Music for Sleep: Music-based interventions to promote sleep in adults

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Music carries through…

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Chapter 1: Systematic Review

Music for sleep: Overview of reviews of music-based interventions for sleep in adults

Prepared in accordance with the author requirements for Sleep Medicine Reviews
https://www.elsevier.com/journals/sleep-medicine-reviews/1087-0792/guide-for-authors

1.1. Abstract

Background: Poor sleep can be experienced by people of all ages but is more common in older adults, hospitalised individuals, and neurological or psychiatric presentations.

Aim: The aim of this overview of reviews was to describe the characteristics and effects of music-based interventions for sleep in adults, as reported in published systematic reviews.

Methods: Seven electronic databases: Ovid (MEDLINE), Ovid (Embase), CINAHL (EBSCO host), PsycINFO (EBSCO host), Cochrane database of systematic review, Epistemonikos.org, and Web of Science core collection were searched from inception to 18 May 2023 to identify systematic reviews focussing on music-based interventions with sleep outcomes. A narrative synthesis was undertaken with risk of bias assessed using the AMSTAR-2. The review protocol was registered on PROSPERO (CRD42021240327).

Results: Of the 1071 records identified through database searches, 16 met inclusion criteria, with slight overall overlap of the primary studies within the included reviews. The reporting of intervention characteristics was variable but there is some indication of individually tailored regular music listening of around 30 minutes at bedtime being supportive of positive effects. Five of the six meta-analytic reviews using PSQI, and all meta-analyses of sleep quality, reported medium-to-large effects, with considerable heterogeneity. Significant reduction in insomnia severity and anxiety were also reported but the effects for sleep onset latency, sleep efficiency and depression were mixed.

Conclusions: Music-based interventions appear promising in improving sleep quality. Future studies should focus on understanding their effects on other sleep outcomes, and effects associated with intervention characteristics in different populations and settings.

Keywords: adults; insomnia; interventions; music; sleep; umbrella review; systematic review of reviews

1.2. Introduction

Sleep difficulties

Sleep is essential to human health and wellbeing with respect to physical, cognitive and psychological functioning. During sleep, the body optimises energy utilisation for different bodily functions such as tissue repair, regulation of hormones and the immune system with poor sleep associated with an increased risk of chronic illness, such as cardiovascular disease, diabetes and cancer (Barone & Krieger, 2015). It is well established that sleep facilitates learning and memory consolidation (Chambers, 2017) and supports mental wellbeing.

The prevalence of sleep difficulties varies greatly based on the definition used. Insomnia disorder encompasses a difficulty in initiating and/or maintaining sleep, and early-morning awakening for at least three nights per week for at least three months with an impact on daytime functioning (American Psychiatric Association, 2013). The definition of poor sleep, on the other hand, is broader including one or more insomnia symptoms. It is estimated that in the general adult population approximately one in three experience some insomnia symptoms such as difficulty initiating or maintaining sleep, with insomnia disorder prevalence estimated at 6-10% (Morin & Jarrin, 2022). Insomnia prevalence rates are reported to be higher in the elderly (Endomba et al., 2023), individuals with mild traumatic brain injury Montgomery et al., 2022) and clinical populations such as stroke (Baylan et al., 2020).

Disturbed sleep is associated with an increased risk of depression in older adults (Bao et al., 2017), with a recent meta-analysis indicating that insomnia is a significant predictor for the onset of several mental disorders, including depression, anxiety and psychosis (Hertenstein et al., 2019). Given that poor sleep and insomnia can negatively impact quality of life (Ishak et al., 2012) and everyday functioning with a high reported economic burden (Morin & Jarrin, 2022), interventions to address sleep difficulties are needed.

Insomnia can be treated using pharmacological and/or non-pharmacological approaches. A recent meta-analysis of behavioural and psychological treatments for insomnia disorder identified a number of behavioural approaches to treating insomnia, including cognitive-behavioral therapy for insomnia (CBT-I), brief behavioural therapies for insomnia (BBTI), stimulus control, sleep restriction therapy, relaxation training, sleep hygiene, biofeedback, paradoxical intention, intensive sleep retraining, and mindfulness (Edinger et al., 2021). The

review identified a large evidence base supportive of non-pharmacological treatment approaches, particularly CBT-I, with a large effect on reduction in insomnia severity, medium to large effect on sleep quality and fatigue, with reduction in sleep onset latency and time spent awake after sleep onset.

Music as a sleep aid

There has been an increased interest in the use of music as a sleep aid in recent years but this approach was not included in the Edinger et al. (2021) review. Trahan et al. (2018) found that 62% of the general population surveyed reported using music to help them sleep, with greater use in younger individuals. Their qualitative analysis indicated that music was perceived to induce a physical/mental state conducive to sleep, support sleep routine, stimulate sleep, and block out internal and external distractions. Other studies and reviews have proposed that music promotes sleep through inducing relaxation and enjoyment (Dickson & Schubert, 2019), alteration of physiological responses such as heart rate and blood pressure (Lai & Li, 2011), and improvement in poor bedtime habits linked to ruminative tendencies and hyperarousal (Dickson & Schubert, 2019). Music listening activates the limbic system (Reybrouck et al., 2021) thus it is not surprising that studies have reported reduction in cortisol levels (Lai & Li, 2011), anxiety and depression (Zhang et al., 2012) following music-based interventions, with positive effects on pain management (Richard-Lalonde et al., 2020).

Rationale for current review

Two recent literature reviews have examined the impact of music-based interventions on sleep quality, reporting positive outcomes of large effect (Dickson & Schubert, 2020; Pan & Pan, 2021). A number of systematic reviews and meta-analyses with sleep outcomes have recently been published focusing on randomised controlled trials or multiple study designs of different music interventions such as music listening (Jespersen et al., 2022) and five-element music therapy (Yang et al., 2021); or on different populations such as older adults (Wang et al., 2021) or individuals with dementia (Mu et al., 2022). An umbrella review of the effectiveness of music-based interventions in intensive care units (Chen et al., 2021a) included some studies with sleep outcomes, however no umbrella review has examined the characteristics and effectiveness of music-based interventions for sleep in adult more broadly.

This review aims to synthesise evidence from existing systematic reviews focused on music-based interventions for sleep, to better understand the characteristics of music-based sleep interventions in adults, and whether the current evidence is supportive of sleep improvement through music-based interventions.

1.3. Methods

Protocol and registration

The protocol (Appendix 1.1) for this umbrella review, hereafter referred to as overview of reviews, was registered with PROSPERO (International Prospective Register of Systematic Reviews (CRD42023404788). The review is reported according to the PRIOR statement, a reporting guideline for overviews of reviews of healthcare interventions (Gates et al., 2022).

Eligibility criteria

Inclusion and exclusion criteria were established using the PICOS (population, intervention, comparison, outcome, study type) framework (Richardson et al., 1995) as follows:

Population: adults, aged 18 or over, with or without a diagnosed sleep disorder. Reviews of paediatric populations were excluded. For reviews including studies of both children and adults, only findings related to adults were included.

Interventions: music-based interventions where the primary intervention component comprised of active or passive approaches utilising music such as music listening, music therapy, instrument playing or singing. Reviews of non-music based auditory stimulation (e.g. white noise) were excluded. No restrictions were placed on minimum intervention dose, duration, delivery method (e.g. individual, group, in-person, online), intervention setting, geographic location or person delivering the intervention (e.g. music therapist, researcher, healthcare professional, carer).

Comparators: any type of comparator such as treatment as usual, active psychological or pharmacological interventions, passive interventions such as waitlist control, no intervention.

Outcomes: the primary outcomes were changes in subjective/objective sleep characteristics and/or insomnia symptoms e.g. sleep quality/sleep time/onset latency, measured using sleep diaries, standardised questionnaires or actigraphy. Secondary outcomes were descriptions of

psychological outcome variables (e.g. change in depressive symptoms) but no conclusions were drawn based on these. Other outcome variables such as changes in physiological parameters (e.g. heart rate) were excluded. No restrictions were placed on the measures of effect reported in the included reviews.

*Study type: s*ystematic reviews of music-based interventions with or without meta-analysis published in scientific journals with explicit focus on sleep outcomes. Where reviews included both relevant and non-relevant studies (e.g. no sleep outcome), only data from the relevant studies were included. For updates of previously published reviews, only the most recent version was included to avoid double counting studies. Reviews focused on pharmacological, non-pharmacological or psychological interventions for sleep that did not involve music as their primary focus were excluded. Reviews of qualitative studies, reviews included in theses, book chapters, and conference proceedings were excluded. Due to resources available for translation, reviews published in language other than English were excluded.

Changes to the registered protocol: No changes to the protocol were made but systematic review definition was refined following registration, to improve transparency of review inclusion and exclusion. Cochrane's definition, which defines systematic review as a "a clearly stated set of objectives with pre-defined eligibility criteria for studies; an explicit, reproducible methodology; a systematic search that attempts to identify all studies that would meet the eligibility criteria; an assessment of the validity of the findings of the included studies, for example through the assessment of risk of bias; and a systematic presentation, and synthesis, of the characteristics and findings of the included studies" was chosen (Higgins & Green, 2011). Where, additional clarification was required, guidance from Krnic Martinic et al. (2019) review of systematic review definitions was used.

Search strategy

Seven electronic databases were searched from inception to 18 May 2023: Ovid (MEDLINE), Ovid (Embase), CINAHL (EBSCO host), PsycINFO (EBSCO host), Cochrane database of systematic review, Epistemonikos.org, Web of Science core collection. Clinical trial registries were not searched due to focus being on systematic reviews. A search strategy was developed in collaboration with a librarian using MESH (medical subject headings) and key word terms related to "music" and "sleep" alongside validated SIGN (Scottish Intercollegiate Guidelines Network) systematic review filters. These were combined with boolean operators OR or AND.

The search strategy for Ovid (Medline) is presented in Appendix 1.2, which was adapted to the other databases. The sensitivity of the search strategy was piloted in two databases with two relevant reviews (Jespersen et al., 2022; Mu et al., 2022).

Selection process

Records from the database searches were imported into Covidence (www.covidence.org) and duplicates removed through automatic and manual deduplication. Two reviewers independently screened titles and abstracts, followed by full-text screening against inclusion criteria. Discrepancies were resolved through discussion and a third arbitrator consulted where needed. Interrater reliability was calculated using Cohen's Kappa (κ) (Cohen, 1960).

Data extraction

Data extraction was completed by one reviewer using a data extraction template piloted and implemented in Covidence. The following types of data were extracted; publication details (e.g. authors, year); review type and focus (e.g. meta-analysis, review aims); included study characteristics (e.g. number of included studies; study designs); participant characteristics (e.g. number of participants, population type); music-based intervention characteristics (e.g. type, dose, duration); outcome measures (e.g. instruments used), intervention effects and key findings, comorbidity (e.g. depression) where reported. Relevant items from the Robb, Burns & Carpenter (2011) reporting guideline for music-based Interventions were used to guide data extraction of intervention characteristics alongside a bottom-up process for other relevant categories.

For meta-analytic reviews, data on standardised mean difference (SMD) or mean difference (MD) effect estimates of Hedge's g with 95% confidence intervals and heterogeneity statistics (I^2) were extracted. Effect sizes were classed using Cohen (1998) classification as small (0.2), medium (0.5), and large (0.8).

Risk of bias

Risk of bias in the included studies was assessed using the AMSTAR 2 (Assessment of Multiple Systematic Reviews) tool (Shea et al., 2017). AMSTAR 2 consists of 16-items, with items scored as yes, partial yes or no. Seven of the items are deemed critical (2, 4, 7, 9, 11, 13, 15), but these can be altered by the authors. Item 7 (full citation for excluded studies) was not

considered critical in the current review. This criteria was not included in the PRISMA reporting guidelines until the 2020 revision. The remaining six items therefore contributed towards the overall quality classification: high (none/one non-critical weakness), moderate (>1 non-critical weakness), low (1 critical weakness) or critically low (>1 critical weakness). All ratings were performed by one reviewer with a sample of 25% independently rated by a second reviewer.

Data synthesis

Overlap across the original studies included in the relevant systematic reviews and meta-analyses was calculated using the corrected covered area (CCA), which assesses the degree of overlap between studies through the creation of a citation matrix (Pieper et al., 2014). The GROOVE tool (Perez-Bracchiglione et al., 2022) implemented in Excel (http://doi.org/10.17605/OSF.IO/U2MS4) was used to calculate CCA. Overlap was defined as slight (<5%), moderate (≥5% to < 10%), high (≥10% to < 15%), or very high (≥15%).

Due to resource limitations, a re-analysis/meta-analysis of primary data to avoid overlap was not feasible, hence a narrative synthesis approach was undertaken. Sample and intervention characteristics of the included reviews were synthesised in tabular and narrative formats. For meta-analyses, summary of standardised effect sizes (MD or SMD) with confidence intervals, Hedges *g* and heterogeneity estimates (I^2) were summarised as originally reported in each review.

Tabular and narrative synthesis of risk of bias in the included reviews was undertaken.

1.4. Results

The Prisma flow chart is presented in Figure 1.1. The database searches identified 1071 records. A total of 364 duplicates were removed using Covidence's automated deduplication tool with a further 24 identified manually. Following removal of duplicates, 683 titles and abstracts were screened with 651 excluded. Of the 32 studies included in full-text screening, 16 met criteria for inclusion. A detailed list of excluded full texts, with reasons, is provided in Appendix 1.3. The included reviews comprised 101 original articles.

The inter-rater reliability of both title and abstract screening (κ= 0.81), and full-text screening (κ= 0.94) was high.

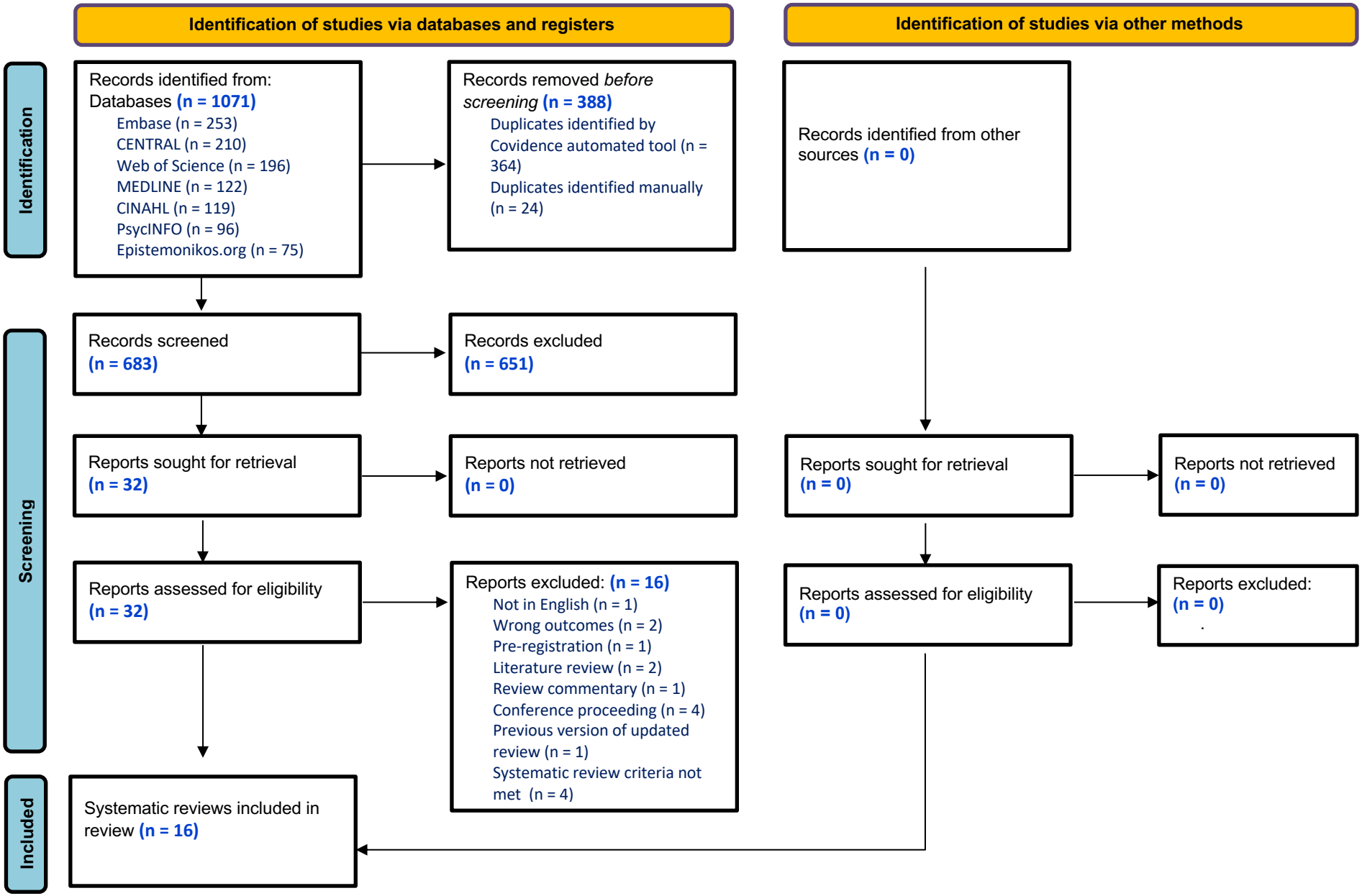

Figure 1.1. PRISMA flow diagram

Characteristics of the included reviews are presented in Table 1.1. The reviews were published between 2009 and 2023, with 81% (n=13/16) published since 2020. Twelve were systematic reviews with meta-analysis (MA). Of these, nine were MAs of RCTs, including one network meta-analysis of RCTs and three included multiple study designs. The remaining were systematic reviews of RCTs (n=2) or multiple study designs (n=2).

