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A randomized controlled trial of bedtime music for insomnia disorder

Kira Vibe Jespersen[1] | Marit Otto[2] | Morten Kringelbach[1,3] | Eus Van Someren[4,5] | Peter Vuust[1]

[1]Department of Clinical Medicine, Center for Music in the Brain, Aarhus University & the Royal Academy of Music, Aarhus/Aalborg, Denmark

[2]Department of Clinical Neurophysiology, Aarhus University Hospital, Aarhus, Denmark

[3]Department of Psychiatry, University of Oxford, Oxford, UK

[4]Department of Sleep and Cognition, Netherlands Institute for Neuroscience, Amsterdam, The Netherlands

[5]Departments of Integrative Neurophysiology and Psychiatry, Amsterdam Neuroscience, VU University and Medical Center, Amsterdam, The Netherlands

Correspondence
Kira Vibe Jespersen, Center for Music in the Brain, Aarhus C, Denmark.
Email: kira@clin.au.dk

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Summary

Music is often used as a self-help tool to alleviate insomnia. To evaluate the effect of bedtime music listening as a strategy for improving insomnia, we conducted an assessor-blinded randomized controlled trial. Fifty-seven persons with insomnia disorder were included and randomized to music intervention (n = 19), audiobook control (n = 19) or a waitlist control group (n = 19). The primary outcome measure was the Insomnia Severity Index. In addition, we used polysomnography and actigraphy to evaluate objective measures of sleep, and assessed sleep quality and quality of life. The results showed no clear effect of music on insomnia symptoms as the group × time interaction only approached significance (effect size = 0.71, p = .06), though there was a significant improvement in insomnia severity within the music group. With regard to the secondary outcomes, we found a significant effect of the music intervention on perceived sleep improvement and quality of life, but no changes in the objective measures of sleep. In conclusion, music listening at bedtime appears to have a positive impact on sleep perception and quality of life, but no clear effect on insomnia severity. Music is safe and easy to administer, but further research is needed to assess the effect of music on different insomnia subtypes, and as an adjunctive or preventive intervention.

KEYWORDS

insomnia, music, randomized controlled trial, self-help, sleep

1 | INTRODUCTION

Insomnia is a major health problem associated with reduced quality of life, disturbed mood, cognitive impairments and elevated risk for mental disorders, such as depression and anxiety (Riemann et al., 2015). Insomnia is the most common sleep disorder, and it is characterized by persistent difficulties initiating or maintaining sleep, including early morning awakening (EMA), accompanied by daytime impairments (APA, 2013). It is highly prevalent in the modern society, with about 30% of the general population experiencing insomnia symptoms and 6%–20% of the population fulfilling the criteria for an actual insomnia disorder (Ohayon, 2002; Roth et al., 2011).

Standard treatments for insomnia include both pharmacological and psychological treatments. Pharmacotherapy shows good short-term effects, but is associated with negative side-effects and is only recommended for short-term use (Riemann et al., 2015). Cognitive behavioural therapy for insomnia (CBT-I) has strong empirical support and is recommended as first-line treatment for persistent insomnia (Riemann et al., 2017). CBT-I works by using a combination of behavioural and cognitive strategies (e.g. sleep restriction, stimulus control, cognitive therapy and sleep hygiene education) to target factors that perpetuate the insomnia disorder. However, CBT-I requires substantial time and behavioural change from the patients if they are to benefit from the therapy, and not all patients reach this goal (Morin & Benca, 2012; Riemann et al., 2015).

As such, the standard treatments have certain limitations, and studies show that the majority of individuals with insomnia do not seek conventional treatment (Morin, Leblanc, Daley, Gregoire, & Mérette, 2006). Instead, many use complementary health approaches such as herbal or dietary products to promote sleep or initiate self-help strategies such as reading or listening to music, even though the effects are not well documented. Music is a commonly used tool for sleep improvement (Aritake-Okada, Kaneita, Uchiyama, Mishima, & Ohida, 2009; Urponen, Vuori, Hasan, & Partinen, 1988), and a Canadian study found that among individuals with insomnia disorder, 43.6% had used music to promote sleep (Morin et al., 2006). Therefore, it is highly relevant to clarify whether music listening can actually improve sleep or not; research indicates that there is a scientific rationale for impact of music on insomnia.

Music is increasingly used in clinical settings including oncology and neurorehabilitation (Bro et al., 2017; Sihvonen et al., 2017), and music psychology and neuroscience research highlight a number of mechanisms that could underlie the putative effect of music on sleep. First, studies show that there is a close link between music and emotion, and music is commonly used for emotional self-regulation (Koelsch, 2010; Saarikallio, 2011). This could be relevant for insomnia, as insomnia is often associated with emotional disturbances including depression and anxiety. The ability of music to induce positive mood states would be expected to facilitate sleep in persons with insomnia. Similarly, music may work as a positive distraction from ruminations or worries (Garza-Villarreal et al., 2014). Worries about sleep can be a perpetuating factor leading to the persistence of the insomnia condition, and distraction from sleep-onset worries would be expected to ease the transition into sleep.

