1.01 P < 0.001 ↓ **SOL:** *Baseline:* 39.65 ± 28.45 *Post-test:* 16.21 ± 0.95 *Change:* - 23.44 ± 29.21 P = 0.001 ↑ **TST:** *Baseline:* 6.58 ± 1.27 *Post-test:* 7.45 ± 0.90 *Change:* 0.87 ± 1.041 P = 0.005

rating of 4 or higher on any one of three sleep items that assessed the problem of falling asleep at night, waking up during the night, and waking and getting up in the morning.

No. Recruited: 118
No. Analyzed: 118
Mean Age ± SD: 75.38 ± 11 yrs
 # Female (%) : 96 (81)

Insomnia Details:
Moderate sleep complaints, with ratings ≥ 3 on two of three sleep items drawn from the Sleep Questionnaire and Assessment of Wakefulness or a rating ≥ 4 on any one of three sleep items that assessed the problem of falling asleep at night, waking up during the night, and waking and getting up in the morning.

Data Extraction

Passos et al. [40]: Effect of Acute Physical Exercise on Patients with Chronic Primary Insomnia

Study Details & Design	Participant Details	Interventions/Comparators	Outcomes Measures	Results
***G.S. Passos et al.* 2010, [40] Brazil** **Type of publication:** Full publication **Study Design:** RCT **Setting:** General Community **Duration of Recruitment:** NR	**Inclusion Criteria:** (a) 30–55 yrs of age; (b) clinical diagnosis of insomnia according to DSM-IV; (c) complaints of insomnia > 6 months; and (d) at least one complaint of daytime due to insomnia (mood, cognition, or perceived fatigue). **Exclusion criteria:** (a) insomnia directly related to medical condition or to side-effects from medications; (b) use of psychotherapeutic drugs for insomnia/psychiatric disorder; (c) depression (Beck Depression Inventory Score >20) or other psychiatric disorders; (d) shift work; (e) abnormalities in the cardiology evaluation, resting ECG, or exercise stress test; (f) blood test results contraindicating physical exercise; (g) practice of regular (≥ 1 time/week) physical exercise. **No. Recruited:** 48 **No. Analyzed:** 48 **Mean Age ± SD:** 44.4 ± 8 yrs **# Female (%) :** 38 (79) **Insomnia Details:** Duration of insomnia (years). **MAE:** 10.9 ± 10 **HAE:** 6.4 ± 8 **MRE:** 9.6 ± 7 **CTL:** 9.5 ± 11	**Intervention # 1:** MAE (Treadmill). Intensity based on 1st ventilatory threshold. 50 continuous minutes. 1 single exercise session. *No. recruited:* 12 *No. Analyzed:* 12 *Mean Age ± SD:* 42.7 ± 7 yrs *# Female (%) :* 10 (83) **Comparator # 1:** HAE (Treadmill). Intensity based on 2nd ventilatory threshold. 3 periods of 10 mins of exercise alternating with 10 mins rest. 1 single exercise session. *No. recruited:* 12 *No. Analyzed:* 12 *Mean Age ± SD:* 42.2 ± 9 yrs *# Female (%) :* 9 (75) **Comparator # 2:** MRE (.shoulder press, chest press, vertical traction, leg press, leg curl, leg extension, abdominal crunch, and lower back). 1 single exercise session *No. recruited:* 12 *No. Analyzed:* 12 *Mean Age ± SD:* 42.4 ± 9 yrs *# Female (%) :* 10 (83) **Comparator # 3:** No physical exercise *No. recruited:* 12 *No. Analyzed:* 12 *Mean Age ± SD:* 45.2 ± 8 yrs *# Female (%) :* 9 (75)	**1. Polysomnography (PSG):** - Sleep onset Latency, SOL (min) - Sleep duration, TST (hr) **2. Daily Sleep Log (DSL):** - SOL (min) - TST (hr)	**POLYSOMNOGRAPHY** **Intervention MAE** **↓ SOL:** *Baseline:* 37.6 ± 31 *Post-exercise* 16.8 ± 16 P< 0.05 **↑ TST:** *Baseline:* 4.9 ± 1 *Post-exercise:* 5.8 ± 1 P <0.05 **DAILY SLEEP LOG** **Intervention MAE** **↓ SOL:** *Baseline:* 80.8 ± 45 *Post-test:* 49.0 ± 32* P < 0.05 **↑ TST:** *Baseline:* 3.9 ± 1 *Post-test:* 4.9 ± 1* P < 0.05

MAE = Moderate-intensity aerobic exercise; HAE = High-intensity aerobic exercise; MRE = Moderate-intensity resistance exercise; and CTL = Control.