The number of relevant studies within reviews ranged from 1-22, with a total reported sample size of 10,019, not accounting for study overlap. It was not possible to obtain a breakdown of age and gender of participants from the data reported. The number of the participants within individual studies ranged from 1-906 with a narrower range for RCTs (10-259). The reviews spanned several populations including adults with (deNiet et al., 2009; Feng et al., 2018; Gassner et al., 2022; Jespersen et al., 2022; Wang et al., 2014) or without (Tang et al., 2022) sleep complaints/insomnia, older adults (Chen et al., 2021; Petrovsky et al., 2021; Wang et al., 2021), patients in acute hospital settings (Chen et al., 2022; de Niet et al., 2009; Fang et al., 2023; Kakar et al., 2021; Tang et al., 2022; Wang et al., 2014), singers and wind instrument players (van der Weijden et al., 2020), individuals with COPD (Huang et al., 2021), cancer (Yang et al., 2021) and dementia (Mu et al., 2022).

Geographically, the reviews included studies from Asia (China, Hong Kong, India, Iran, Israel, Japan, Korea, Singapore, South Korea, Taiwan), Australia, Europe (Austria, Cyprus, Denmark, Finland, France, Germany, Hungary, Italy, The Netherlands, Switzerland, Turkey, UK) and North America (USA). No studies were conducted in South America or Africa. Eight reviews applied no language restriction, six included studies published in more than one language, and two included studies published in English.

The Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989) was the most used sleep outcome (n=15/16), followed by the Richards-Campbell Sleep Questionnaire (RCSQ; Richards, O'Sullivan, Phillips, 2000), (n=6/16). Only three studies reported mood outcomes alongside sleep outcomes.

Table 1.1. Review characteristics

Author, year country	Type	Study designs	Language	Data bases	Studies[#] (overall)	MA [#]	Population	Sample n[#] (Overall)	Study size[#] x̄, range	Countries[#]	Outcomes		Risk of Bias	
											Sleep	Mood	Tool	AMSTAR 2 rating
Reviews with meta-analyses including RCTs only														
Chen, 2022 **China**	MA	RCT	English; Chinese	12	11 (29)	7	ICU patients	884 (2198) I: 439 C: 445	range 17-219	Australia; China; Cyprus; Denmark; Korea; USA	PSQI; RCSQ VSH; NRS; AIS; PSG	NR[#]	CRoB	Low
Chen, 2021 **Taiwan**	MA	RCT	English; Chinese	5	5	5	Adults with disturbed sleep aged ≥60	288 I: 142 C:146	range 42-64	China; Singapore; Hong Kong; Taiwan	PSQI	GDS	CRoB	Critically low
deNiet, 2009 **Netherlands**	MA	RCT	English; Dutch; French; German	5	5	5	Sleep complaints excluding neurological conditions	308 I: 170 C: 138	x̄ =69, range 28-96.	Austria; Hungary; Taiwan; USA	PSQI; RCSQ		Delphi list for RCTs	Critically low
Fang, 2023 **Taiwan**	NMA	RCT	No restriction	6	5 (24)	5	Critical care	313 (1507) I: 138 C: 175	range 28 - 93	China; India; Iran; South Korea; Taiwan	VSH; RCSQ		CRoB; GRADE CINeMA	Mode-rate
Jespersen, 2022 **Denmark**	MA	RCT	No restriction	12	13	10	Adults with sleep complaints	1094 I: 603 C: 491	range 30-159	Austria; China; Denmark; Hungary; Italy; Iran; Taiwan; Singapore	PSQI; ISI	DASS-21; HADS	CRoB; GRADE	High
Kakar, 2021 **Netherlands**	MA	RCT	English + posthoc Persian	4	5	5	Critically ill ICU, CCU	259 I: NR C: NR	range 28-259	Denmark; Iran; USA; Taiwan; South Korea	PSQI; RCSQ; VSH		CRoB; GRADE	Low

Author, year country	Type	Study designs	Language	Data bases	Studies[#] (overall)	MA[#]	Population	Sample n[#] (Overall)	Study size[#] x̄, range	Countries[#]	Outcomes		Risk of Bias	
											Sleep	Mood	Tool	AMSTAR 2 rating
Tang, 2022 **Malaysia**	MA	RCT	No restriction	5	22	6	No sleep disorder	1514 I: 813 C: 701	range 10-219	Australia; China; UK; Denmark; Finland; Italy; Iran; Taiwan; Turkey; USA; Singapore; South Korea	PSQI; RCSQ VSH; PSG		CRoB; GRADE	Low
Yang, 2021 **China**	MA	RCT	No restriction	8	4 (22)	4	Cancer	371 (2053) I: 203 C: 168	range 58-120	China	PSQI	NR[#]	CRoB	Low
Wang, 2014 **China**	MA	RCT	No restriction	3	10	10	Sleep disorders (acute post-operative hospital; chronic)	557 I: NR C: NR	range 28-96	Austria; Italy; USA; Taiwan; Hungary; Hong Kong; South Korea	PSQI; RCSQ; VSH; VAS		Moher 1998 checklist	Critically low
Reviews with meta-analysis including multiple study designs														
Feng, 2018 **China**	NMA	RCT; CCT; RCO	No restriction	4	20	20	Primary insomnia	1339 I: 684 C: 655	x̄= 67, range 14-145	China; France; Israel; USA; Singapore, Netherlands	PSQI; SE; SOL		PeDRO; CASP	Critically low
Van der Weijden, 2020 **Netherlands**	MA	RCT; CS; OBS	No restriction	3	4 (6)	3	Singers; wind instrument players	1269 (2508) I: 671 C: 598	range 26-906	Switzerland; UK; USA;	PSQI; ESS		GRADE; VdW checklist	Critically low
Wang, 2021 **China**	MA	RCT; RCO; NRES; QE	No restriction	5	9	6	Older adults	489 I: 289 C: 200	range 15-100	China; Taiwan Turkey; Singapore; USA	PSQI		CRoB; ROBINS-I	Critically low

Author, year country	Type	Study designs	Language	Data bases	Studies[#] (overall)	MA [#]	Population	Sample n[#] (Overall)	Study size[#] x̄, range	Countries[#]	Outcomes		Risk of Bias	
											Sleep	Mood	Tool	AMSTAR 2 rating
Systematic reviews without meta-analysis of relevant studies														
Gassner, 2022 **Austria**	SR	RCT	English; German; Spanish	4	3 (10)	N/A	Insomnia	249 I: NR C: NR	NR range 57-121	NR	PSQI, ISI, PSG, EEG	PSS; S-STAI	CRoB	Critically low
Huang, 2020 **China**	MA*	RCT	English; Chinese	7	1 (12)	0	medically diagnosed stable COPD	60 (812) I: 30 C: 30	60[#]	China	PSQI		CRoB	Low
Petrovsky, 2021 **USA**	SR	RCT; RCO; QE	English	5	16	N/A	Adults aged ≥50	812 I: 559 C: 253	x̄ = 51 (SD 41), range 20-189	China; Germany; USA, Hong Kong, Taiwan, Singapore, Israel, Korea, Japan	PSQI, EEG actigraphy, SSS, VAS		JBI checklist	Critically low
Mu, 2022 **USA**	SR	RCT; QE; case study	English	9	8	N/A	Dementia	213 I: 120 C: 93)	range 1-59	Germany; Hong Kong; Italy; Japan; USA	PSQI, NPIQ, VAS, ESS, OBS		CRoB; GRADE	Critically low

* relevant studies not included in the meta-analysis

in relevant studies. Overall denotes the total number of studies/participants including relevant and non-relevant studies

AIS, Athens Insomnia Scale; AMSTAR 2, A MeaSurement Tool to Assess systematic Reviews version 2; CASP, Critical Appraisal Skills Programme checklist; CCU, cardiac care unit; CRoB; Cochrane risk of bias tool, CINeMA, Confidence in Network Meta-Analysis tool; C, control; CCT, Controlled clinical trials; CCU, Cardiac Care Unit; CS, cross-sectional studies; DASS-21, The Depression, Anxiety and Stress Scale - 21 Items; EEG, Electroencephalography; ESS, Epworth sleepiness scale; GDS, Geriatric depression scale; GRADE, Grading of Recommendations, Assessment, Development and Evaluation; HADS, Hospital Anxiety and Depression Rating Scale; I, intervention; ICU, intensive care unit; ISI, Insomnia Severity Index; JBI, Joanna Briggs Institute checklist for randomised controlled trials and quasi-experimental trials; MA, meta-analysis; NMA, network meta-analysis; NRES, non-randomised experimental studies; NRS, numerical rating scale (NRS); NPIQ, Neuropsychiatric inventory questionnaire; OBS, observational studies/scale; PeDRO, Physiotherapy Evidence Database (PEDro) scale; PSQI, Pittsburgh Sleep Quality Index; PSS, Perceived Stress Scale; PSG, polysomnography; RCO, randomised cross-over trials; RCSQ, Richards-Campbell sleep questionnaire; RCT, randomised controlled trials; ROBINS-I, Risk Of Bias In Non-randomized Studies - of Interventions; SE, sleep efficiency; SOL, sleep onset latency; SSS, Sleepiness- Stanford Sleepiness Scale; S-STAI, State Anxiety Inventory; VAS, visual analogue scale; VdW checklist, Van der Weijden checklist; VSH, Verran and Synder-Halpern sleeping scale; QE, quasi-experimental studies

A summary of intervention characteristics is provided in Table 1.2. Most reviews were focused on music listening, either on its own or in combination with another intervention aimed at promoting sleep (e.g. relaxation instruction, hand massage or sleep hygiene). Reviews included studies using instrument playing or singing (Chen et al., 2021; Huang et al., 2021; Petrovsky et al., 2021; Tang et al., 2022; van der Weijden et al., 2020; Wang et al., 2021). The comparators included music-based interventions, non-music interventions, treatment as usual, waitlist and no controls.

The interventions were delivered in a range of different settings including home, hospital and rehabilitation units, nursing homes, community activity centres, university and sleep laboratories. Some studies/reviews did not report when music was listened to. In those that did, music tended to be delivered at bedtime through music players or speakers. A few studies also provided live music or music making sessions.

The level of detail relating to intervention delivery varied. Some reviews did not report details of music selection or type of music listened to. Reviews often included of studies of both participant and researcher selected music without always summarising their effects separately. A review of five-element music therapy reported that music selection was done by medical staff based on the organ affected by cancer (Yang et al., 2021). In RCTs, music tended to be selected from a pre-set list. The type of music listened to included a range of different genres with classical, instrumental, jazz, soothing music or music low in tempo, most commonly used. De Niet et al. (2009) review included music specifically composed for sleep.

Listening session duration ranged from 5-420 minutes across all reviews but was narrower (10-60 minutes) in reviews including only RCTs with music typically listened to at least once a day. The duration of the intervention varied greatly from one day to 12 months but was no longer than 6 months in reviews of RCTs, and no longer than 3 months in meta-analytic reviews of RCTs.

Only a handful of reviews reported details of who was responsible for intervention delivery.

Table 1.2 Summary of music intervention characteristics

Author, year	Intervention type	Comparator	Setting	Session length	Frequency	Duration	Music selection	Music genre	Delivery (person)	Delivery mode
Reviews with meta-analyses including RCTs only										
Chen 2022	ML	NR for relevant studies	hospital (CCU, MICU, CSICU, ICU)	10-52 mins	1-2 times/ day	1-7 days	patient; researcher	classical; instrumental; soothing or soft music; jazz, country and western, new age, easy-listening; nature sounds; contemporary; delta wave control music; deep sad, active and cheerful, relax quiet, beautiful lyric, exciting passion; live harp music	NR	via mp3/CD player, loud speaker, head/ear phones or live
Chen 2021	ML; ML + sleep hygiene; rhythm-centered music making	NMI, NC	community	30 - 60 mins	NR	2 days to 3 mths	NR	sedative music; soft + slow music, slow + flowing music; Western or Chinese classic, meditative, orchestra, harp, synthesizer, piano, jazz, and new age music; playing of rhythmic music	NR	NR
deNiet 2009	ML; ML with relaxation instruction/ exercise	NMI, TAU, NC	hospital (n=3); community (n=2)	20-45 minutes	daily or at least once a day	2 days to 3 wks	patient from a list; standardized music composed for sleep promotion (n=1)	traditional folk-music (Chinese orchestra), instrumental new age (synthesizer), classical and modern instrumental soothing music (harp, piano, orchestra), vocal	NR	at bedtime, in the afternoon ; early evening; no time specified

								soothing music		
Author, year	Intervention type	Comparator	Setting	Session length	Frequency	Duration	Music selection	Music genre	Delivery (person)	Delivery mode
Fang 2023	ML	NMI, OMI; TAU	hospital (CCU; CSICU; ICU; MICU)	20-53 mins	1-2 times/day	1-2 nights	NR	Non-commercial music, nature sounds; NR	NR	NR
Jespersen 2022	ML (pre-recorded); ML and relaxation instructions (n=2); ML + weekly live music session (n=1)	NMI, OMI, WL, TAU	home (n=11); sleep laboratory (n=1); inpatient rehabilitation; low-back pain and post-stroke rehabilitation (n=2)	Approx. 45 mins	once a day	3-90 days	participant own music (n=1) or from 4 or 6 researcher-playlists (n=4); database with 169 pieces of slow music in various genres (n=1); researcher (n=7)	Western and Chinese classical music, Buddhist songs, new age, lullabies, Persian traditional music, Chinese five Elements tone music, eclectic, ambient, popular oldies and jazz	NR	at bedtime, time of the day not specified (n=4)
Kakar 2021	ML	NMI; TAU	Hospital: ICU (n=2), CCU (n=2), Ward (n=1)	30-53 mins	1-3 times/day	30-135 mins	participant from five audiotapes (n=1); researcher (n=4)	soothing, sleep inducing or sedating (60%)	NR	Head/ear phones; loudspeaker; CD player
Tang 2022	ML (n=19); ML of live music (piano and violin, n=2); ML of live singing (n=1)	NMI, OMI; TAU	sleep centre/ laboratory; home; ICU; CCU; hospital; NR	12-60 mins	2 times/ day – once a wk	1day – 6 weeks / 1-42 sessions	researcher; pre-recorded standardised playlist (n=19); live music (n=3)	Western classical period (60-80 beats/ min). Sedative music composed for the study; a choice from: lullabies, modern jazz, electronic synthesizer, guitar, harp and cello; classical piano music	NR	Music player (MP3/CD/ cassette player); head-phone or speaker