Another important mechanism is the impact of music on arousal. Experimental and clinical studies have shown that music can affect our level of arousal as reflected in measures of autonomous nervous system function (Bernardi et al., 2009; Chanda & Levitin, 2013). For example, studies have shown that listening to slow instrumental music can promote relaxation reflected in reduced cortisol levels during operational procedures (Nilsson, 2009), as well as decreases in heart rate and respiratory rate (Chlan, 1998). This is important in relation to insomnia, as the prevailing "hyperarousal" theory states that insomnia involves increased levels of arousal as reflected in both psychological and neurophysiological measures (Bonnet & Arand, 2010; Riemann et al., 2010). As such, soft music could potentially work as a sleep aid in persons with insomnia by reducing physiological and cognitive arousal.

Still, the effect of music for relieving insomnia is not well documented. A number of systematic reviews state that music listening can improve sleep quality in adults with sleep problems (De Niet, Tiemens, Lendemeijer, & Hutschemaekers, 2009; Jespersen, Koenig, Jennum, & Vuust, 2015; Wang, Sun, & Zang, 2014). In 2016 an additional randomized controlled trial (RCT) was published reporting a significant effect of music on sleep quality in elderly persons with poor sleep (Wang, Chair, Wong, & Li, 2016). These previous studies seem to support the use of music as a sleep aid. However, the results are limited by lack of information on the nature of the sleep problems and assessment of sleep parameters. The populations of the previous studies are very diverse and none of these included adults with insomnia disorder. Furthermore, several studies suffer from substantial risk of bias due to no blinding of outcome assessors and other methodological limitations, such as baseline differences and differences between groups in the data collection procedure. Finally, the reported outcomes include mainly the Pittsburgh Sleep Quality Index (PSQI), and no studies assess insomnia symptoms. Only one RCT included polysomnography (PSG) to assess objective sleep changes, and found shortened stage 2 sleep and prolonged rapid eye movement (REM) sleep in the music group compared with controls (Chang, Lai, Chen, Hsieh, & Lee, 2012). However, the effects were rather small, and more studies are needed to assess the impact of music on sleep architecture.

To address these shortcomings, we conducted an assessor-blinded RCT to evaluate if bedtime music can alleviate insomnia in adults with insomnia disorder. We hypothesized that the participants listening to music would experience improvement in sleep compared with the active and passive control group. Additionally, we expected the music group to experience improved quality of life.

2 | METHODS

2.1 | Design

We used an assessor-blinded RCT design with three parallel groups. The intervention group was asked to listen to music every night at bedtime. The active control group listened to audiobooks, and the waitlist control group received no intervention. The study was approved by the Danish Ethical Committee (Central Denmark Region) and the participants received no economic compensation for participating in the study. The protocol was registered at clinicaltrials.gov with identification number NCT02321826.

2.2 | Participants

Participants were recruited between March 2015 and April 2017 through newspaper announcements and, occasionally, via face-to-face contact (e.g. sleep clinic patients). Persons between the ages of 18 and 65 years were considered for inclusion if they met the DSM-5 criteria for insomnia disorder, including difficulties initiating or maintaining sleep despite adequate opportunity to sleep and associated daytime impairment. The sleep problems had to be present for at least 3 nights per week for at least 3 months (American Psychiatric Publishing, 2013). People were excluded if they (a) were pregnant or had children below the age of 2 years; (b) used hypnotic or psychotropic medications; (c) had sleep-disruptive medical conditions (e.g. pain disorders or neurodegenerative disorders); (d) had a current psychiatric disorder or a history of psychotic disorder; (e) abused alcohol or other substances; (f) had more than mild symptoms of other sleep disorders, e.g. periodic leg movement syndrome (> 25) or sleep apnea (apnea–hypopnea index > 15). Participants were assessed for inclusion in a semi-structured clinical interview using the Diagnostic