Extraction table

Reid et al. [41]: Aerobic Exercise Improves Self-reported and Quality of life in Older Adults with Insomnia

Study Details & Design	Participant Details	Interventions/Comparators	Outcome Measures	Results
Reid *et al.* 2010, [41] USA **Type of publication:** Full publication **Study Design:** RCT **Setting:** General Community **Duration of Recruitment:** Not reported. :	**Inclusion:** 1) independent in activities of daily without significant cognitive deficits as determined by a MMSE score ≥ 26; 2) a sleep efficiency (SE) less than 80% and/or awakening earlier than desired if before 6 AM; and a total sleep time of less than 6.5 hours, as determined by actigraphy and sleep diary for a period of 7 days; 3) sedentary, defined as participation in exercise of mild to moderate intensity for less than 30 minutes per day and less than two times per week on a regular basis. **Exclusion:** 1) other sleep disorders by history or documented on screening polysomnography (apnea index > 10, periodic leg movement arousal index > 15, or REM behavior disorder; 2) history of cognitive or other neurological disorders; 3) history of DSM-IV criteria for any major psychiatric disorder, including mania or alcohol or substance abuse; 4) significant depressive symptoms as assessed by the Center for Epidemiological Studies Depression Scale (CES-D score > 22); 5) unstable or serious medical conditions or cardiopulmonary disease that contraindicate exercise; 6) current use or use within the past month of psychoactive, hypnotic, stimulant or analgesic medications; 7) shift work or other types of self-imposed irregular sleep schedules; 8) BMI > 35 Kg/m2; 9) history of habitual	**Intervention:** Combination of walking, stationary bike and/or treadmill exercise (at least two). 10 to 40 minutes sessions; 4 times per week; 16 weeks. *No. recruited:* 11 *No. Analyzed:* 10 *Mean Age ± SD:* 62.0 ± 4.5 yrs *# Female (%):* 10 (100%) **Comparator:** No intervention *No. recruited:* 11 *No. Analyzed:* 7 *Mean Age ± SD:* 63.5 ± 4.3 yrs *# Female (%) :* 6 (85.7%)	**PSQI** - Sleep onset Latency, SOL (sub-score) - Sleep duration, TST (sub-score) - Sleep quality (sub-score)	**PHYSICAL ACTIVITY** ↓ **PSQI-SOL:** Baseline: 1.6 ± 1.27 Post-exercise: 1.0 ± 0.94 P = 0.049 ↑ **PSQI-TST:** Baseline: 2.0 ± 0.67 Post-exercise: 1.1 ± 0.740 P = 0.04

	smoking (3 or more cigarettes per week); or 10) caffeine consumption greater than 300 mg per day. **No. Recruited:** 22 **No. Analyzed:** 17 **Mean Age ± SD:** 61.6 ± 4.3 yrs **# Female (%) :** 16 (94%) **Insomnia Details:** Primary insomnia (≥ 3 months)

Data Extraction

Passos et al. [42]: Effects of Moderate Aerobic Exercise Training on Chronic Primary Insomnia