Author, year	Intervention type	Comparator	Setting	Session length	Frequency	Duration	Music selection	Music genre	Delivery (person)	Delivery mode
Yang 2021	Five element music therapy	NMI, OMI; TAU	NR	range 20-60 mins	range 1-2/ day	3 days to 3 mths	Medical staff	Selected based on affected organ as per five-element music therapy protocol	NR	Quiet ward; support for comfortable position
Wang 2014	ML	NR	hospital (CCU, post CABG/ anorectal operation/ coronary angiography); women's shelter; rehabilitation; university; community	NR	NR	range: 1 day to 4 wks	NR	NR	NR	NR
Reviews with meta-analysis including multiple study designs										
Feng 2018	ML +/- acupuncture or language induction); music-assisted relaxation; music with exercise	NMI, OMI; TAU	hospital; community	30-60 mins	daily to 1 /wk	up to 12 mths	participant; researcher	personalised, Chinese Guqin music, five element music, horn music, soothing music, soft, instrumental slow sedative music without lyrics	NR	
Van der Weijden 2020	instrument playing (n=3); singing (n=1)	NMI; WL	community	lessons (NR) + home	at least 5 days /wk	4 mths	NR	NR	NR	Didgeridoo lessons; self practice

				practice (>20min)						
Author, year	Intervention type	Comparator	Setting	Session length	Frequency	Duration	Music selection	Music genre	Delivery (person)	Delivery mode
Wang 2021	ML (n=8); music making (n=1)	NMI, TAU, NC	home; private nursing home; pension agency; community activity centre	30-420 mins	daily to once/wk	1-12 wks	participant; researcher	Western classical, Chinese classical, New Age, Jazz, meditative music, five elements music and the Ussak Maqam music, accompanied by slow and soft melody	researcher, prerecording	active; passive: mostly at bedtime/ night, CD, cassette
Systematic reviews without meta-analysis of relevant studies										
Gassner 2022	ML	NMI, OMI; TAU; WL	home	30 mins	daily	6days - 3 wks	NR	NR	NR	bedtime
Huang 2020	ML combined with singing	NMI, TAU	NR	ML: 15-30 mins, Singing: 5-30 mins	ML: 3 times/ day Singing: 2 times/day	for 6 mths	NR	NR	NR	not specified
Mu 2022	ML; MT; MM; voice-based intervention	NMI	home-based	ML: 20-30 mins MT: 30-45mins MM: 60.5mins Voice: 60 mins	ML: x̄1.6 times/ day – 2 times/ wk MT: 2/wk - total of 30 sessions MM: 4 times/ wk Voice: 1 times /wk	ML: 4-8wks + one study 20.25hrs over 36 months MT: 2-16 wks MM: 8wks Voice: 6 mths	participant; dementia daycare directors, activity therapists; music therapist; NR	personalised; Broadway musicals and sing-along medleys (e.g., patriotic music), general or familiar music; rhythmic and melodic instruments; NR	music therapist caregiver researcher; nursing staff; NR	NR; in-person (music therapy)

Author, year	Intervention type	Comparator	Setting	Session length	Frequency	Duration	Music selection	Music genre	Delivery (person)	Delivery mode
Petrovsky 2021	ML (n=11); MT (singing); ML + videos/ hand massage/ percussion music making/ tai chi/ art therapy/ mindfulness awareness practice (n=5)	NMI; WL; TAU; NC	Community, nursing home	ML: 12-45 mins MC: 5 mins-2hrs	ML: daily - twice/wk MC: 2/wk - once/ every 2 wks	ML: 1wk - 3 mths (median 4 wks) MC 1 night - 12 mths	participant (n=3); researcher	relaxing characteristics (i.e., tempo 60-80 beats per minute without accented beats); culturally appropriate music	NR	MP3 or a CD player before going to bed; relaxation instructions

CCU, Cardiac OR Coronary care unit; CABG, Coronary artery bypass grafting; CSICU, Cardiac Surgical ICU; ICU, Intensive Care Unit; MC, multi-component interventions; MICU, Medical Intensive Care Unit; MT, music therapy; MM, music with movement; ML, music listening; MT, music therapy; NC, no control; NMI, non-music intervention; NR, not reported; OMI, other music-based intervention; WL, waitlist; TAU, treatment as usual

Assessment of overlap revealed slight overall overlap between the included studies (CCA=3.56%) with 27 of the primary studies included in more than one review.

Among reviews focused on older adults, very high overlap (CCA= 21.43%) was present. Therefore, the review consisting of only RCTs (Chen et al., 2021) should be used to interpret findings, given that this is similar in recency to the other two reviews both of which include mixed study designs, with one including no meta-analysis (Petrovsky et al., 2021).

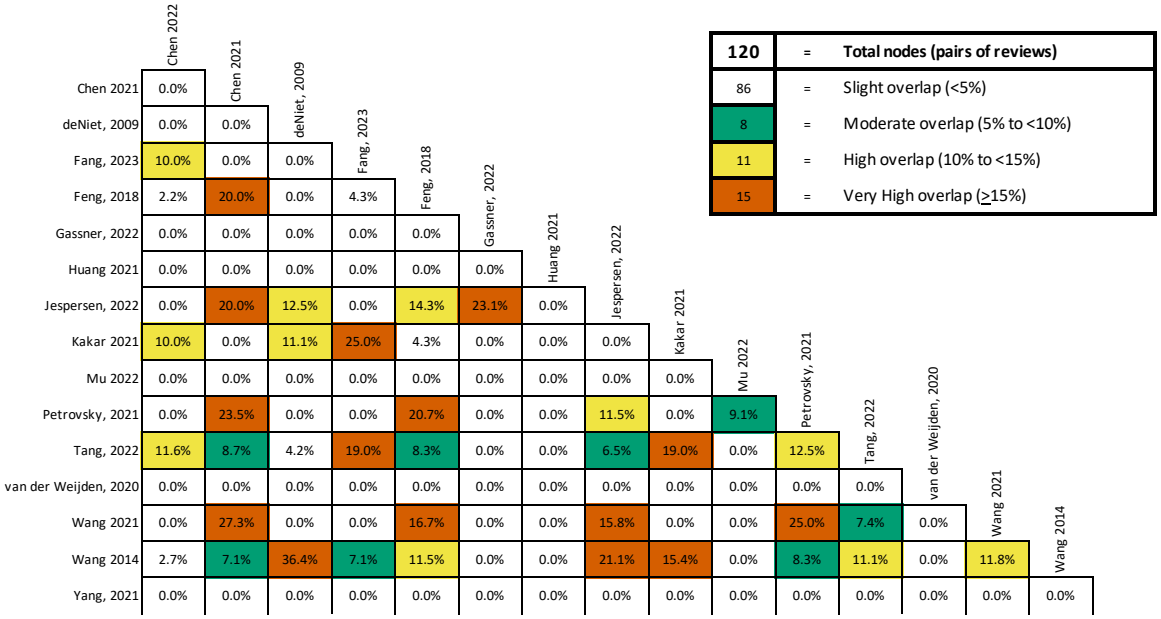

Figure 1.1. Overlap matrix

Effects of interventions

Sleep outcome effect sizes as reported in the meta-analytic reviews are summarized in Figures 1.3-1.6. No statistical synthesis was undertaken due to the degree of primary study overlap.

All reviews assessing sleep quality using the PSQI found a medium to large effect of music-based interventions on sleep quality compared to control interventions (Figure 1.3). Positive effects of medium to large effect were also seen on overall sleep quality (Figure 1.4).

Two of the reviews assessing sleep onset latency found medium effects of music listening on sleep onset latency, whereas one review reported non-significant effects (Figure 1.5).

The findings for sleep efficiency were mixed with two reviews reporting no effect and one study reporting a reduction in sleep efficiency of a large effect (Figure 1.6).

Author, year	Population	Number of studies	n (Intervention/ Control)	Model	Value (95% CI)	p-value	I^2(%)	AMSTAR 2
Chen, 2021	Older adults	5	142/ 146	RE	−1.96 (−3.23 to −0.69)	0.002	67%	Critically low
Feng, 2018	Primary Insomnia	10	269/272	RE (NMA)	0.61 (−1.01 to −0.20)	NR	NR	Critically low
Jespersen, 2022	Adults	10	358/350	RE	−2.79 (−3.86 to −1.72)	NR	81%	High
Tang, 2022	Adults without sleep disorder	6	218/ 206	RE	−0.80 (−2.15 to 0.54)	0.24	87%	Low
Wang, 2021	Older adults	6	191/200	RE	−2.64 (− 3.76, − 1.53)	<0.001	75%	Critically low
Yang, 2021	Cancer	4	168/ 168	RE	−1.73 (−2.34 to −1.12)	<0.001	68%	Low

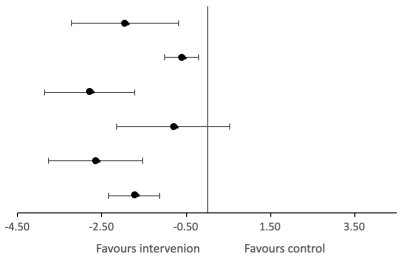

Figure 1.2 Meta-analyses reporting PSQI effect sizes

Author, year	Population	Number of studies	n (Intervention/ Control)	Model	Value (95% CI)	p-value	I^2(%)	AMSTAR 2
Chen, 2022	ICU	7	294/313	RE, FE	−0.93 (−0.49 to −1.38)	<0.001	83%	Low
deNiet, 2009	Sleep complaints	5	170/138	FE	−0.74 (−0.52 to −0.96)	<0.001	36%	Critically low
Fang, 2023	Critical care	3	NR	RE (NMA)	−1.27(−0.28 to −2.27)	NR	NR	Moderate
Feng, 2018	Acute and chronic sleep disorders	NR	NR	RE	−0.54 (−0.25 to −0.82)	<0.001	89%	Critically low
Kakar, 2021	ICU, CCU	4	129/130	RE	−1.21 (−0.5 to −1.91)	0.01	85%	Low
Wang, 2014	Primary insomnia	10	557 overall	RE	−0.63 (−0.34 to −0.92)	<0.001	64%	Critically low

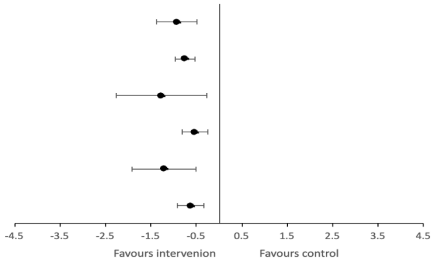

Figure 1.3 Meta-analyses reporting sleep quality effect sizes

Author, year	Population	Number of studies	n (Intervention/ Control)	Model	Value (95% CI)	p-value	I^2(%)	AMSTAR 2
Feng, 2018	Acute and chronic sleep disorders	1	44/14	RE	−0.54 (−0.82 to −0.25)	<0.001	88%	Critically low
Jespersen, 2022	Adults	3	97/100	RE	−0.60 (−0.83 to −0.37)	<0.001	0%	High
Tang, 2022	Adults without sleep disorder	4	177/182	RE	−0.04 (−0.43 to 0.34)	0.82	65%	Low

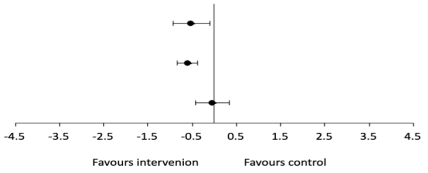

Figure 1.4 Meta-analyses reporting sleep onset latency effect sizes

Author, year	Population	Number of studies	n (Intervention/ Control)	Model	Value (95% CI)	p-value	I^2(%)	AMSTAR 2
Feng, 2018	Acute and chronic sleep disorders	NR	NR	NMA	0.08 (-0.16 to 0.32)	NR	NR	Critically low
Jespersen, 2022	Adults	3	97/100	RE	−0.96 (-1.38 to -0.54)	<0.00001	62%	High
Tang, 2022	Adults without sleep disorder	2	52/57	RE	−0.59 (-3.15 to 1.97)	0.65	97%	Low

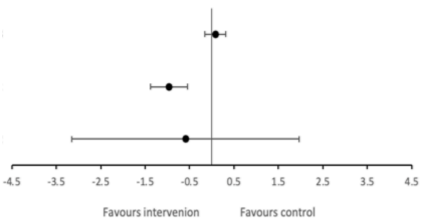

Figure 1.5 Meta-analyses reporting sleep efficiency effect sizes

Subgroup analyses

Insomnia severity

Jespersen et al. (2022) reported a six-point reduction in insomnia severity (-6.96 [95% CI -15.21, 1.28]) following music listening on the Insomnia Severity Index (ISI).

Listening duration and frequency

Two reviews reported data on the impact of listening duration on outcome but test for subgroup difference was not reported. Chen et al. (2022) reported significant effects with both shorter (30~⩽45min SMD 0.94 [95% CI 0.15, 1.73], p= 0.02) and longer (＞45-⩽60min: SMD 0.96 [95% CI 0.45, 1.48], p= 0.0003) listening durations. Tang et al. (2022) reported large effect for durations less than 30 minutes (MD −0.50 [95% CI −0.90, −0.10], p=0.01) but non-significant effect for listening durations of 30 mins to 1hr (MD −0.88 [95% CI −3.00, 1.24], p=0.42). Tang et al. (2022) did not find significant effects (p=0.30) related to listening frequency: once (MD 0.00 [95% CI −2.13, 2.13]) vs. daily (MD −0.95 [−2.74, 0.85]), vs. once weekly (MD −0.90 [95% CI −2.80, 1.00]).

Intervention duration

The findings related to intervention duration were mixed. Jespersen et al. (2022) reported no significant difference (Chi^2= 0.86, df=1, p=0.35) between those listening 8-21 days (MD −2.24 [95% CI −2.90 to −1.58]) compared to those listening 22-90 days (MD −3.36 [95% CI −5.63, −1.10]) with both indicative of improvement, Chen et al. (2021b) found that although listening durations longer than 4 weeks (MD −2.61, [95% CI −4.72, −0.50], p=0.02) had a better outcome than those less than 4 weeks (MD −2.00, [95% CI −3.99, −0.00], p=0.05), this difference was not significant (Chi^2= 0.17, df=1, p=0.68). Tang et al. (2022) also found that durations longer than 3 weeks resulted in significant improvement in outcome (<3wks MD 0.34 [95% CI -1.19, 1.87], p=0.45 vs >3wks MD -2.09 [95% CI -3.84, -0.34], p= 0.02), however test for subgroup difference was not reported.

Music type and selection

Chen et al. (2021b) reported that use of sedative music (MD −2.35 [95% CI −3.59, −1.10), p=0.0002) was superior (Chi^2= 3.09, df=1, p=0.08) to rhythm-centered music (MD −0.25 [95% CI −2.23 to 1.73], p= 0.80).

Chen et al. (2022) found a large significant improvement in outcome with non-patient selected music (SMD 1.14 [95% CI 0.76, 1.53]), and a large non-significant improvement with patient-selected music (SMD 0.74 [95% CI -0.21, 1.68], p<0.00001), with no test for subgroup difference reported. Jespersen et al. (2022) reported no significant differences (Chi^2= 0.71, df=1, p=0.40) between researcher (MD −3.31, [95%CI −5.32, −1.29]) and participant-selected music (MD −2.33 [95%CI −3.37, −1.29] with both suggestive of positive benefits from listening.

Participant characteristics

Wang et al. (2014) reported that the geographical location (USA and Europe vs. Asia) had no significant impact on the outcome (p=0.91) .

Psychological outcomes

Psychological outcomes were poorly reported. Both Chen et al. (2022) and Jespersen et al. (2022) found that music-based interventions for sleep significantly improved anxiety (SMD 1.12 [95% CI 1.55, 0.69], p< .00001; SMD -0.52 [95% CI -0.75, -0.28], p<0.0001, respectively) but only Chen et al. (2022) reported a significant reduction in depression (SMD 1.08 [95% CI 1.62, 0.55], p< .0001; SMD -2.04 [95% CI -4.45, 0.37], p=0.10, respectively). Gassner et al. (2022) systematic review also reported significant reduction in anxiety and stress on the S-STAI and PSS in a prenatal group following bedtime music listening (p<0.05).

Risk-of-bias

A summary of risk of bias in the included reviews is presented in Figure 1.7 with review level summary provided in Appendix 1.4.