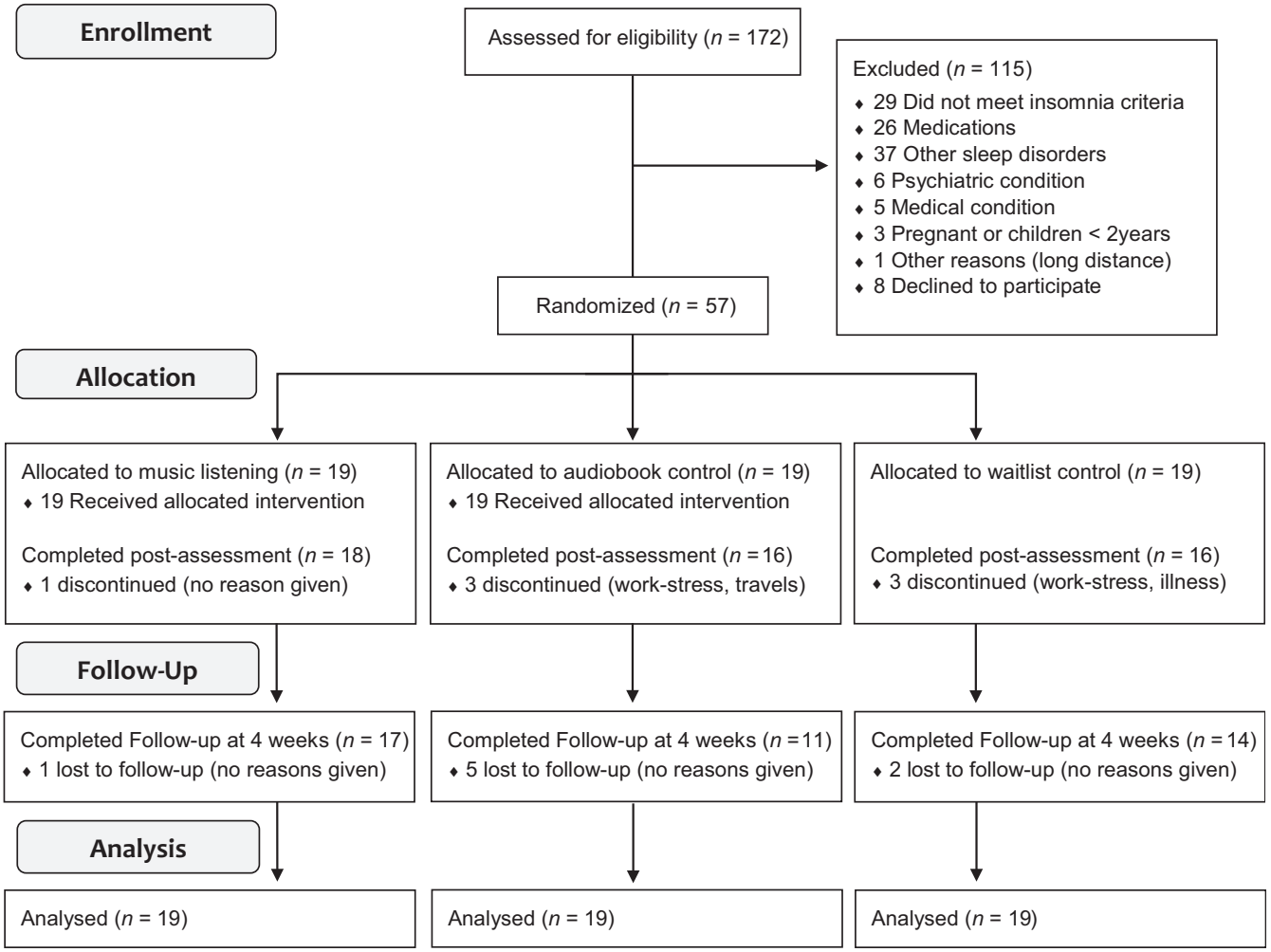

FIGURE 1 CONSORT study flow diagram. The intervention period was 3 weeks. Outcome measures were registered at baseline and after the intervention period, and follow-up measures were taken 4 weeks after the intervention ended

and Statistical Manual of Mental Disorders, fifth edition (American Psychiatric Publishing, 2013) and clinical guidelines (Schutte-Rodin, Broch, Buysse, Dorsey, & Sateia, 2008). Volunteers who fulfilled the inclusion criteria and wished to participate filled in consent forms and were assigned for initial PSG. Fifty-seven persons were randomly allocated to one of the three groups by the drawing of lots. The bowl was prepared by administrative staff with no knowledge of the study. Figure 1 shows the participant flow.

2.3 | Music intervention and control groups

In line with previous studies, the intervention period was 3 weeks, and participants were instructed in using the intervention in their own home during this period. Participants allocated to the music listening group received an audio player designed to be used in bed. The audio player had an inbuilt fade function, and participants were asked to listen to music for minimum 30 min every night at bedtime. They were also invited to use the music if they had difficulties going back to sleep during the night. Participants in the music group had the choice among four types of music playlists in different genres matched on musical characteristics (see Supplementary Material S1). The music genres were classical, jazz, new-age and ambient. All music was instrumental and characterized by a slow tempo (50–80 bpm), stable dynamics and a simple structure. These characteristics seem to be optimal for a relaxation response, and were chosen based on experimental research on music relaxation properties and analyses of lullabies (Bernardi et al., 2009; Gomez & Danuser, 2007; Trehub & Trainor, 1998). To control for placebo effects and non-musical effects of bedtime audio stimulation, we included an active control group listening to audiobooks. Reading or listening to audiobooks is another common strategy for sleep improvement and thus can be considered ecologically valid. The participants in the active control group had the same audio player and were asked to listen to an audiobook for minimum 30 min every night at bedtime. They had the choice among four different audiobooks in different genres but all with a low emotional intensity (see Supplementary Material S1). The genres were: short stories, tales and fairy tales, auto-biographical novel and magical realism. The participants in the waitlist control group had no intervention.

TABLE 1 Demographic characteristics of the participants

Variable[a]	Music group (n = 19)	Audiobook group (n = 19)	Control group (n = 19)	All (n = 57)	p-value t-test/ chi-square
Age, years	50.9 (10.9)	48.0 (14.9)	51.6 (8.2)	50.2 (11.6)	.60
Female gender	15 (79)	15 (79)	15 (79)	45 (79)	1.00
Education, years	14.7 (2.2)	14.5 (1.6)	14.5 (1.8)	14.6 (1.9)	.94
Occupation					
High-school student	0	1 (5.3)	0	1 (1.8)	.45
University student	1 (5.3)	3 (15.8)	0	4 (7.0)	
Full-time job	7 (36.8)	7 (36.8)	8 (42.2)	22 (38.6)	
Part-time job	7 (36.8)	2 (10.5)	4 (21.0)	13 (22.8)	
Unemployed	1 (5.3)	1 (5.3)	3 (15.8)	5 (8.8)	
Retired	3 (15.8)	5 (26.3)	4 (21.0)	12 (21.0)	

[a]Data are presented as mean (standard deviation) or number (%).