Study Details & Design	Participant Details	Interventions/Comparators	Outcomes Measures	Results (Intervention)
G.S. Passos et al. **2011, [42] Brazil** **Type of publication:** Full publication **Study Design:** RCT **Setting:** General Community **Duration of Recruitment:** NR	**Inclusion Criteria:** (a) 30–55 yrs of age; (b) clinical diagnosis of insomnia according to DSM-IV; (c) complaints of insomnia > 6 months; and (d) at least one complaint of daytime due to insomnia (mood, cognition, or perceived fatigue). **Exclusion criteria:** (a) insomnia directly related to medical condition or to side-effects from medications; (b) use of psychotherapeutic drugs for insomnia/psychiatric disorder; (c) diagnosis of depression or another psychiatric disorder; (d) apnoea-hypopnoea index >15; (e) periodic leg movement index > 15; (f) shift or all-night worker; (g) regular physical exercise (> once per week) over the 6 previous months. **No. Recruited:** 19 **No. Analyzed:** 19 **Mean Age ± SD:** 45.0 ± 1.9 yrs **# Female (%) :** 15 (78.9)	**Intervention # 1:** Morning moderate aerobic exercise. 50 minutes; 3 times per week; 24 weeks *No. recruited:* 10 *No. Analyzed:* 10 *Mean Age ± SD:* 42.3 ± 2.6 yrs *# Female (%) :* 8 (80) **Intervention # 2:** Late-afternoon moderate aerobic exercise. 50 minutes; 3 times per week; 24 weeks *No. recruited:* 9 *No. Analyzed:* 9 *Mean Age ± SD:* 48.0 ± 2.5 yrs *# Female (%) :* 7 (78)	**1. Polysomnography (PSG):** - Sleep onset Latency, SOL (min) - Sleep duration, TST (hr) **2. Sleep Diary:** - Sleep onset latency, SOL (min) - Sleep duration, TST (hr)	**COMBINED INTERVENTIONS** ↓ **PSG-SOL** Baseline: 17.2 ± 2.6 Post-test: 8.7 ± 1.4 P<0.01 ↓ **Sleep Diary-SOL** Baseline: 76.2 ± 21.5 Post-test: 35.2 ± 12.1 P<0.01 :

Data extraction

Chen et al. [43]: The Effect of a Simple Traditional Exercise Programme (Baduanjin exercise) on Sleep Quality of Older Adults: A Randomized Ttrial.

Study Details & Design	Participant Details	Interventions/Comparators	Outcome Measures	Results (Intervention)
Chen MC *et al.* 2011, [43] Taiwan **Type of publication:** Full publication **Study Design:** RCT **Setting:** General Community **Duration of Recruitment:** Not reported	**Inclusion criteria:** (a) 60 years or older; (b) no regular exercise within six months; (c) able to communicate; (d) independent in self-care. **Exclusion Criteria:** Depression tendency score of 8 or higher on the Geriatric Depression Score (Chinese version); (b) impaired mobility; (c) unstable health status **No. Recruited:** 56 **No. Analyzed:** 55 **Mean Age ± SD:** 71.75 ± 8.13 yrs **# Female (%) :** 36 (65.45) **Insomnia Details:** Moderate sleep complaints. The mean of overall sleep quality on PSQI= 11.5 ± 3.43; indicating sleep disturbance.	**Intervention:** 12 weeks of Baduanjin exercise training (30 mins; three times per week). *No. recruited:* 28 *No. Analyzed: 27* *Mean Age ± SD :* 70.48 ± 7.90 yrs *# Female (%) :* 17 (62.96) **Comparator:** No intervention *No. recruited:* 28 *No. Analyzed: 28* *Mean Age ± SD :* 72.96 ± 8.30 yrs *# Female (%) :* 19 (67.86)	**1. Pittsburgh Sleep Quality Index (PSQI)** - Sleep quality (sub-score) - Sleep onset Latency, SOL (sub-score) - Sleep duration, TST (sub-score)	**BADUANJIN EXERCISE** ↑ **Sleep quality:** Baseline: 2.44 ± 0.58 Post-exercise: 1.33 ± 0.48 P < 0.001 ↓ **SOL:** Baseline: 2.74 ± 0.53 Post-exercise: 1.78 ± 0.42 P < 0.001 ↑ **TST:** Baseline: 1.22 ± 0.58 Post-exercise: 0.33 ± 0.48 P < 0.001

Extraction table

Kalak et al. [44]: Daily Morning Running for 3 Weeks Improved Sleep and Psychological Functioning in Healthy Adolescents Compared With Controls