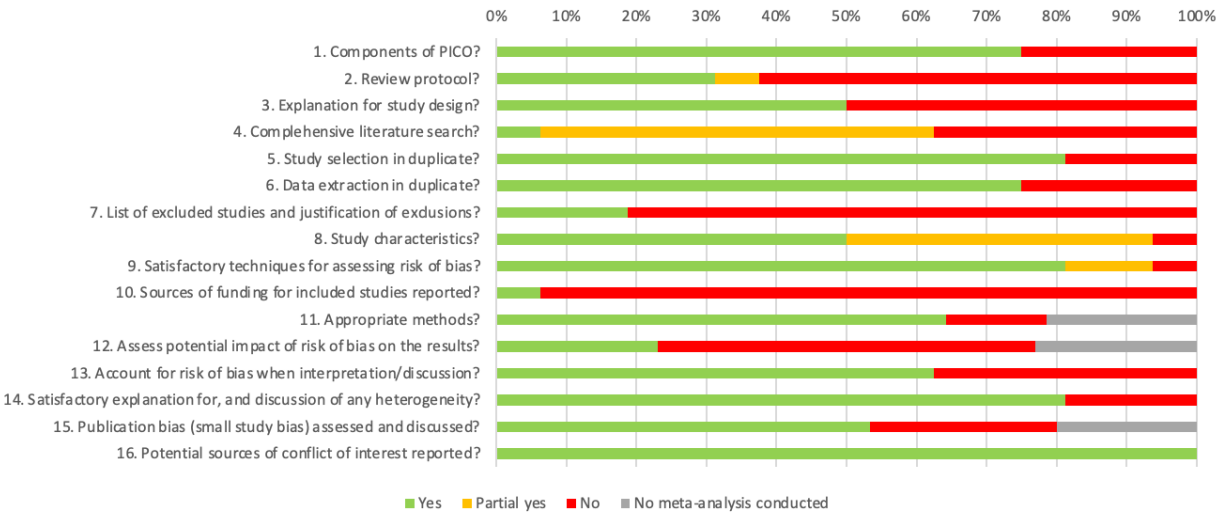

Figure 1.6 AMSTAR 2 risk of bias ratings of included reviews

Only Jespersen et al.'s (2022) Cochrane Review met 'yes' rating for all domains assessed, resulting in an overall 'high' quality rating. One review was of 'moderate' quality (Feng et al., 2023), five of 'low' quality (Chen et al., 2022; Huang et al., 2020; Kakar et al., 2021; Yang et al., 2021; Tang et al., 2021), and the remaining of 'critically low' quality (Table 1.1).

Three quarters had included all components of PICO (item 1) and performed data extraction in duplicate (item 6). One review followed a previously published protocol (Jespersen et al., 2022) and seven had registered their review protocol on PROSPERO, however one them (Feng et al., 2018) did not include a search strategy, resulting in a 'No' rating (item 2). The number of databases searched ranged from to 3 to 12 (mean= 6; item 4). Most 'partial yes' comprehensive literature search ratings were due to non-justification of language restrictions, non-consultation of experts or the grey literature. Less than 20% of reviews included a list of full-texts excluded with reasons for exclusion (item 7), and less than 10% provided sources of funding for the individual studies included in the review (item 10). More than 80% of reviews used satisfactory techniques for assessing risk of bias (item 9) with the majority (n=11) using the Cochrane Risk of Bias Tool (Table 1.1). Chen et al. (2022) included one non-RCT but assessed study quality using the CRoB tool intended for RCTs. Only half of the studies provided adequate detail on included study characteristics (item 8), with 45% providing partial detail.

Risk of bias was accounted for in the interpretation of results by more than 60% of reviews (item 12) but only a quarter assessed the potential impact of the risk of bias on the results

(item 13). By contrast, heterogeneity was relatively well reported (item 14), and all reviews declared potential sources of conflict and funding for the review authors (item 16).

1.5. Discussion

The aim of this overview of reviews was to describe the characteristics of music-based sleep interventions for adults reported in published systematic reviews and meta-analyses, and to assess whether the current evidence base supports the effectiveness of music-based interventions on improving sleep outcomes.

The results provide evidence of increased recent interest towards music-based interventions for sleep with 13 of the 16 included reviews published within the last three years. No studies within the included reviews were published in South America or Africa but Wang et al.'s (2014) analysis indicates that the benefits of music-based interventions on sleep are comparable within studies conducted in the west (USA/Europe) and in Asia.

Sleep outcomes

Sleep quality was the most commonly reported sleep outcome, often assessed using the PSQI and RCSQ, with the latter used in studies conducted in critical care settings. Meta-analytic reviews of sleep quality reported medium to large effects across different populations from older adults to cancer and the critically ill, with only one review by Tang et al. (2022) reporting non-significant effects in adults without sleep disorders. This finding is in line with Pan & Pan (2021) meta-analytic literature review of 21 studies using PSQI, which found a large effect (SMD -1.28), with Dickson & Schubert (2020) literature review reporting an average reduction of −1.15 points on the PSQI with each week for music listening. Both meta-analyses assessing sleep quality in older adults reported large effects, with a larger effect (SMD -2.64) reported in the review containing mixed study designs (Wang et al., 2021) compared to a review of RCTs (SMD -1.96) only (Chen et al., 2021).

Regarding studies in critical care settings, meta-analyses of the included reviews reported large effect sizes of SMD -0.93, -1.21 and -1.27, which are similar to the large effect (SMD 1.55) reported in a very recently published meta-analysis of the effects of music on sleep quality in hospitalised patients (Jespersen et al., 2023).

Only one of the included reviews reported the impact of music listening on insomnia severity with the finding based on only two studies (Jespersen et al., 2022). Similar large reduction in insomnia severity was reported in a meta-analysis of 30 studies assessing CBT-I interventions (Edinger et al., 2021). Future studies should therefore aim to incorporate an assessment of insomnia using a diagnostic tool such as the ISI (Bastien et al., 2001) or the sleep condition indicator (Espie et al., 2014) to support clinical decision making and to enable assessment of changes in diagnostic classification post-intervention to be evaluated.

Only a small number of reviews reported other sleep outcomes with the evidence for sleep onset latency and sleep efficiency being mixed. Reporting of nocturnal awakenings and time spent awake after sleep onset was lacking. The current evidence base is not indicative of reduction in nocturnal awakenings following CBT-I but clinically significant reduction in nocturnal awakenings have been reported following stimulus control and sleep restrictions interventions, with mixed evidence for brief therapies for insomnia (Edinger et al., 2021).

Psychological effects

The psychological effects of music-based interventions for sleep were poorly reported. All reviews with psychological outcomes reported a significant reduction in anxiety following music listening but the evidence for depression was mixed. With regard to the broader music listening and psychological wellbeing literature, a meta-analysis by Harney et al., (2022) reported a large effect of music listening reducing symptoms of anxiety. Recent meta-analytic evidence also indicates that music listening reduces depressive symptoms in adults (Tang, Huang, Zhou & Ye, 2020) with large reported effect size. In older adults, meta-analysis by Dhippayom et al., 2022 reported high certainty of evidence of large effect on depression with listening of preferred music for 60 minutes or longer per week.

Intervention characteristics

The level of detail provided about intervention characteristics was variable with some reviews providing no or limited detail relating to music selection and intervention delivery. Robb et al. (2018) systematic review previously highlighted that less than half of published music intervention studies conducted in healthcare, reported their intervention in adequate detail.

Poor reporting makes the interpretation, comparison of findings across reviews and the generation of recommendations for future studies challenging. Robb et al. (2011) have produced reporting guidance for music intervention to support their reporting, which future studies and reviews could utilise (Robb et al., 2011; Robb et al., 2018).

The intervention duration, frequency, length and type of music listened to varied greatly across reviews, with less variation among reviews of RCTs compared to reviews of mixed study designs. Positive effects were reported with listening durations of around 30 minutes, however subgroup differences were not reported. Dickson et al. (2020) has previously reported that music listening durations of 30 minutes for at least 3 weeks are associated with improved sleep quality. Similarly, Jespersen et al., (2023) found that most studies including hospitalised adults administered music for 30 minutes in the evening with positive effects on sleep quality. There was some indication that sedative music may improve outcome but if was not possible to assess this in detail due to methodological limitations. Analysis of a large number of Spotify playlists for sleep indicate that although music for sleep was often softer, slower, instrumental and without lyrics, some included music was faster, louder and energetic highlighting variation in individual music choices for promoting sleep (Scarratt et al., 2023).

Methodological considerations and risk of bias

The quality of included reviews was variable with only the Cochrane review by Jespersen et al. (2022) classed as 'high quality' on the AMSTAR-2. This was also the most comprehensive review with regard to range of outcomes reported. Interestingly, their reported effect sizes for sleep quality (measured using the PSQI), SOL and SE were the highest amongst meta-analytic reviews suggesting that lower quality studies are not inflating the overall intervention effects. A high number of reviews failed to report the full references of excluded studies with reasons for exclusions. List of exclusions is relevant for reviews of overviews given that 'systematic review' needs to be clearly defined from the outset to ensure objective inclusion/exclusion of reviews. A small number of meta-analytic literature reviews were excluded at full-text review due to quality appraisal not being conducted, and thus not meeting systematic review criteria. By contrast, funding and conflicts of interests for the review authors were reported by all included studies. Given that a range of study designs

were included, the findings from RCTs and non-RCT reviews were often not considered separately to account for differences in methodological quality.

Strengths, limitations, and future directions

A strength of the current review is a comprehensive database search that allowed identification of both RCT and non-RCT reviews of music-based interventions for sleep in adults. Had only reviews of RCTs been included, no reviews focused on clinical groups such as dementia and COPD would have been identified. All relevant reviews were also included regardless of their quality. The current review Included a wide range of interventions based on the original study author definition of a music-based intervention, which allows an assessment of the breadth of the current evidence base but also limits conclusions that can be drawn due to interventions not only involving music listening but also music making, instrumental playing, and nature sounds (Fang et al., 2023). Some also combined music listening with other interventions such as sleep education.

Notable heterogeneity was present in the majority of included meta-analyses. Therefore caution should be exercised in the interpretation of the findings. With overlap between the included reviews, there is also risk of over counting outcome data due to primary study overlap. Although slight overall, the overlap was higher within some subgroups with multiple published reviews such as older adults. Overlap between reviews is known to increase the methodological complexity (Pollock et al., 2023), and it was not possible to perform meta-analysis of the findings without double counting data or re-extracting and re-analysing outcome data from the included primary studies due to resource limitations.

Another limitation identified by the current review is the limited objective outcome reporting in the included meta-analytic reviews, for example, through actigraphy in addition to the reporting of sleep outcomes beyond sleep quality. Future studies should consider including both subjective and objective sleep outcomes and measures of psychological wellbeing. Future reviews should also provide greater analysis of subgroup effects using the PICOS framework, such as examining the effects of active and passive comparators on outcome given that this has received little attention within the published reviews.

1.6. Conclusions

Music-based interventions appear promising in improving sleep quality in adults with some indication of reduction in insomnia severity. The reporting of other sleep outcomes remains limited. Although highly heterogeneous with issues around poor reporting of intervention characteristic, the findings indicated that future studies should aim to provide individually tailored regular music listening for around 30 minutes at bedtime.

Conflicts of interest
None

Funding
None

1.7. References

*denotes review included in the overview of reviews

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Chapter 2: Major Research Project

Music for sleep after stroke (MUSAS): Mindful music-listening to improve sleep post-stroke – A single case experimental design study.

Prepared in accordance with the author requirements for Neuropsychological Rehabilitation https://www.tandfonline.com/action/authorSubmission?show=instructions&journalCode=pnrh20#checklist

2.1 Plain language summary: Music for sleep after stroke (MUSAS)

Rationale: Sleep difficulties are common after stroke. Approximately one in three individuals experience insomnia after a stroke. Insomnia is a difficulty in initiating/maintaining sleep, and/or early-morning awakening and waking up not feeling rested on at least three nights per week for a minimum of three months with impact on daytime functioning. A small number of studies have investigated the use of music as an approach to improve sleep, suggesting that music listening may have a positive impact on sleep. Similarly, there is some evidence that mindfulness-based interventions, (non-judgmental awareness of the present), may improve sleep quality. We proposed that mindful music-listening, combining music listening and elements of mindfulness, may improve sleep.

Aims: This study assessed whether mindful music-listening intervention can reduce insomnia symptoms and improve wellbeing after stroke.

What was done: Six adults with insomnia symptoms who had experienced a stroke at least three months ago were recruited from the NHS Greater Glasgow and Clyde stroke services. They were asked to continue with their normal sleep routine for 7, 11 or 15 days. They then completed a five-week intervention consisting of practical guidance to improve sleep (sleep hygiene) and music-listening with an instruction to return their attention to the music if their mind wandered (mindfulness instruction). Participants kept a daily sleep diary throughout the study. In addition, changes in sleep, mood and fatigue were measured using questionnaires at the start of the study, at the end of intervention and at follow up three weeks after the end of intervention. Data from these were analysed to assess change between the start and end of intervention / follow-up.

Findings: All participants completed the study. Four of the six participants had significantly improved their sleep efficiency (percentage of time spent asleep) post-intervention indicating that they spent less time awake in bed. This was maintained at follow-up with one further participant improving. Five of the six participants showed reduction in depressive symptoms, two in anxiety and one in daytime sleepiness post-intervention, with improvements

maintained at follow-up. Findings for fatigue were mixed. The intervention did not improve how refreshed participants felt on awakening.

Practical applications: Mindful music-listening incorporating sleep hygiene appears to be a promising approach to improving sleep difficulties after stroke, however, the current findings do not allow differentiation of the effects of the sleep hygiene and mindful music-listening components.

2.2 Abstract

Sleep difficulties are common post-stroke. A number of studies have investigated the use of music to improve sleep. Using single case experimental design methodology, this study examined whether a mindful music-listening intervention incorporating sleep hygiene can reduce insomnia symptoms and improve wellbeing post-stroke. Six adults with stroke, scoring ≤16 on the Sleep Condition Indicator, were randomised to a baseline phase of 7, 11 or 15 days, followed by a five-week intervention. Changes in sleep, mood, fatigue and daytime sleepiness were assessed at baseline, post-intervention and at follow-up (3 weeks post-intervention). The data were analysed using visual analysis and Tau-U. All participants completed the study. The majority (n=4/6) displayed significant improvement in sleep efficiency post-intervention and at follow-up (n=5/6). Clinically significant reduction in depressive symptoms (n=5/6), anxiety (n=2/6) and daytime sleepiness (n=1/6) was seen post-intervention with improvements maintained at follow-up. Findings for fatigue were mixed. At group level, significant improvement in sleep variables, ranging from small to large effect, were present with most effects maintained at follow-up. The intervention did not improve perceived sleep restoration. The intervention appears promising for improving sleep post-stroke, however the findings do not allow differentiation of the effects of sleep hygiene and mindful music-listening.

Keywords: insomnia; music; mood; sleep condition indicator; sleep hygiene

2.3 Introduction

Stroke is one of the leading causes of long-term disability (WHO, 2020). In addition to high prevalence of physical, cognitive and emotional impairments (McKevitt et al., 2011), poor sleep is a common complaint post-stroke. A third of stroke survivors are estimated to meet the diagnostic criteria for an insomnia disorder post-stroke (Baylan et al., 2020a) compared to 6% in the general population (Ohayon, 2002). Insomnia disorder is defined as difficulty in initiating/maintaining sleep, or early-morning awakening for at least three nights per week over a period of at least three months with an impact on daytime functioning (American Psychiatric Association, 2013).

The causes of post-stroke insomnia are still poorly understood but likely multi-factorial including medication side effects, environmental factors and comorbidities (e.g. mood disorders, pain). A meta-analysis of polysomnographic characteristics of sleep post-stroke found that individuals with stroke had poorer sleep efficiency, shorter total sleep time and longer wake after sleep onset duration (Baglioni et al., 2016). Stroke location has also been indicated as a factor, with increased insomnia prevalence reported following thalamic and brainstem stroke (Cai, Wang & Young, 2021).