2.4 | Measures

The participants in all three groups completed the same outcome measures before and after the intervention period, as well as at 4-weeks follow-up. All questionnaires were administered digitally at all three time-points. Demographic information was collected at baseline, including information on insomnia frequency and duration. After the intervention period, all participants rated whether their sleep had improved or not during the intervention period.

The primary outcome was insomnia severity as measured with the Insomnia Severity Index (ISI). The ISI consists of seven items that are each rated on a five-point scale yielding a total score between 0 and 28, with higher scores indicating more insomnia (Bastien, Vallieres, & Morin, 2001). The PSQI was used to assess changes in subjective sleep quality. It is a self-report questionnaire with 19 items (range 0–21). Higher scores indicate more sleep problems, and a score > 5 separates poor sleepers from good sleepers (Buysse, Reynolds Iii, Monk, Berman, & Kupfer, 1989). Both the PSQI and ISI have good psychometric properties and are recommended as essential outcome measures in treatment studies (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006).

Quality of life was measured with the psychological domain of the WHOQOL-BREF (psychological quality of life [pQoL]). The psychological domain includes six items, which are all rated on a five-point Likert scale. The domain summary score ranged from 4 to 20, with higher scores indicating a better quality of life. The WHOQOL-BREF has shown suitable psychometric properties (Bech, 2001).

Before and after the intervention period, each participant underwent one full-night ambulatory PSG. Participants came to the sleep lab (Department of Clinical Neurophysiology, Aarhus, Denmark) in the late afternoon or early evening hours to have the equipment attached and went home afterwards to sleep in their own beds at their normal bedtime. Montage was done in accordance with the guidelines of the American Academy of Sleep Medicine (Iber, Ancoli-Israel, Chesson, & Quan, 2007) using a 24-channel XLtec Trex HD ambulatory headbox (Natus Medical). The recordings were analysed with the SleepWorks software (Natus Medical) by an experienced technologist trained in sleep scoring. They were visually scored in 30-s epochs according to the AASM criteria (Iber et al., 2007), and the scoring was re-examined by a neurologist who specialized in sleep medicine. Both were blinded to the allocation of the participants. The main PSG outcome measures included total sleep time (TST), sleep-onset latency (SOL), wake after sleep onset (WASO) and sleep efficiency (SE, percentage TST of time in bed).

Sleep estimates were also obtained using wrist actigraphy (wGT3X-BT monitor, ActiGraph, Pensacola, Florida, USA) for 7 nights before and after the intervention period. Actigraphy measures were downloaded in 1-min epochs and scored using the Cole-Kripke sleep-scoring algorithm in the ActiLife 6 software, making use of information from a sleep log (lights out time and getting up time). The main actigraphic sleep estimate outcomes included TST, SOL, WASO and SE. The assessor was blinded to group allocation.

2.5 | Statistical analyses

The statistical tests were two-sided with a significance level of 5%. We used one-way ANOVAs and χ^2-tests to compare the demographic characteristics and baseline characteristics of the three groups. Paired t-tests and Wilcoxon signed-rank tests were used to assess within-group changes. We calculated within-group effect sizes for the questionnaire data using Cohen's d ($d = (M_1 - M_2)/SD_{pooled}$, where M_1 = baseline mean, M_2 = post-test or follow-up mean, and SD_{pooled} = the pooled standard deviation of baseline SD across groups). Linear mixed model analyses were used to assess the amount of change in outcomes in the three groups over the treatment phase (baseline to post-intervention) and over the whole study period (baseline, post- and follow-up). To test the hypotheses, we compared the intervention group with controls, and compared all three groups. Analyses were done in R (R Core Team, 2017) using lme4 (Bates, Maechler, Bolker, & Walker, 2015) and lmerTest (Kuznetsova, Brockhoff, & Christensen, 2017) for the linear mixed models. Fixed effects included group, time and their

interaction, and random effects included intercepts for subjects. For the actigraphy data, we also included random effects for the variability within the 7 days of measurement. As these analyses allow for the inclusion of participants with missing data at one or more time-points, we included all participants in the analyses and did not impute missing data.

Sample size estimation was based on the effect and standard variation found in the most recent meta-analysis (Jespersen et al., 2015), and was conducted with GPower v.3.1 setting alpha at 5% and beta at 20%. It was found that 15 participants were needed in each group and, to account for attrition, we included 19 in each group.

3 | RESULTS

3.1 | Participants

Table 1 gives an overview of the demographic characteristics of all participants. The average age of the participants was 50 years (*SD* 11.6) and 79% were female. There were no significant differences between groups in any of the demographic characteristics.

The years of suffering from insomnia ranged from 1 to 30 years, with an average of 10.3 years (*SD* 8.1). There were no significant differences between groups in the number of years suffering from insomnia (F = 1.04, p = .36). The ISI showed that the nature of the sleep problems differed among participants, with 15.8% experiencing only sleep initiation problems, 36.8% had only difficulties with sleep maintenance and 1.8% experienced only EMA. A combination of sleep initiation and maintenance problems was experienced by 22.8% of the participants, while 15.8% experienced both sleep maintenance problems and EMA. Seven percent of the participants had problems initiating and maintaining sleep as well as EMA. There were no significant differences between the groups in the characteristics of the insomnia symptoms (χ^2 = 15.24, p = .12).