Study Details & Design	Participant Details	Interventions/Comparators	Outcome Measures	Results
Kalak *et al.* 2012, [44] Switzerland **Type of publication:** Full publication **Study Design:** RCT **Setting:** General Community **Duration of Recruitment:** Not reported. :	**Inclusion:** (a) High school adolescents (b) No psychiatric disorders; (c) No medical illnesses, allergies and cardiovascular, pulmonary or orthopedic diseases; and (d) Refrain from any intake of psychoactive or sleep-altering substances for 2 weeks before commencement of and during study itself. **Exclusion:** N/A **No. Recruited:** 56 **No. Analyzed:** 51 **Mean Age ± SD:** 18.30 ± 0.89 yrs **# Female (%) :** 27 (53%) **Insomnia Details:** Sub-threshold insomnia, with a mean insomnia severity score (according to the Insomnia Severity Index) = 13.53 ± 4.88.	**Intervention:** 30 minutes of running at moderate intensity during weekdays (5 times per week) for 3 consecutive weeks. *No. recruited:* 28 *No. Analyzed:* 27 *Mean Age ± SD: 18.1 ± 0.85 yrs* *# Female (%) :* 14 (52%) **Comparator:** No intervention *No. recruited:* 28 *No. Analyzed:* 24 *Mean Age ± SD: 18.1 ± 0.90 yrs* *# Female (%) :* 13 (54%)	**1. POLYSOMNOGRAPHY** - Sleep onset Latency, SOL (min) - Sleep duration, TST (hr)	**RUNNING** ↓ **PSG-SOL:** *Baseline:* 10.17 ± 5.33 *Post-test:* 7.42 ± 4.73 P < 0.05

Fontys Paramedische Hogeschool

B4 Assessment form project plan

Name: Ngome Ntoko Student no: 230500

Date: 12-03-2013

Title: Aerobic exercise treatment of insomnia... : literature review

General

- The project plan is according to format — yes / ~~no~~
- Spelling and language are correct — yes / ~~no~~

Problem description and problem definition (introduction)

- The problem description is sufficiently clearly formulated — yes / ~~no~~
- The problem description reflects social and paramedical relevance — yes / ~~no~~
- A concrete and relevant research question (or questions) can be formulated based on the problem definition, including possible sub questions — yes / ~~no~~

Objective

The objective is:

- Sufficiently clearly and concretely formulated — yes / ~~no~~
- Relevant for a selected target group within the (paramedical) professional practice — yes / ~~no~~
- Practically feasible — yes / ~~no~~
- Achievable within the set time — yes / ~~no~~

Project product

The project product:

- Is in line with the problem definition, research question and objective — yes / ~~no~~
- Is usable for the selected target group — yes / ~~no~~
- Is in line with the client's wishes — yes / ~~no~~
- The product requirements are accurately described — yes / ~~no~~

Activities/method

Sufficient insight is given into the type of activities and types of sources for the performance of the research and the realization of the product — yes / ~~no~~

Time schedule

- The time schedule gives a global phasing and time investment for the project as a whole and for the coming weeks an increasingly detailed schedule — yes / ~~no~~
- Important moments are recorded in the table (typographically noticeable) (e.g. contact moments, handing-in moments) — yes / ~~no~~
- The time schedule gives a global task division of the planned activities — yes / ~~no~~

Estimated costs

Clear insight is given in:

- The costs to be expected concerning money and hours — yes / ~~no~~
- The division of these costs (project leader, student, programme) — yes / ~~no~~

Literature

- Used and planned literature is specific and mentioned to a sufficient extent — yes / ~~no~~
- Relevant and recent literature is referred to — yes / ~~no~~
- Literature references, in the text and in the literature list, are made according to the Writer's Guide (Wouters 2012) — yes / ~~no~~

Comments: See extended feedback send on 13-3-2013.
- Too much values in introduction
- Work definitions
- a bit less strict on quality criteria.

All points under B3.1 up to and including B3.8 must be answered with a 'yes' in order to receive a GO for the project. The supervisor discusses with the student which points need adjustment.

GENERAL: GO / ~~NO GO~~

Name assessor: Date + Signature

Anke Voesenek 12-03-2013

Steven Onkelinx