Treatment of Insomnia

European guideline for the treatment and management of insomnia (Riemann et al., 2017) recommends Cognitive Behavioural Therapy for Insomnia (CBT-I) as the first line treatment. Medications can also be used when CBT-I is not effective or available (Morin et al., 2009), however they may increase the risk of stroke (Bassetti et al., 2020) and falls (Westerlind et al., 2019). Despite the high prevalence of post-stroke insomnia, the evidence base for non-pharmacological interventions in this population is sparse. The most recent systematic review identified only two small studies assessing CBT-I post-stroke (Ford et al., 2020). Herron et al. (2018) reported reduction of insomnia severity following seven sessions, with three of the five participants meeting criteria for reliable improvement but no significant reduction in fatigue. Nguyen et al. (2019) reported significant reduction in fatigue, sleep quality and depression compared to treatment as usual following seven sessions of CBT-I. They also reported improved quality of life post-treatment, but this was not maintained at follow-up.

Given the high prevalence of fatigue (Alghamdi et al., 2021), mood disturbance (Liu et al., 2023) and cognitive impairment (Sexton et a., 2019) post-stroke simple interventions with low cognitive demand are needed.

Music based interventions

Recent reports indicate an increase in the utilisation of music-listening using self-selected material to support wellbeing during the global COVID-19 pandemic in non-clinical samples (Torun et al., 2021; Vidas et al., 2021). Feng et al. (2018) meta-analysis suggests that music interventions have a medium effect on insomnia in the general adult population. Music-associated relaxation was found to have a small but significant effect on overall sleep quality with both music-associated relaxation and music listening improving sleep onset latency. A meta-analysis of randomised controlled trials of pre-recorded daily music listening reported large treatment effect compared to control conditions (Jespersen et al., 2022). Systematic reviews focusing on older adults have reported mixed findings. Chen et al (2021) reported that music listening significantly improved sleep quality compared to no listening (large effect) with greatest improvement when listening to "sedative" music and for interventions longer than four weeks (large effect). However, another recent review found that the efficacy of music interventions in improving sleep quality, objective and subjective sleep in older adults was inconclusive (Petrovsky et al., 2021).

Although listening to self-selected music daily for one hour has been used with the aim of improving cognitive recovery and mood post-stroke (Baylan et al., 2020b; Särkämö et al., 2008) very few studies have examined the impact of music listening on sleep post-stroke. Doğru et al. (2018) reported reduction in insomnia and depression symptoms following ten hours of Western music listening post-stroke. Although not focused on sleep per se, qualitative findings from a post-stroke music listening trial also suggest potential of daily mindfulness-based music listening of self-selected material on promoting sleep (Baylan et al., 2018). Mindful music-listening differs from music-listening in that it actively encourages redirecting focus back to the music when attention wanders as opposed to listening to music without specific instructions or having music playing in the background whilst engaging in other activities. The study further found that 'classical music' was the most selected genre in the mindful-music listening group compared to 'pop' in the group that was asked to listen to

their preferred music (Baylan et al., 2018). Participants in the mindful-music listening group also reported it inducing relaxation more frequently than those listening to music without specific instructions (Baylan et al., 2018). A recent meta-analysis (Rusch et al., 2019) examining mindfulness meditation interventions reported significantly improved sleep quality compared to active controls post-intervention and at follow-up. We propose that mindful music-listening, combining music listening and elements of mindfulness, may improve sleep.

Aims

This study examined whether a mindful music-listening intervention can reduce subjective and objective insomnia symptoms and improve wellbeing post-stroke.

Research Questions

Primary

Does daily mindful music-listening improve subjective and/or objective sleep in individuals with insomnia post-stroke?

Secondary

Does mindful music-listening improve mood and fatigue in individuals with insomnia post-stroke?

2.4 Methods

Single Case Experimental Design (SCED) methodology using multiple baseline design (MBD) across six participants with three phases was employed: A (baseline) - B (intervention) plus maintenance phase (Morgan & Morgan, 2009). The MBD allows the baseline length to be varied between participants and thus increase confidence in any changes being due to the intervention. The baseline (phase A) was 7, 11 or 15 days and randomly allocated across participants. This was followed by an intervention (phase B) lasting 5 weeks and a 3-week follow-up (maintenance phase). In total, participants were in the study between nine or ten weeks depending on their baseline length. The intervention length was determined based on

current evidence suggesting that changes in outcomes are typically seen after at least three weeks of listening (Dickson & Schubert, 2020), with additional weeks added for the delivery of sleep hygiene and mindful music-listening instructions.

The Oxford Centre for evidence Based Medicine classifies SCEDs (N-of-1 randomised trials) as providing the highest level (level 1) of evidence for treatment decision purposes in individual patients alongside systematic reviews (Howick et al., 2011). Reporting follows the SCRIBE (The Single-Case Reporting Guideline In BEhavioural Interventions) guidelines (Tate et al., 2016). A study protocol was developed (Appendix 2.1), and ethical approval was obtained from the NHS Health Research Authority East Midlands – Derby Research Ethics Committee (23/EM/0033, Appendix 2.2) with R&I approval from the NHS Greater Glasgow and Clyde (GN22ST470, Appendix 2.3). The study was registered with clinicaltrials.gov (NCT05867290). Insurance and indemnity were provided through NHS CNORIS for harm arising from the management, design and conduct of the study, and through the University of Glasgow clinical trials for harm arising from the design of the study.

Participants

Inclusion criteria

Participants were included if they were aged 18+ (no upper age limit), had clinically and/or radiologically confirmed diagnosis of stroke, were at least 3-months post-stroke and scored ≤16 on the Sleep Condition Indicator (SCI; Espie et al., 2014). Participants may or may not have had an insomnia disorder diagnosed as part of routine care. Inclusion in the study was determined based on the SCI score and solely for research purposes.

Exclusion criteria

Participants were excluded if they had experienced a Transient Ischemic Attack or subarachnoid hemorrhage, had commenced sleep medication within the last 2 weeks (stable medication was accepted), or had significant receptive aphasia or major psychiatric/substance abuse problem preventing engagement in the intervention. Deafness or severe hearing impairment preventing engagement in the intervention (use of hearing aids did not lead to exclusion if these supported adequate level of hearing) or being unable to give informed consent also led to exclusion.

Participants could also be excluded due to participation in another intervention study to ensure non-contamination of the research findings. This was assessed on a case-by-case basis.

Recruitment

Participants were recruited from the NHS Greater Glasgow and Clyde Stroke Service and were enrolled between 6 April and 12 May 2023. Potential participants were invited into the study by a member of clinical team working at the service, who briefly explained the study rationale and gave them a copy of the participant information sheet (PIS), if they were currently receiving therapeutic input. If they expressed interest in participating the clinician forwarded their contact details to the researcher, who contacted the participant no less than 24hrs after receiving the PIS (Appendix 2.4) to ascertain interest, assess eligibility and to obtain written informed consent (Appendix 2.5). Potentially eligible participants who had been discharged within the last six months were identified by the service through medical records and were mailed a copy of the PIS with information how to contact the study team. Potential participants were able to contact the researcher for further information about the study, without an obligation to participate.

Outcome measures

Data on participant demographics (age, gender, level of deprivation based on the Scottish Index of Multiple Deprivation), previous mindfulness practice, stroke (type, reoccurrence, time since stroke) and pre-stroke insomnia characteristics were collected at baseline.

A summary of outcome assessment administration time points is provided in appendix 2.6. All baseline measures were administered during visit 1, end of intervention outcomes during visit 7 and follow-up measures during visit 8. The following outcomes were administered:

Subjective sleep

The Sleep condition indicator (Espie et al., 2014) is an eight-item questionnaire comprising severity, sleep satisfaction, and daytime consequences of poor sleep. Each item is scored on a 5-point scale ranging from 0-4 with higher scores indicating better sleep with a maximum score of 32. Total score of ≤16 is considered to meet the DSM-5 diagnostic threshold for insomnia disorder with scores in the range of 0-2 indicative of threshold at an item level.

Clinically significant change is considered a score above the clinical cut-off of 16 or an increase of seven scale points (reliable change index (RCI) = 6.54) or greater (Espie et al., 2018).

The Epworth Sleepiness Scale (ESS) was used to assess daytime sleepiness in eight different daily life situations (Johns, 1992). The ESS has been reported to have internal consistency (Cronbach's α of 0.68) following stroke (Kim et al., 2022). Clinically significant change is considered a decrease of six points (RCI = 5.89) or greater (Smith & Sullivan, 2007).

Participants kept a daily sleep diary of their sleep throughout the study (Appendix 2.7). Sleep diaries and widely used in sleep research (Natale et al., 2015) and allow the calculation of sleep onset latency (SOL; time taken to fall asleep), time in bed, frequency of night-time awakenings (NA), time spent awake after sleep onset (WASO), perceived level of sleep restoration (SR; refreshed, somewhat refreshed, fatigued), total sleep time (TST; Time in bed minus, SOL, WASO and time spent in bed after waking up) and sleep efficiency (% time spent sleeping whilst in bed). Using a conservative estimate, sleep efficiency of <80% is considered poor (Ohayon et al., 2017) with SE <80% associated with increased risk of mortality in the elderly (Desjardings et al., 2019). Although the study was not designed to directly examine the mechanism through which mindful music-listening operates, it was hypothesised that if the intervention operates through improved relaxation and 'here and now' focus, this may translate to reduced SOL in particular, with positive impact on sleep overall (SE).

Objective sleep

Actigraphy is a non-invasive method of assessing sleep-wake cycles and uses accelerometers to detect activity based on body movement. Throughout the study, participants wore an Axivity 3 actiwatch (Axivity) on their dominant wrist or if they had hemiparesis, on the wrist of their non-affected hand. This data is reported elsewhere.

Mood and fatigue

The Patient Health Questionnaire (PHQ-9) was used to assess changes in depression severity. The PHQ-9 is a nine-item questionnaire mapping onto DSM-IV criteria for depression (Kroenke et al., 2001). Each item is scored on a 4-point scale ranging from 0 (not at all) to 3 (nearly every day) and added together to form a total score (maximum 27). Total score was

interpreted as none-minimal (0-4), mild (5-9), moderate (10-14), moderately severe (15-19) or severe depression (20-27). The PHQ-9 has been shown to have good interrater reliability (0.98, 95%CI 0.96-0.99) measured using the intraclass correlation (ICC) (de Man-van Ginkel et al., 2012), as well as good internal consistency (Cronbach's α= 0.85) (Kim et al., 2022), sensitivity (0.86, 95%CI 0.70-0.94) and specificity (0.79, 95%CI 0.60-0.90) post-stroke (Meader et al., 2014). Clinically significant change (reliable change index, RCI) is considered as a decrease of six points (RCI= 5.20) or greater (Gyani et al., 2013).

The General Anxiety Disorder Questionnaire (GAD-7) was used to assess changes in anxiety symptoms (Spitzer et al., 2006). The GAD-7 consists of 7 questions measured on a 3-point scale with a total score of 0 to 21. Total score was interpreted as minimal (0-4), mild (5-9), moderate (10-14) or severe anxiety (15 or greater). The GAD-7 has reported to have good internal consistency (Cronbach's α = 0.91) post-stroke (Kim et al., 2022). The reliable change index for the GAD-7 is 3.53 = 4 points (Gyani et al., 2013).

Fatigue Severity Scale (FSS; Krupp et al., 1989) is a nine-item questionnaire with greater scores indicating higher level of fatigue. The FSS has been found to have good reliability (Cronbach's alpha of >.90) in individuals with stroke (Nadarajah et al., 2017). No reliable change index for FSS has been reported.

Randomisation and blinding

Participants were randomly allocated to different baseline lengths following baseline assessment. The person responsible for randomisation using the Randomizer tool (www.randomizer.org/#randomize) was not involved in outcome assessment or intervention delivery. It was not possible to blind the participant to the intervention phase, and due to resources available for the study, it was not possible to blind outcome assessor to the intervention phase. Participants' knowledge of the study focusing on sleep through music listening, carried a risk of participants consciously or unconsciously increasing their music listening. To mitigate this, it was emphasised that participants should continue with their normal routine during the baseline phase with an explanation for this provided. Guidance on mindful music listening instruction was only provided during the intervention phase.

Intervention

The manualised intervention consisted of sleep hygiene and mindful music-listening delivered over five sessions lasting up to an hour (Table 2.1). The intervention manual was adapted from a previous mindful music-listening study (Baylan et al., 2020b) with key changes summarised in Table 2.2. The intervention was delivered approximately weekly, to each individual, by a Trainee Clinical Psychologist at the participant's home or via telephone. The person delivering the intervention had completed an 8-week training course in Mindfulness Based Stress Reduction (MBSR).

Table 2.1 Intervention components

Intervention session (visit)	**Key content**
1 (Visit 2)	Information on sleep hygiene and sleep problems after stroke provided. Guidance on how to complete sleep diaries. Exploration of music preferences.
2 (Visit 3)	Review of sleep diary. Introduction to the concept of mindful music-listening, including 'leaves on the stream' exercise. Creation of a playlist.
3-5 (Visits 4-6)	Review of sleep and music listening over the past week Provision of further guidance if required. Week 5: participants were encouraged to continue listening at bedtime post-intervention should they wish to.

In session 2, participants completed a brief mindfulness-based exercise – 'leaves on the stream' - from Acceptance and Commitment Therapy to elicit a busy mind akin to worries that may prevent a person from falling asleep. Participants were encouraged to adopt a non-judgmental approach, and to practice the noticing, letting go of thoughts and returning their focus to the present moment. They were then instructed to apply the principle of refocusing to the present (music), instead of thoughts and worries, while listening to music at bedtime.

Participants were asked to listen to their preferred music daily for 30 mins or until they were about to fall asleep, if sooner, using Spotify (or equivalent) on their existing device such as a mobile phone. Participants were free to choose music from any genre but were encouraged to select music slow in tempo and music that they perceived physically relaxing or soothing.

As part of playlist creation (session 2), participants were advised that should music listening bring back painful memories from the past or evoke difficult emotions causing distress, they should remove this from their playlist, and identify alternative listening material. Our previous research has indicated that most individuals tend to find music listening an enjoyable experience post-stroke (Baylan et al., 2018).

If the participant had sensory, cognitive or physical disability, efforts were made to overcome barriers to participation such as agreeing an individualised prompting system to remind about appointments. Details of adaptations were recorded.

Table 2.2 Key intervention adaptations

Domain	**Baylan et al., (2020b)**	**Current study**	**Reason**
Listening duration	Up to 60 minutes per day	30 minutes (or until about to fall asleep, if sooner) at bedtime	Evidence base
Intervention duration	8 weeks	5 weeks	Evidence base, pragmatic
Follow-up duration	3 months	3 weeks	Pragmatic
Mindfulness component outwith listening	'Body scan' or 'following the breath' exercise prior to mindful music listening	Leaves on the stream exercise (to induce a wandering mind and to practice noticing, letting go, and refocusing of attention)	Theoretical, pragmatic
Music type/genre	Any preferred	Music perceived relaxing or soothing by the participant. Encouraged to select music slow in tempo / without lyrics but not compulsory	Evidence base
Device	IPod	Smart phone	Pragmatic
Guidance for sleep	None	Sleep hygiene (1 session)	Evidence base

Music listening engagement

Participants were asked to keep a diary of their daily listening to assess to what extent participants engaged with music listening. This included whether music was listened to each day (yes/no), duration listened for (minutes) and a rating of ease of listening to music mindfully (0-10, with higher scores indicating greater ease).

Statistical methods

The sample size was determined based on recommendations described in the SCRIBE guidelines (Tate et al., 2016) and the RoBiNT scale (Risk of bias assessment tool in N-of-1 trials (Tate et al., 2013). All participants were assigned an ID to allow all data to be pseudonymized.

Descriptive statistics, mean (SD), median (IQR), value (%), based on the distribution of the data, were used to summarise participant characteristics. Assessment of clinically significant change (SCI, PHQ-9, GAD-7, ESS) and visual analysis of questionnaire and diary data was carried out in Excel.

The Manolov web application https://manolov.shinyapps.io/Overlap/ was used to inspect the level and stability envelopes to assess whether 80% of datapoints fall within 25% of the phase median. Singlecasedesign.org Tau-U 'Kendall' online calculator was used to test for baseline trend and to control for this where significant trend was present. Tau-U examines data non-overlap between phases A (baseline) and B/C (intervention/follow-up). The online calculator was first used to calculate phase contrasts to assess the impact of the intervention on participant level sleep characteristics from baseline to post intervention and from baseline to follow-up. Following this, phase contrasts (adjusted for baseline trend where appropriate) from all participants were combined to calculate a group level omnibus effect size with 95% confidence intervals to assess the impact of the intervention on group level sleep characteristics. TAU-U value 0.2 or less is considered a small change, 0.20 to 0.60 a moderate change, 0.60 to 0.80 a large change, and values above 0.80 a large to very large change (Ninci & Vannest 2015).