3.2 | Acceptability and compliance

In the music group, 94% of the participants liked the music intervention "much" or "very much", indicating that the music playlists were well suited for bedtime listening and that the choice among four different genres was sufficient (see Supplementary Material S2 for details on music choice). The satisfaction within the audiobook control group was less, with 44% liking the audiobooks "much" or "very much". Some participants were indifferent and a few disliked the audiobooks (see Supplementary Material S3 for details). With regard to compliance, 94% of the participants in the music group reported using the intervention 5 days a week or more. In the audiobook control group, 69% listened 5 days a week or more (see Supplementary Material S3).

3.3 | Baseline sleep characteristics

The baseline questionnaire scores are shown in Table 2. The ISI scores reflect moderate insomnia at baseline, with a mean score of 18.1 (*SD* 4.35, range 9–26). The PSQI score ranged from 6 to 19, with a mean score of 11.5 (*SD* 2.75), indicating substantial sleep problems. There were no baseline differences between the groups on any of the questionnaire outcomes.

According to the PSG data it took participants on average 21 min to fall asleep (SOL). They were awake after sleep onset (WASO) for about 50 min, and the mean TST for all participants was 397 min

TABLE 2 Questionnaire data: means, standard deviations and effect sizes (Cohen's D)

	Baseline Mean (*SD*)		Post-test Mean (*SD*)		Baseline to post-test, Cohen's *D*	Follow-up, Mean (*SD*)		Baseline to follow-up, Cohen's *D*	Between-group effect size[a]	
	n		*n*			*n*			Post	Follow-up
ISI										
Music	19	17.0 (3.4)	18	13.9 (5.3)	0.71[b]	17	13.3 (4.0)	0.83[b]	–	–
Audiobook	19	19.2 (4.5)	16	17.7 (3.3)	0.35	11	16.2 (4.2)	0.70	0.85	0.71
Waitlist	19	18.2 (4.9)	15	16.5 (4.9)	0.39	14	15.9 (3.7)	0.51	0.51	0.67
PSQI										
Music	19	10.8 (3.1)	18	8.7 (3.8)	0.77[b]	17	8.9 (3.4)	0.69	–	–
Audiobook	19	11.9 (2.6)	16	10.4 (3.1)	0.57	11	9.8 (2.5)	0.77[b]	0.49	0.29
Waitlist	19	11.8 (2.6)	15	11.2 (3.0)	0.21	14	11.1 (2.8)	0.26	0.72	0.70
pQoL										
Music	19	14.4 (2.7)	18	15.2 (2.6)	0.30[b]	17	15.6 (2.6)	0.43[b]	–	–
Audiobook	18	13.3 (3.0)	15	13.3 (3.6)	0.01	11	13.8 (2.7)	0.18	0.61	0.68
Waitlist	18	13.9 (2.7)	16	13.0 (2.3)	−0.31	13	13.8 (2.8)	-0.05	0.89	0.67

ISI, Insomnia Severity Index; *n*, number of datasets in each group; pQoL, psychological domain of the WHO quality of life questionnaire—abbreviated version; PSQI, Pittsburgh Sleep Quality Index; *SD*, standard deviation.

The table reports observed values. Estimations from linear mixed models are reported in the results section.

[a]Between-group effect sizes compares the music group to each of the two control groups. [b]p < .05, paired t-test

(6.6 hr). The proportion of time spent in bed that the participants were asleep was 83.7% (SE). There were no significant differences between the groups at baseline (Table 3).

Wrist actigraphy data suggested a shorter SOL estimate than the PSG-derived SOL (mean 3 min), but a similar WASO (mean 53 min). The TST was 419 min (7 hr) at baseline and SE was about 88%. The three groups were similar on all actigraphy variables at baseline (Table 3).

3.4 | Outcomes

3.4.1 | Subjective sleep measures

When looking at the ISI change from baseline to post-intervention within each group, the music group showed a significant reduction of 3.1 (95% CI: −5.4 to −0.8) compared with non-significant reductions of 0.6 (95% CI: −2.2 to 0.9) in the audiobook group and 1.2 (95% CI: −2.7