Actigraphy data (reported elsewhere) was processed using the Axivity AX3/AX6 Configuration and Analysis Tool and analysed in the GGRI package implemented in R. The data is split into epochs representing sleep or awake to calculate sleep parameters.

2.5 Results

Sixteen individuals were screened. Two were <3 months post-stroke; two did not experience significant sleep difficulties; the timing or the nature of the intervention did not suit four; one was too unwell; and one decided not to participate but provided no reason. The remaining six consented to participate.

Participant characteristics are summarised in Table 2.3. The mean age of the participants was 58.2 (SD 5.5). Half were male (50%). Median time since stroke was 6.25 months (IQR 4.75, 14.5). Two had a bed partner. One participant wore the actiwatch on their left wrist and five on their right wrist primarily due to hemiparesis. Five participants had radiologically confirmed stroke. Four had a right hemisphere stroke and all but one participant had experienced their first stroke.

The majority of participants came from the most deprived areas (range 30 – 5267) with 83.3% (n=5) having a SIMD quintile 1 (0-20%) and 16.7% (n1) quintile 4.

Table 2.3 Participant characteristics

ID	Age, sex	Time post-stroke (mths)	First stroke	Radiology, regions affected	Affected hemi-sphere	Baseline GAD-7 (max 21)	Baseline PHQ-9 (max 27)	Pre-stroke sleep difficulties
1	58, F	6	Y	MRI not tolerated; unknown	Right	19	22	N
2	68, M	10	Y	CT; lacunar	Right	14	18	Y
3	54, F	5	Y	CT, MRI; MCA/ACA	Right	17	21	Y
4	59, M	6.5	Y	CT; occipital	Right	9	17	Y
5	52, M	28	N	CT; frontal and occipito-parietal infarct	Left	9	16	
6	58, F	4	Y	CT; Intracerebral hemorrhage	Left	17	24	Y

CT, computerised tomography; F, female; M, male; MRI, magnetic resonance imaging,

The sample had high levels of medical comorbidity, including asthma, agoraphobia, breast cancer, diabetes, chronic obstructive pulmonary disease (COPD), stage 4 chronic kidney disease (CKD4), hypertension, ischemic heart disease (IHD), left ventricular systolic dysfunction (LVSD), prostate cancer, hepatitis C. These have been summarised to protect privacy.

At baseline, two participants were classed as having mild anxiety on the GAD-7, one moderate and three severe anxiety. Similarly, three experienced moderately severe depressive symptoms, and three severe depressive symptoms on the PHQ-9 at baseline. Five of the six participants had experienced sleep difficulties prior to their stroke, however most indicated that these had worsened post-stroke.

Study completion

All participants completed the intervention, post-intervention, and follow-up questionnaire outcome measures. Most study visits (85.4%) were completed in person, at participants' home. The remaining sessions (14.6%) were completed via telephone.

Intervention adaptations

One participant required support from a family member with diary completion and one required appointment reminders and an addition of an elastic band to their actiwatch to enable them to undo the standard strap as a result of their hemiparesis.

Music characteristics

The type of participant selected music varied and included easy listening, pop, country music, hymns, instrumental music and football songs. Participants 1, 2 and 6 found their initial music choice too arousing and changes to their playlist were made after first week of listening.

Five of the six participants used Spotify on their mobile phone for listening, and one used YouTube on their mobile phone or screen casted onto their TV.

Engagement with music listening

Summary of engagement with music listening and bedtime is provided in Table 2.4. The frequency of listening during the intervention phase ranged from 32.1% to 70%. The

frequency of listening during the follow up phase ranged from 0% to 100%. The duration of music listening during the intervention phase ranged from 105 to 750 minutes, and during the follow up from 0 to 465 minutes. The total listening duration ranged from 2 hours to 20hrs and 15 minutes.

Although participant 1 reported relatively good engagement during the intervention and follow up, they said that they were unable to focus on the music due to significant general worry and high levels of anxiety, reporting that music was somewhere in the background rather than the focus of their attention. Due to a technical difficulty with Spotify, participant 2 started music listening a week later at session 3 (visit 4).

Table 2.4 Engagement with music listening at bedtime

	Days listened			**Listening duration (mins)**		
	Intervention (/28)	Follow-up (/21)	Total	Intervention	Follow-up	Total
Participant 1	16 (57.1%)	10 (47.6%)	53.1%	750	465	1215
Participant 2	18 (64.3%)	1 (4.8%)	38.8%	495	60	555
Participant 3	21/30 (70%)	3 (14.3%)*	47.1*	105	15*	120*
Participant 4	16 (57.1%)	21 (100%)	75.5%	125	39	164
Participant 5	18 (64.3%)	9 (42.9%)	55.1%	680	295	975
Participant 6	9 (32.1%)	0 (0%)	18.4%	270	0	270

* missing data for two weeks. For period assessed, engagement during intervention = 42.9%, and 64.9% overall.

Visual and between conditions analysis

Sleep efficiency

Figure 2.1 summarises sleep efficiency across study phases with significance values for the intervention phase.

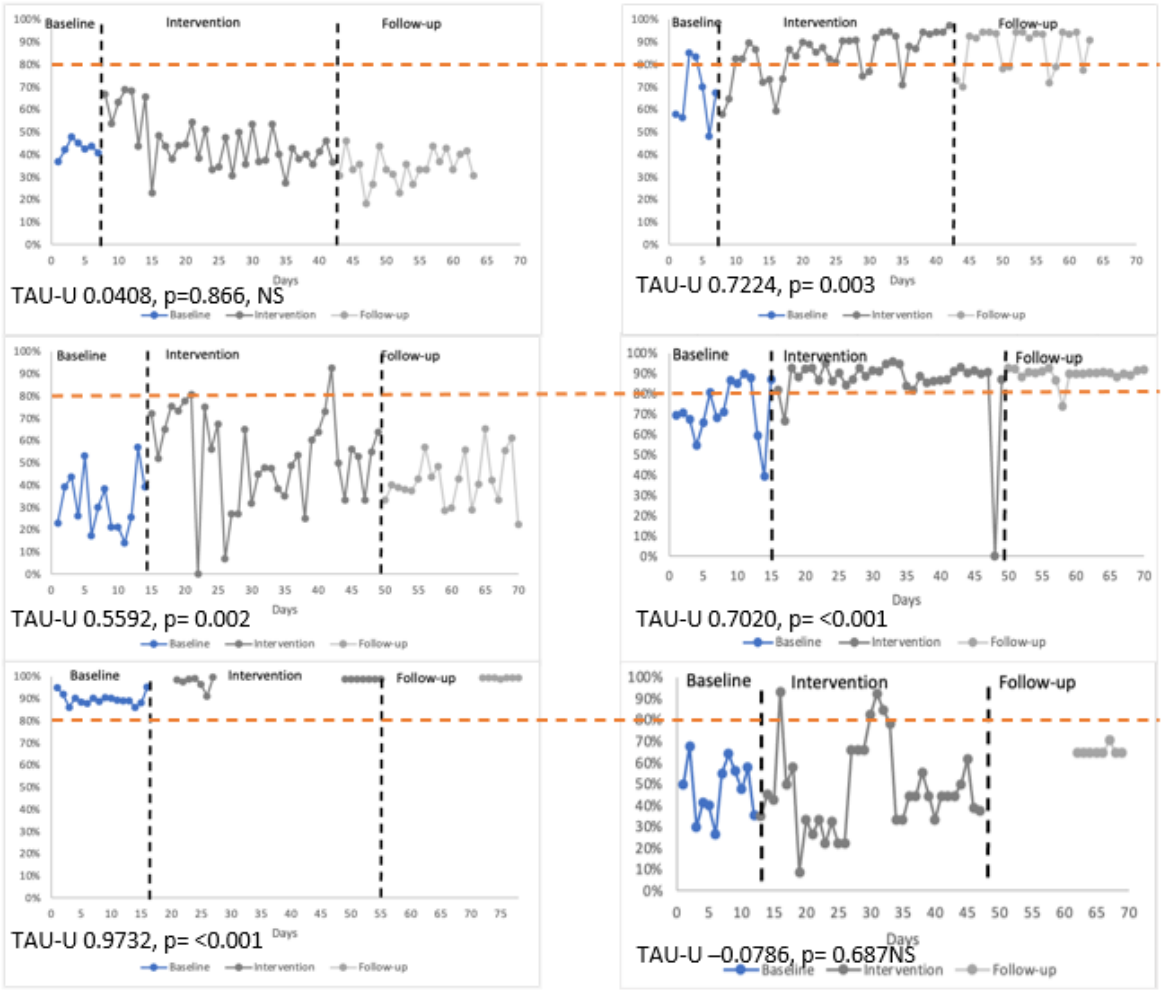

Figure 2.1 Sleep efficiency. The left panel shows sleep efficiency for participants 1-3 (set 1), the right panel for participants 4-6 (set 2). Dashed line denotes good sleep efficiency.

No significant baseline trend was observed (all p>0.05). Participants 1 and 6 did not show significant improvement in SE from baseline to post-intervention (TAU= 0.0408, p= 0.866 and TAU= -0.0786, p= 0.6873 respectively). The remaining participants (2-5) showed significant improvement in their SE (p<0.05) from baseline to post-intervention. For participants 3-5, mean SE was classed as good at the end of the intervention (≥80%). Visual analysis suggests that apart from participant 2, improvement in SE was maintained at follow-up.

TAU-U analysis found that improvement in SE from BL to follow-up was significant for participants 2-6 (TAU=0.446, p= 0.027; TAU= 1, p<0.001; TAU= 0.796, p= 0.002; TAU = 0.903, p=<0.001; TAU= 0.854, p=0.002), whereas participant 1 displayed significant reduction in their SE (-0.694, p= 0.007).

Sleep onset latency

Figure 2.2 summarises SOL across study phases with significance values for the intervention phase.

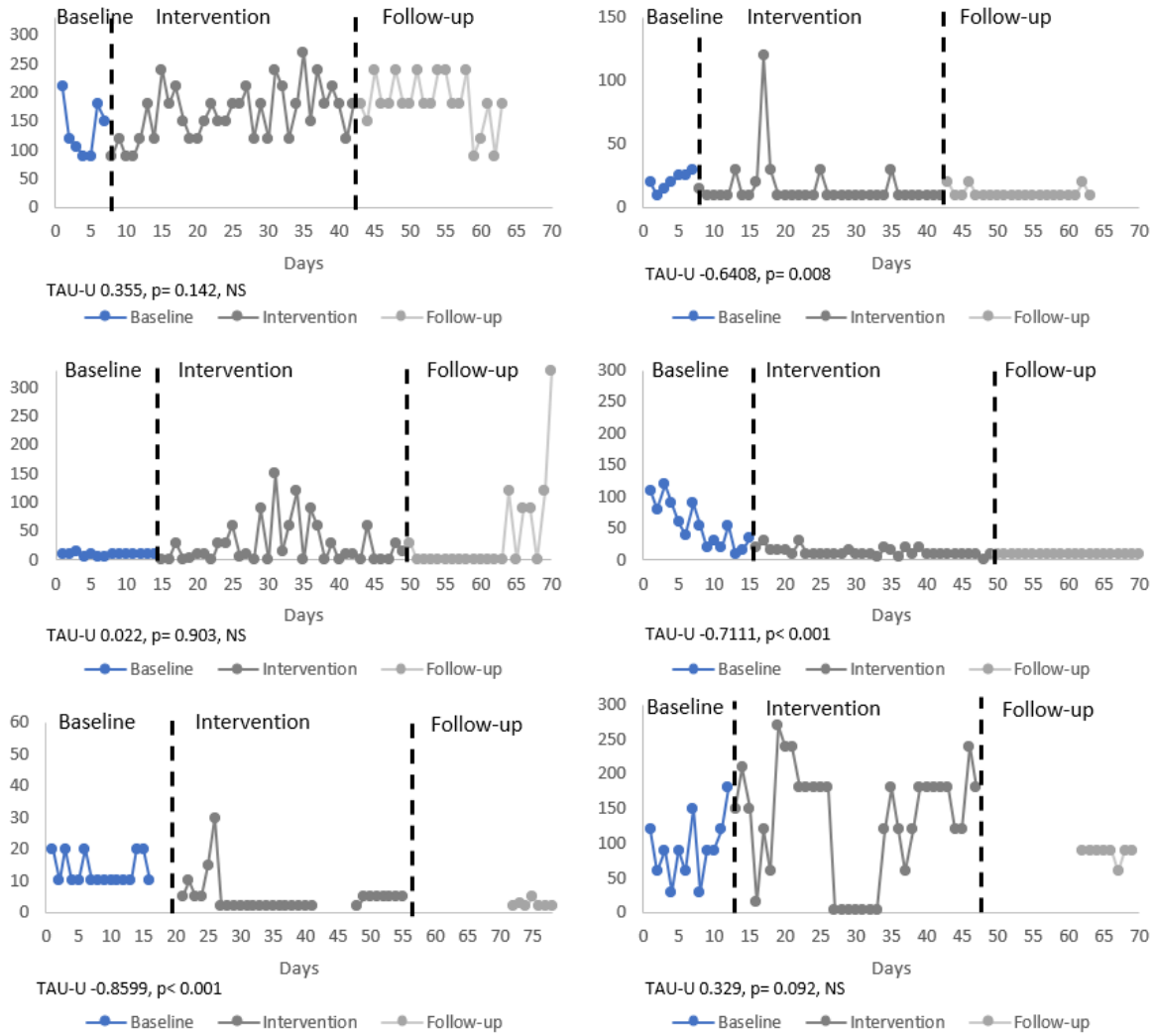

Figure 2.2 Sleep onset latency. The left panel shows SOL (mins) for participants 1-3 (set 1), the right panel for participants 4-6 (set 2) with significance values for the intervention phase.

Significant baseline trend was present for participants 4 and 5 with baseline correction applied. Participants 1, 2 and 6 did not show significant improvement in SOL from baseline to post-intervention (TAU= 0.355, p= 0.142, TAU= 0.022, p= 0.903 and TAU= 0.329, p= 0.092 respectively). The remaining participants (3-5) showed significant reduction in SOL ($p<0.05$) with the effect maintained throughout the follow-up phase.

Improvement in SOL was significant for participants 2-5 from BL to follow-up (TAU= -0.429, p= 0.034; TAU= -1, $p<0.001$; TAU= -0.857, $p<0.001$; TAU= -0.733, $p<0.001$).

Time in bed

Figure 2.3 summarises TIB across study phases with significance values for the intervention phase.