TABLE 3 Objective sleep measures

	Baseline		Post-test		Δ post
	n	Mean (*SD*)	*n*	Mean (*SD*)	Mean (*SD*)
PSG					
SOL (min)					
Music	19	20.6 (18.2)	18	10.9 (7.2)	−9.7 (18.0)
Audiobook	19	21.2 (26.9)	15	18.5 (17.3)	−5.3 (19.5)
Control	17	21.1 (14.6)	15	17.6 (15.8)	−2.0 (17.6)
WASO (min)					
Music	19	56.4 (35.8)	18	57.6 (30.6)	0.3 (36.7)
Audiobook	19	47.5 (44.0)	15	48.8 (28.9)	5.4 (42.7)
Control	17	44.6 (22.9)	15	43.9 (24.5)	−1.1 (32.7)
SE (%)					
Music	19	83 (9.4)	18	83 (8.3)	−0.1 (7.7)
Audiobook	19	84 (11.1)	15	84 (7.4)	2.3 (12.0)
Control	17	84 (6.2)	15	85 (4.3)	0.1 (5.6)
TST (min)					
Music	19	407 (83.9)	18	400 (51.3)	−9.4 (69.9)
Audiobook	19	397 (48.8)	15	420 (86.5)	25.1 (94.2)
Control	17	384 (51.2)	15	390 (65.6)	−0.7 (65.4)
Actigraphy					
SOL (min)					
Music	18	3.0 (2.2)	15	3.4 (3.0)	0.3 (2.3)
Audiobook	17	3.4 (3.1)	13	3.9 (2.8)	1.0 (3.8)
Control	19	3.1 (3.4)	14	3.0 (2.5)	0.0 (4.0)
WASO (min)					
Music	18	53.1 (21.1)	15	49.5 (18.9)	−4.5 (20.5)
Audiobook	17	53.6 (18.2)	13	43.3 (18.2)	−12.6 (11.2)
Control	19	52.9 (18.6)	14	42.6 (14.1)	−7.3 (13.7)
SE (%)					
Music	18	88.2 (4.2)	15	87.9 (4.8)	−0.2 (3.9)
Audiobook	17	88.5 (3.2)	13	89.8 (3.8)	1.4 (2.6)
Control	19	88.1 (3.7)	14	88.7 (3.9)	−0.2 (2.8)
TST (min)					
Music	18	416 (35.5)	15	415 (38.2)	−5.3 (29.4)
Audiobook	17	432 (40.3)	13	438 (46.8)	0.5 (20.9)
Control	19	411 (34.1)	14	409 (49.5)	−9.2 (36.3)

n, number of datasets in each group; PSG, polysomnography; *SD*, standard deviation; SE, sleep efficiency; SOL, sleep-onset latency; TST, total sleep time; WASO, wake after sleep onset; Δ post, difference value from baseline to post (numbers do not necessarily add up because of attrition). The table reports observed values.

to 0.3) in the waitlist group (Figure 2). The linear mixed model analyses showed only a trend towards a significant interaction effect in the ISI, with a larger reduction in insomnia severity of 2.0 in the music group compared with the controls after the intervention period (95% CI: −4.0 to 0.1; p = .06). The interaction effect was similar, but less clear when including the follow-up measures (mean change −1.6 [95% CI: −3.5 to 0.3]; p = .09). The linear mixed model analyses showed no significant group differences in the amount of change in PSQI but, similar to the ISI, paired t-tests from baseline to post-intervention showed that there was a significant reduction in PSQI score of 2.2 points in the music group (95% CI: −3.4 to −0.9) compared with non-significant reductions of 1.3 (95% CI: −2.9 to 0.4) in the audiobook group and 0.9 (95% CI: −3.0 to 1.1) in the waitlist group. Means, standard deviations and effect sizes for the ISI and PSQI data are shown in Table 2.

The first three items of the ISI assess difficulties initiating sleep (DIS), difficulties maintaining sleep (DMS) and EMA. To explore if the music intervention had a differential effect on these insomnia symptoms, we tested if there were significant changes in any of the groups using the Wilcoxon signed-rank test. The results showed a trend towards a significant reduction in DIS post-intervention in the music group (p = .06), but no effect in any of the control groups. There were no significant changes in DMS or EMA.

After the intervention period, all participants rated if they had experienced improvement of their sleep or not. Significantly more individuals in the music group responded that they had experienced improvement in sleep compared with the audiobook and waitlist group (χ^2 = 12, p = .02). In the music group, 58% of the participants stated that their sleep improved during the intervention period, compared with 16% in the audiobook group and 16% in the waitlist group (Figure 3).

3.4.2 | Quality of life

There was a significant time by group interaction effect in pQoL scores, with the music group showing significantly greater rates of improvement relative to the control groups after the intervention period (mean difference 1.2 [95% CI: 0.3–2.2]; p = .01) and when including all three time-points (mean difference 1.2 [95% CI: 0.2–2.1]; p = .02; Figure 4).

3.4.3 | Objective sleep measures

The linear mixed effect model analyses of the objective sleep parameters measured with PSG and actigraphy showed no significantly different changes between any of the groups. Table 3 gives an overview of the data. Furthermore, analyses showed no effects of the music on the amount of sleep in the different sleep stages.

3.5 | Drop-out and missing data

As seen in Figure 1, seven participants dropped out during the intervention period. No adverse effects were reported. Reasons for drop-out included work stress, illness and travels. Furthermore, eight participants did not complete the follow-up measure with no reasons provided. Among those who completed the study, there were missing data at different time-points due to a few participants not filling in all questionnaire and technical problems with the actigraphs and PSG equipment.

4 | DISCUSSION

This is the first study to assess the effect of bedtime music listening in adults with insomnia disorder using a rigorous design and comparing the intervention with both an active and passive control group. We found no clear effect of the music on insomnia severity (ISI) as the interaction effect only approached significance. Within-group analyses showed an improvement of insomnia severity and sleep quality in the music group not seen in any of the control groups. Significantly more participants in the music group experienced sleep improvement during the intervention period compared with participants in the control groups (Figure 3), and analyses of the separate insomnia symptoms suggested that music may be most efficient for DIS. Importantly, we found significantly larger improvement in psychological quality of life in the music group compared with the two control groups, but there were no changes in objective measures of sleep.

The results of this study suggest an effect of bedtime music on sleep that is not easily captured by regular questionnaires and objective measures. We found that 58% of the participants in the music group perceived their sleep to have improved during the intervention period. This was significantly more than in the audiobook (16%) or waitlist group (16%). Still, the main analysis of insomnia severity showed only a trend towards a significant interaction effect between group and time. The average reduction in ISI scores in the music group of 3.1 reflects a relatively small improvement (Morin, Belleville, Bélanger, & Ivers, 2011) and, similarly, the average reduction in PSQI scores of 2.2 in the music group is smaller than what has been found in other studies reporting the effect of music on sleep quality.

Previous studies on music as a self-help tool have reported significant positive effects on sleep quality in adult populations with poor sleep (for a review, see Jespersen et al., 2015), and several factors may explain why the results of this study are less clear.

First, this study differs from earlier studies by including adults with insomnia disorder. Previous RCTs have focused on poor sleep evaluated as a PSQI score > 5 (Chang et al., 2012; Harmat, Takács, & Bódizs, 2008; Lai & Good, 2005; Shum, Taylor, Thayala, & Chan, 2014; Wang et al., 2016). These studies report very limited information on the nature of the sleep problems but, in general, the baseline PSQI scores were lower than in our study. This suggests that participants in the present study suffered from more severe and persistent sleep problems, and might indicate that music listening is more efficient for less severe sleep problems. As such, music interventions might be better suited for those with subclinical insomnia to prevent chronification of the disorder. However, the participants in the RCT by Wang et al. had high baseline PSQI scores (mean 12.9)

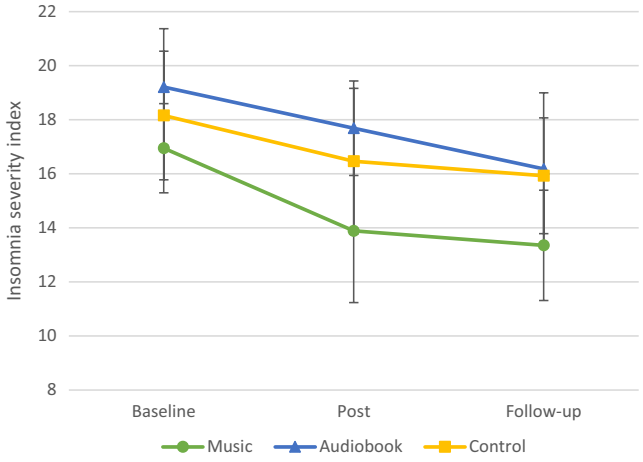

FIGURE 2 Insomnia severity index (ISI) scores and 95% CIs at all time-points in all three groups. There was a significant reduction in insomnia severity within the music group from baseline to post-intervention. However, the time × group interaction only approached significance (p = .06). Higher scores in the ISI indicate more severe insomnia symptoms

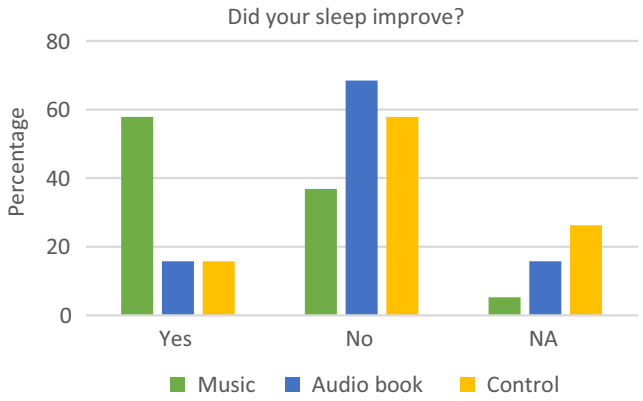

FIGURE 3 Rating of subjective sleep improvement after the intervention period. Significantly more individuals in the music group reported improvement in sleep than those in the other two groups

and still they found a significant interaction effect with the music group showing a larger sleep improvement than the control group. The reason could be the longer time frame. Most previous studies have used a 3-week intervention period, but Wang and colleagues showed a cumulative effect over a 3-month intervention period suggesting that with severe sleep problems a longer intervention period is needed to see an effect.

Secondly, previous results are limited by substantial risk of bias due to methodological limitations such as quasi-randomization procedures (Ardabili, Abdi, Ghezeljeh, Fatemeh, & Hosseini, 2016; Hernández-Ruiz, 2005; Jespersen & Vuust, 2012), group procedure differences (Harmat et al., 2008) and no blinding of outcome raters (Lai & Good, 2005; Shum et al., 2014). It could be that previous studies have over-estimated the effect of music using designs with substantial risk of bias. Furthermore, most studies only compared the music intervention with a passive control group, and just one

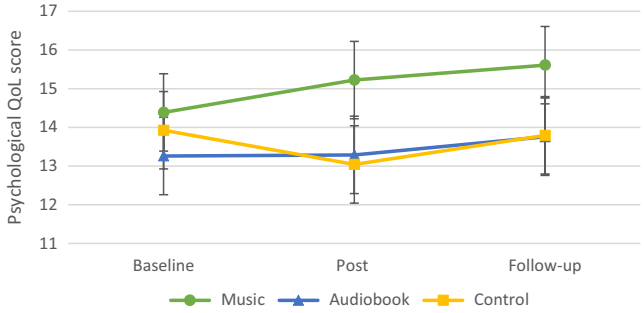

FIGURE 4 Psychological quality of life (pQoL) scores and 95% CIs at all time-points in all three groups. There was a significantly different change between the groups, with the scores of the music group improving more than the other groups. Higher scores in the WHOQOL-BREF questionnaire indicate better quality of life

previous study has included an audiobook control group to assess the effect of music compared with another audio stimulation (Harmat et al., 2008). The present study adds to the existing evidence based on the effect of music as a sleep aid by using a rigorous design and thereby minimizing risk of bias.