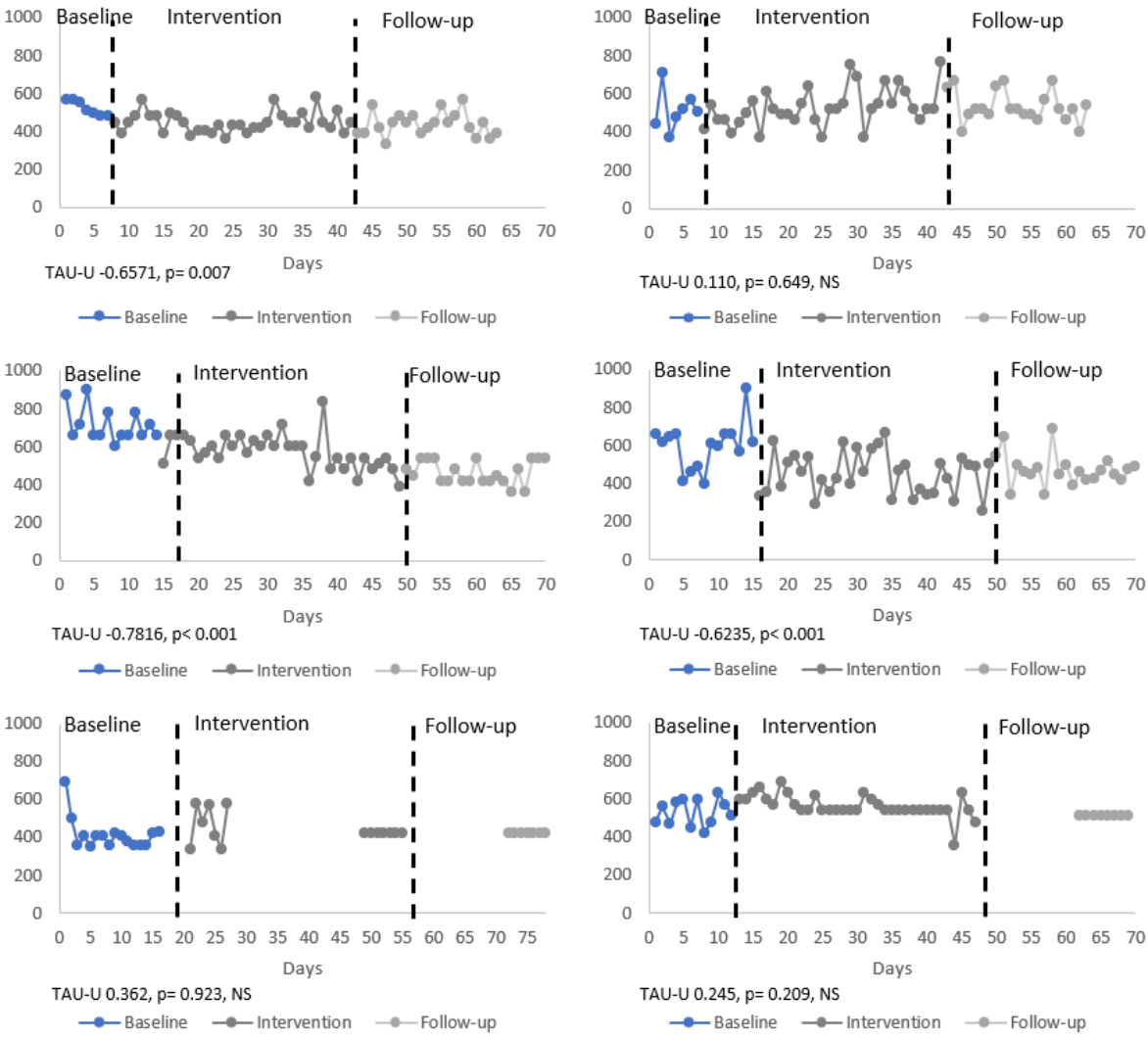

Figure 2.3 Time in bed. The left panel shows TIB (mins) for participants 1-3 (set 1), the right panel for participants 4-6 (set 2) with significance values for the intervention phase.

Significant baseline trend was present for participant 1 and thus a baseline correction was applied. Participants 3, 4 and 6 did not show significant improvement in TIB from baseline to post-intervention (TAU= 0.362, p= 0.923, TAU= 0.110, p= 0.649 and TAU= 0.245, p=0.209 respectively). The remaining participants (1-2, 5) showed significant reduction in TIB ($p<0.05$) with the effect maintained or continuing to reduce (participant 2) at follow-up.

From BL to follow-up, reduction in TIB was significant for participants 1-3 and 5 (TAU= -0.640, p= 0.013; TAU= -1, p<0.001; TAU= 0.625, p= 0.019; TAU= -0.564, p= <0.01).

Nocturnal awakenings

Figure 2.4 summarises NA across study phases with significance values for the intervention phase.

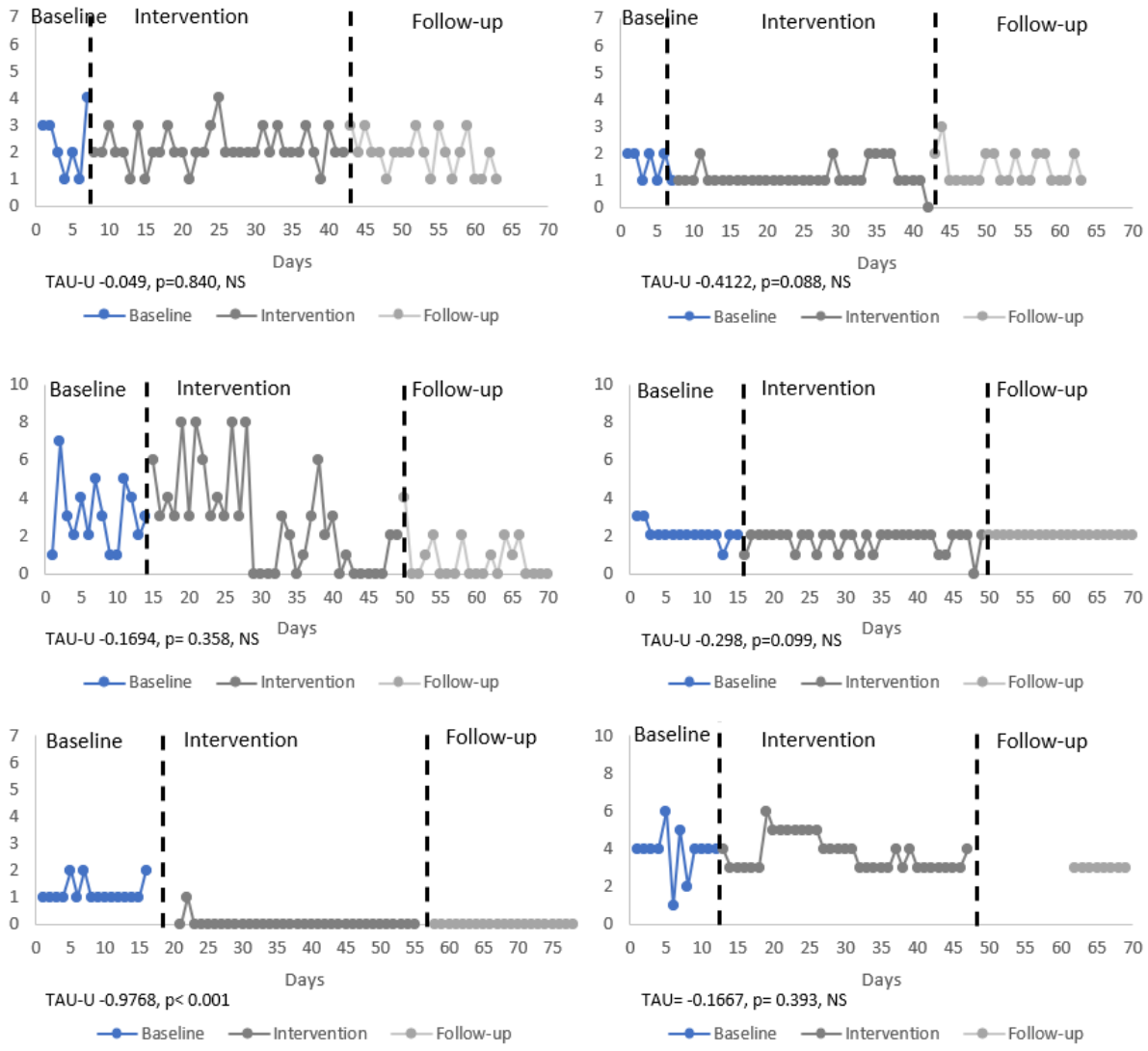

Figure 2.4 Nocturnal awakenings (NA). The left panel shows NA for participants 1-3 (set 1), the right panel for participants 4-6 (set 2) with significance values for the intervention phase.

No significant baseline trends were observed (all p>0.05). Only participant 3 showed a significant reduction in NA from baseline to post-intervention.

Compared to baseline, participants 2, 3 and 6 demonstrated a significant reduction in NA at follow-up (TAU -0.779, p<0.001; TAU= -1, p<0.001; TAU= -0.667, p= 0.01).

The most common reason for awakening was needing the toilet, reported by all participants at baseline. This was followed by worries and stress. Other factors reported included, being too hot, in pain and daylight. Participant 4's sleep was also interrupted due to external factors due to needing to collect a family member from work during the night at weekends.

Wake after sleep onset

Figure 2.5 summarises WASO across study phases with significance values for the intervention phase.

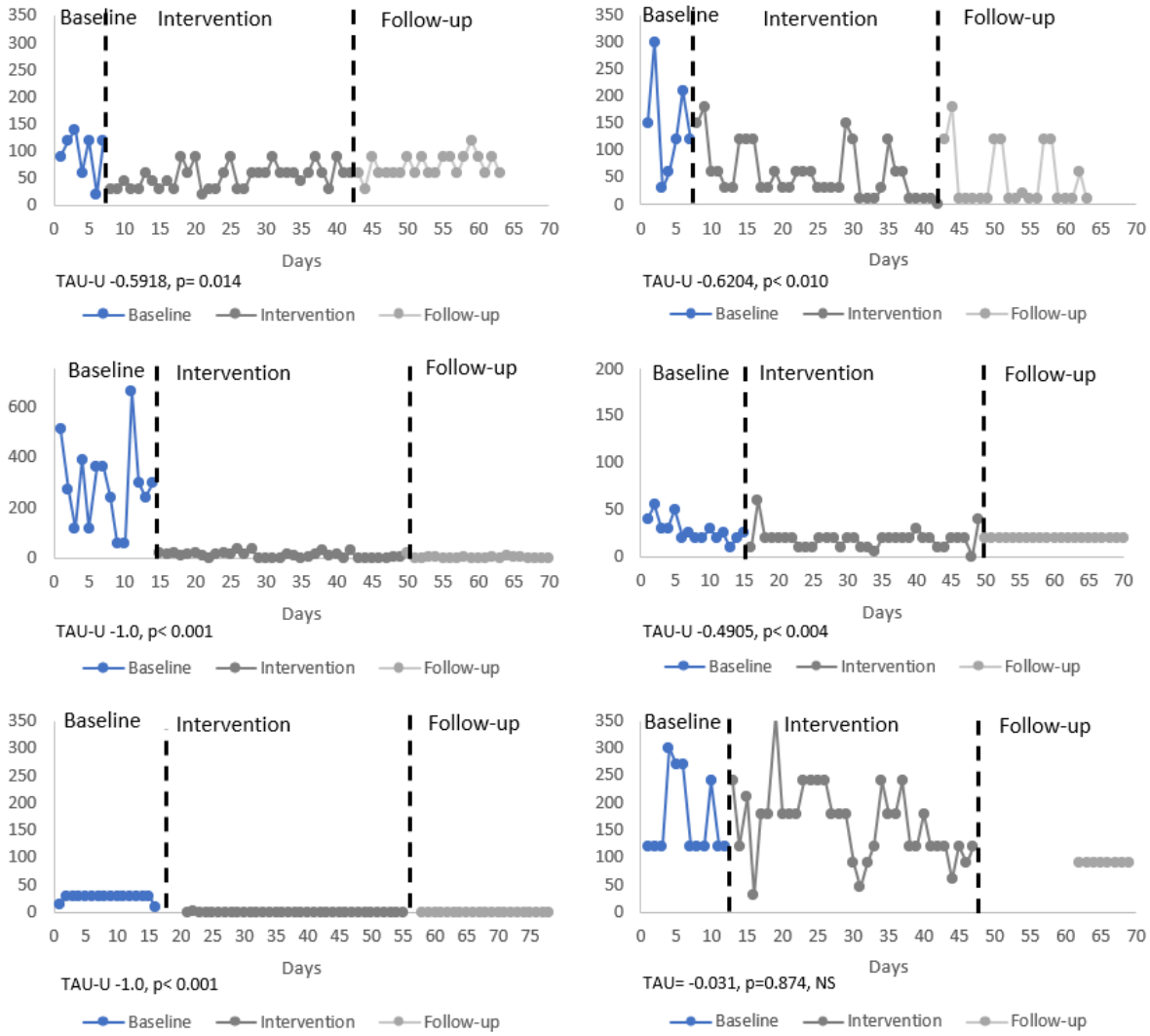

Figure 2.5 Wake after sleep onset. The left panel shows WASO (mins) for participants 1-3 (set 1), the right panel for participants 4-6 (set 2).

Significant baseline trend was present for participant 5 with baseline correction applied. All but participant 6 (TAU= -0.031, p=0.874) showed significant reduction in WASO from baseline to post-intervention.

At follow-up, participant 1 WASO was no longer significant. The remaining participants demonstrated significant reduction in the WASO compared to baseline.

Sleep restoration

Figure 2.6 summarises SR across study phases with significance values for the intervention phase.

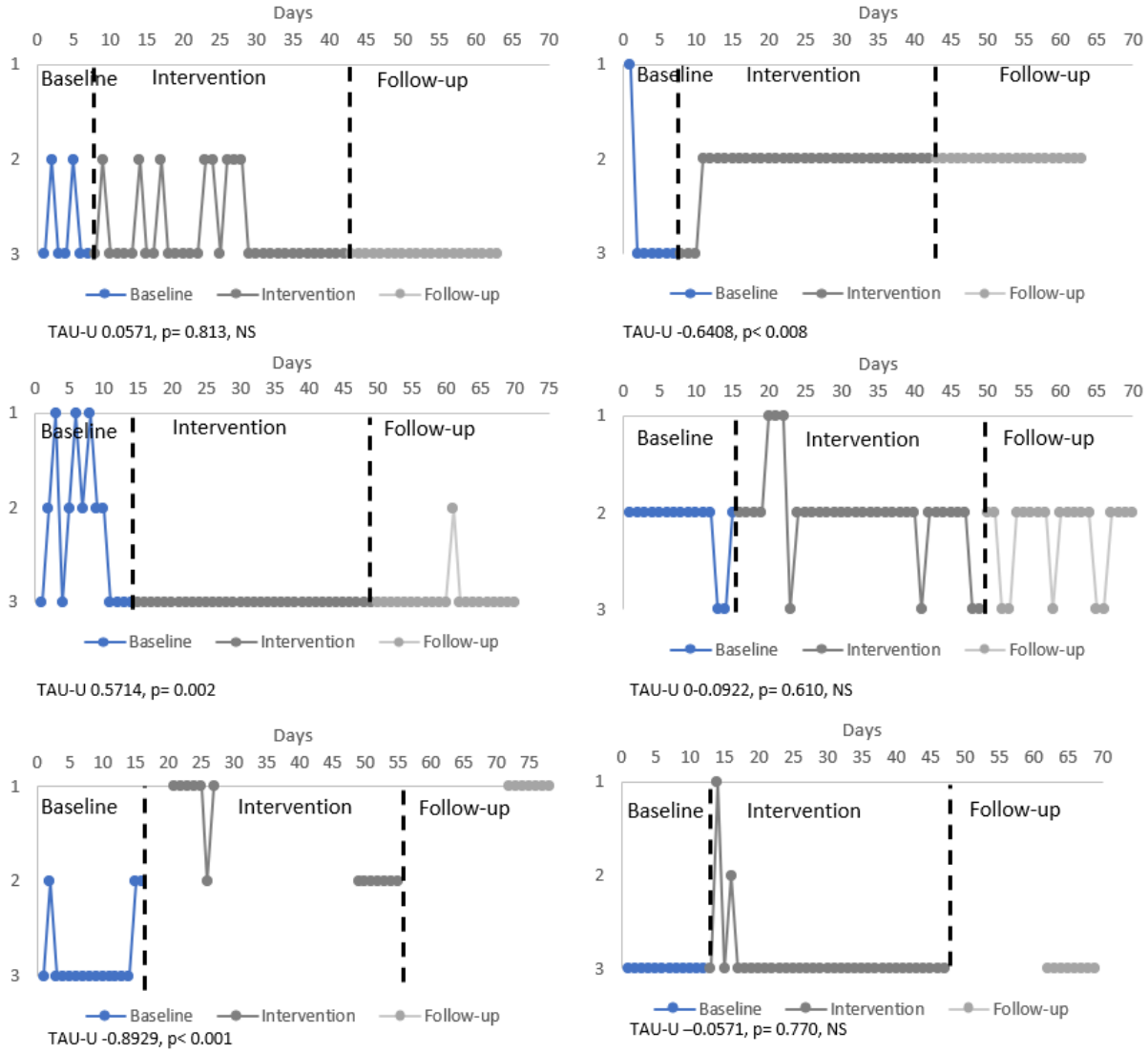

Figure 2.6 Sleep restoration. The left panel shows SR for participants 1-3 (set 1), the right panel for participants 4-6 (set 2).