Another factor that may explain the lack of clear results is the fact that about 55% of the participants in the present study had no DIS, but suffered from DMS and EMA. Because the music intervention is used in the sleep initiation phase, it could be that it would prove more efficient for persons with sleep initiation insomnia. Our analyses suggest that this could be the case, as there was a trend towards significant improvements in sleep initiation difficulties in the music group when looking separately at the insomnia symptoms. No other studies have specified the effect of the music on the different insomnia symptoms, and more research is needed to investigate this finding. In the present study, we included objective measures of sleep using actigraphy and PSG, and baseline measures revealed few severe disturbances of these sleep aspects in our sample. Mean WASO resembled the values found in insomnia populations, whereas TST and SE seemed less affected (Baglioni et al., 2014). The insomnia diagnosis is based on a subjective complaint of poor sleep and the relation to standard objective measures of sleep is not simple. The main analyses in our study showed no significant changes in any of the objective sleep measures. Only one other study has reported the effect of music on PSG measures in adults with sleep problems. In a study from 2012, Chang et al. (2012) reported decreased N2 sleep and increased REM sleep in participants with sleep problems (PSQI > 5) listening to music compared with matched controls. The study used a very different design from ours as it was conducted in a sleep laboratory for four consecutive days, and again the participants were not assessed for insomnia disorder. Data on the effect of bedtime music on sleep architecture are still very scarce and should be investigated further.

Daytime dysfunction is a substantial problem for individuals with persistent insomnia and, importantly, we found a significant positive effect of the music on pQoL. The pQoL reflects aspects of bodily self-image, negative and positive feelings, self-esteem and personal beliefs. This result is consistent with other studies on music and sleep that have reported improvements in mood and well-being

(Harmat et al., 2008; Jespersen & Vuust, 2012). The effect of music on well-being and quality of life is important as daytime impairment is often the main concern of persons with insomnia and the reason for seeking treatment (Morin & Benca, 2012). It is therefore crucial that interventions for insomnia improve not only sleep, but also associated daytime distress.

Still, the effect size of the pQoL improvement is small and the clinical significance of this change is uncertain. Similarly, the effect of the music intervention on insomnia severity was not clear and, even though the significant within-group effect size was medium to large, the clinical significance of the improvement seems modest. The results suggest that a low-intensity intervention like music is not efficient as a standalone treatment for insomnia disorder. As previously mentioned, music may be better suited as a preventive intervention for those with subclinical insomnia, and another option is to use music as an adjuvant to other treatments. CBT-I is recommended as first-line treatment for insomnia disorder, and bedtime music could be used with CBT-I as a strategy to reduce hyperarousal and distract from worries or rumination. From a different perspective, bedtime music listening may be considered in conflict with standard CBT-I advice on stimulus control designed to reinforce the connection between sleep and bed by using the bed for no other activities than sleep (Morin & Benca, 2012). One study has assessed the effect of bedtime music listening as adjuvant to CBT-I, and reports a significantly larger effect of the combined intervention compared with CBT-I alone in elderly persons with insomnia (Mottaghi, Kamkar, & Mardpoor, 2015). However, more high-quality studies are needed to clarify the effect of music as adjuvant to CBT-I.

The findings of this study should be interpreted with caution. First, the study included a relatively small sample size and it may not be sufficiently powered to detect small effects of a music intervention on persistent insomnia. We did power calculations in advance, but because there are few RCTs in this field and no earlier studies included participants with insomnia disorder, they may not have been based on realistic effect size estimates. Furthermore, the power calculations were done on the subjective sleep quality measures, which can differ notoriously from objective measures of sleep. Post hoc power analyses did indicate that with the present results a sample size of 66 participants would be needed to ensure 80% power. Secondly, we could not blind participants to their allocated intervention, as they would clearly know if they listened to music, audiobooks or nothing at all. We did, however, blind the outcome assessors to minimize the risk of bias. Finally, it has been suggested that insomnia is a heterogeneous disorder (Benjamins et al., 2016), and different insomnia subgroups may respond differently to a music intervention. We excluded several participants with co-morbidities, and the sample may not be fully representative to the general population adopting music as self-help strategy. Future studies could benefit from addressing insomnia subtypes more directly.

In conclusion, the present study shows an effect of bedtime music on perceived sleep improvement and quality of life, but no clear effect on insomnia severity. Future studies should focus on insomnia subgroups and test music as an adjuvant to standard treatment or a preventive strategy for persons with transient insomnia to avoid it becoming chronic.

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CONFLICT OF INTERESTS

No conflicts of interest declared.

AUTHOR CONTRIBUTIONS

This study was designed by KVJ, PV, MK and EVS. KVJ and MO performed assessment and data collection. KVJ and EVS analysed the data. KVJ drafted the manuscript. MO, MK, EVS and PV revised the manuscript.

ORCID

Kira Vibe Jespersen https://orcid.org/0000-0002-7183-3849

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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