No significant baseline trends were observed (all p>0.05). From baseline to post-intervention, there was no significant change on how refreshed participants 1, 5 or 6's felt on awakening. Participant 2 reported feeling significantly more fatigued on awakening both post-intervention (TAU 0.571, p= 0.002) and at follow-up (TAU= 0.534, p= 0.008), whereas participants 3 and 4 reported feeling significantly more refreshed on awakening post-intervention (TAU= -0.893, p<0.001; TAU= -0.641, p= 0.008) and at follow-up (TAU= -1, p< 0.001; TAU= -0.714, p= 0.005).

Total sleep time

Figure 2.7 summarises TST across study phases with significance values for the intervention phase.

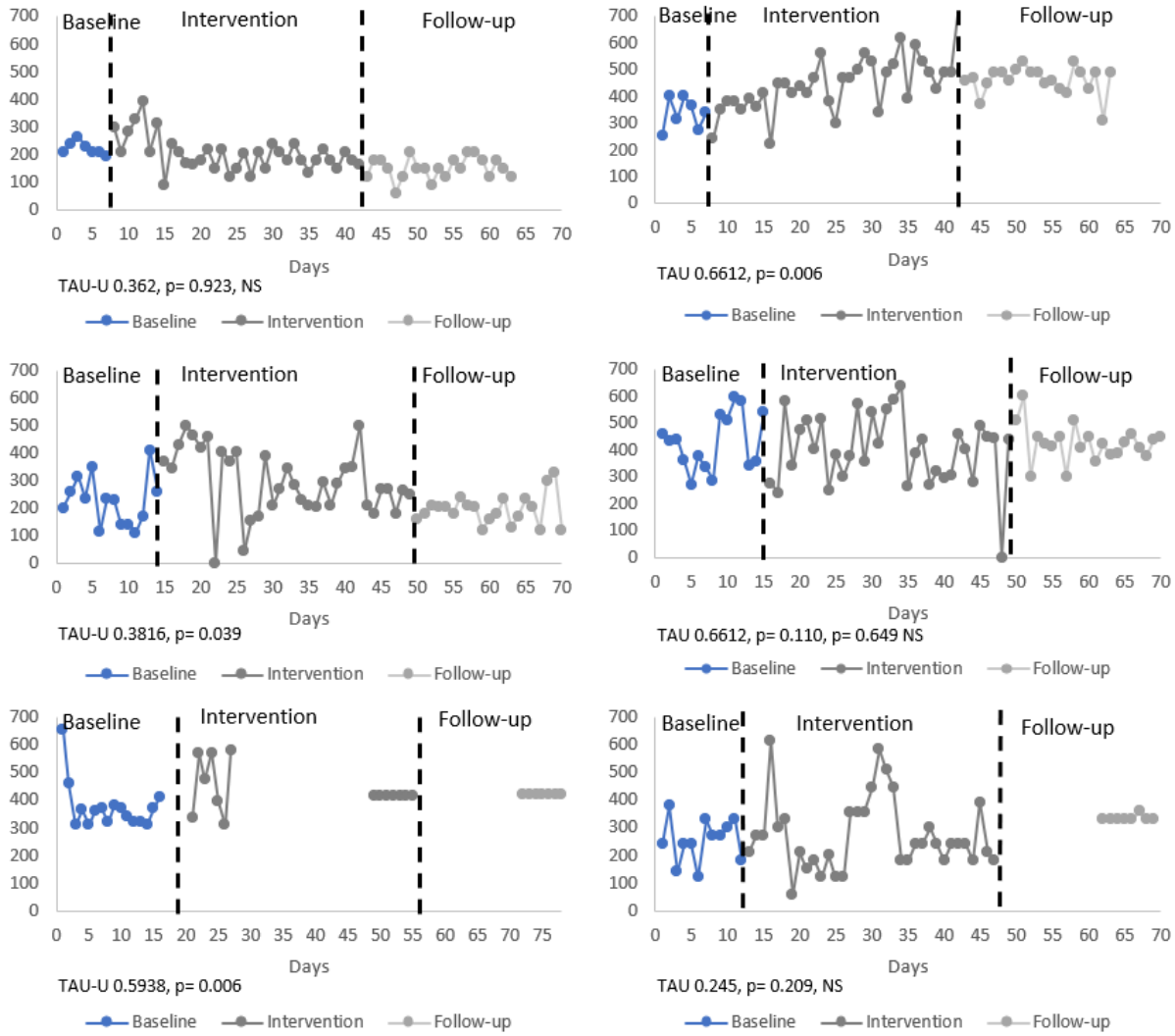

Figure 2.7 Total sleep time. The left panel shows TST (mins) for participants 1-3 (set 1), the right panel for participants 4-6 (set 2).

No significant baseline trends were observed (all p>0.05). Participants 1, 5-6 had no significant change in TST from baseline to post-intervention (TAU= 0.362, p= 0.923; TAU= 0.110, p= 0.649 and TAU= 0.245, p=0.209 respectively). Participants 2-4 showed a significant increase in TST.

At follow-up, participants 3, 4 and 6 showed a significant increase in TST compared to baseline (TAU= 0.75, p= 0.005; TAU= 0.905, p=<0.001; TAU= 0.688, p=0.01). Participants 2 and 5 demonstrated non-significant change and participant 1's TST had significantly reduced (TAU= -0.898, p<0.001).

Overall impact of the intervention on sleep characteristics

The individual phase contrasts were combined to calculate an aggregated omnibus (overall) TAU effect size of change from baseline to end of intervention across participants (n=6). Table 2.5 provides a summary of the overall intervention effects for different sleep outcomes.

Table 2.5 Change in subjective sleep characteristics

	Baseline – End of Intervention		**Baseline – Follow-up**	
Outcome	**Tau-U (95% CI), p-value**	**Effect size**	**Tau-U (95% CI), p-value**	**Effect size**
SE	0.4896 (0.3205, 0.6587), p<0.001	moderate	0.558 (0.3634, 0.7527), p<0.001	moderate
SOL	-0.269 (-0.1040, -0.4340), p= 0.001	moderate	-0.4392 (-0.6338, -0.2445), p<0.001	moderate
TIB	-0.2417 (-0.0726, -0.4107), p= 0.005	moderate	-0.2102 (-0.4141, -0.0062), p= 0.043	moderate
NA	-0.3623 (-0.1981, -0.5265), p< 0.001	moderate	-0.4911 (-0.6762, -0.3059), p<0.001	moderate
WASO	-0.6306 (-0.4677, -0.7935), p<0.001	large	-0.7563 (-0.9415, -0.5711), p<0.001	large
SR	-0.1474 (-0.3165, 0.0217), p= 0.088	small (NS)	-0.0905 (-0.2852, 0.1041), p= 0.362	small (NS)
TST	0.1849 (0.0158, 0.3539), p= 0.032	small	0.1821 (-0.0125, 0.3768), p= 0.067	small (NS)

CI, confidence interval; NA, nocturnal awakenings; NS, non-significant; SE, sleep efficiency; SOL, sleep onset latency; TIB, time in bed; TST, total sleep time, WASO, wake after sleep onset

From baseline to end of intervention, there was a large significant reduction in WASO, with moderate improvement in SE and moderate reduction in SOL, TIB and NA. In addition, small significant improvement was seen in TST but not for SR. Except for TST, the effects were maintained at follow-up compared to baseline.

Generalisation measures

A summary of change scores from baseline to end of intervention on questionnaire measures is provided in Table 2.6.

A graphical summary for changes in SCI scores is displayed in Figure 2.8, anxiety and depression in Figure 2.9, and fatigue and daytime sleepiness in Figure 2.10.

Table 2.6 Questionnaire change scores from baseline to post-intervention / follow-up

Measure / **Participant**	**SCI**		**GAD-7**		**PHQ-9**		**FSS**		**ESS**	
	End	FU	End	FU	End	FU	End	FU	End	FU
Participant 1	-2	+2	+2	+2	+1	+2	+1	-1	-8*	-8
Participant 2	+14*#	+18*#	-6*#	-8*#	-13*#	-12*#	+15	-8	-1	-1
Participant 3	+11*#	+19*#	+1	-10*#	-9*#	-16*#	±0	-27	+6	+6
Participant 4	+19*#	+19*#	-3	-5*#	-9*#	-13*#	-6	-7	-7*#	-5
Participant 5	+18*#	+22*#	-1	-2	-6*#	-7*#	-1	-2	+5	+5
Participant 6	+2	+3	-4*#	-3	-6*#	-1	+7	-4	+12	+13

End, post-intervention assessment; ESS, Epworth sleepiness scale; GAD-7, Generalised anxiety disorder assessment; FSS, Fatigue severity scale; FU, follow-up; PHQ-9, Patient health questionnaire; SCI, Sleep condition indicator

* significant change according to reliable change index

classification category change

Insomnia classification

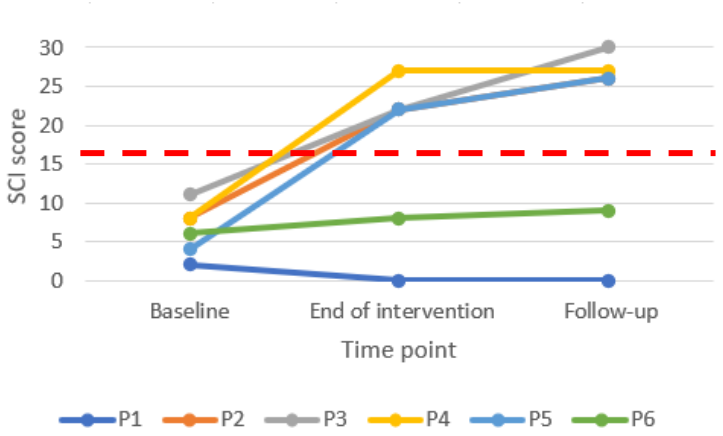

Figure 2.8 Total SCI score at baseline, post-intervention and follow up. Dashed line denotes cut off for insomnia (SCI score 16).

Four of the six participants (67%) demonstrated clinically significant change on the SCI, and no longer met the insomnia disorder threshold (≤16) at the end of the intention. Although not formally measured, both participants with a bed partner reported that their partner's sleep had also improved.

Anxiety and depression

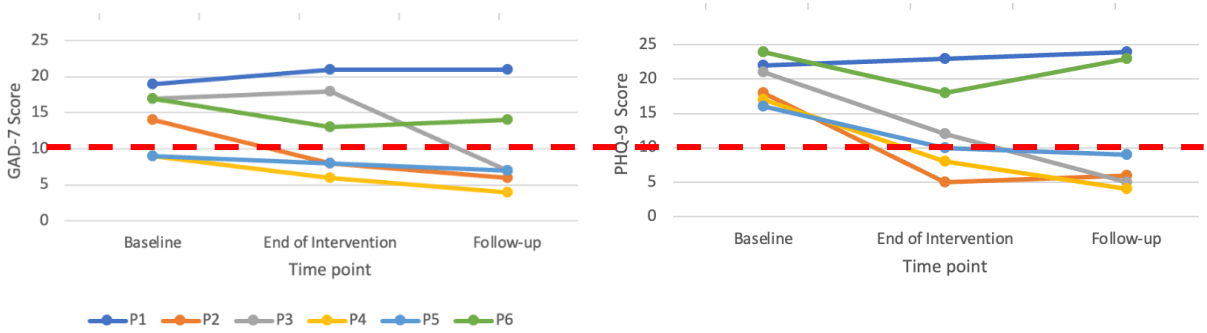

Figure 2.9 Total GAD-7 (left) and PHQ-9 (right) scores at baseline, post-intervention and follow up. Dashed line denotes cut off for moderate symptom severity.

Post-intervention, two participants exhibited clinically significant reduction in anxiety symptoms and five in depressive symptoms, including a change in their symptom severity classification.

At follow-up, three participants displayed clinically significant reduction in anxiety symptoms and four in depressive symptoms compared to their baseline values. For the two participants who had greater symptom severity on both measures, one remained in the severe range and the other displayed a trend towards their baseline values.

Fatigue and daytime sleepiness

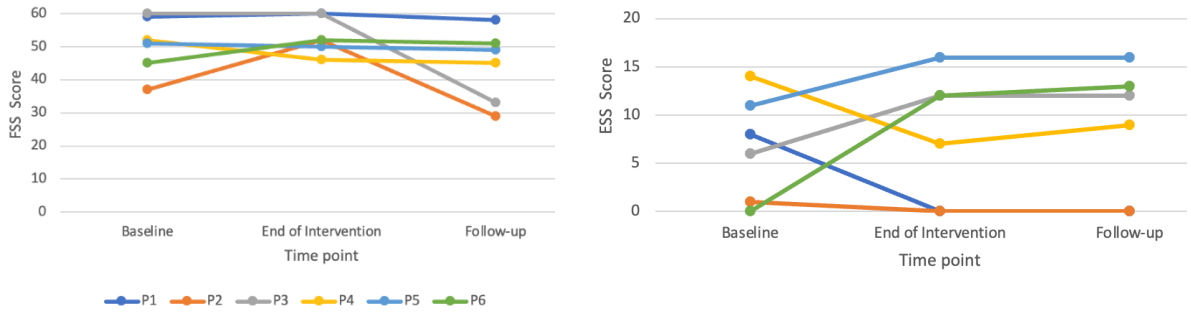

Figure 2.10 Total FSS (left) and ESS (right) scores at baseline, post-intervention and follow up. Higher scores denote greater levels of fatigue and daytime sleepiness.

Only participants 4 and 5 displayed six- and one-point reduction in fatigue from baseline to post-intervention. Qualitatively, participant 4 reported little activity at baseline but reported

going out daily and having more energy at post-intervention and at follow-up. Participant 2 reported an increase in their physical activity qualitatively during the intervention.

From post-intervention to follow-up, participants 2 and 3 displayed a 23- and 27-point reduction in fatigue. The remaining participants remained relatively stable at their post-intervention levels.

With regard to ESS, participants 1 and 4 displayed clinically significant reduction in their daytime sleepiness from baseline to post-intervention. The remaining participants reported either an increase or small reduction. There was little change in total ESS scores at follow-up.

2.6 Discussion

This study examined whether a mindful music-listening intervention combined with sleep hygiene can reduce insomnia symptoms and improve wellbeing with respect to anxiety, depression, fatigue, and daytime sleepiness post-stroke. All six participants completed the 5-week intervention, post-intervention- and follow-up questionnaire outcomes.

Changes in sleep characteristics

At the end of the intervention, four of the six participants no longer met the threshold for insomnia disorder on the SCI, scoring within the normal range (>16). Given that all participants were at least four months post-stroke, and the multiple-baseline design enables a degree of control for factors such as time, it is unlikely that this improvement is due to spontaneous recovery or adjustment from a hospital to home environment. Reduction in insomnia severity has previously been reported following bedtime music listening (Jespersen et al., 2022), following post-stroke brief behavioural treatment for insomnia (BBTI) (Aulina et al., 2021) and post-stroke CBT-I (Ford et al., 2022).

At group level, significant reduction in time spent awake after sleep onset, of large effect size, was seen post-intervention and at follow-up compared to baseline. Significant improvement of medium effect size were also seen on sleep efficiency, sleep onset latency, nocturnal

awakenings and total time spent in bed, with small effect observed for total sleep time post-intervention. Apart from total sleep time, the effects were maintained at follow-up. There was no effect on perceived sleep restoration. The evidence base for post-stroke music listening interventions for sleep is lacking but a systematic review of music listening interventions by Jespersen et al. (2022) reported improvement in SE and reduction in SOL of large and medium effect respectively, whereas a review by Feng et al. (2018) found no significant improvements. Comparing the findings to CBT for insomnia, Ford et al., (2022) also reported significant reduction in nocturnal awakenings following a 6-week blended CBT-I but no change in SE, SOL or sleep quality post-stroke. Reduction in nocturnal awakenings has also been reported following BBTI for older adults (Tiyagi et a., 2014; Tiyagi et al., 2023). Given that nocturia has a high post-stroke prevalence, estimated at around 50%, when the threshold of two voids per night is used (Haddad et al., 2020), these findings are encouraging. Except for sleep quality, the findings are also in line with meta-analysis of internet delivered CBT-I (eCBT-I), which reported improvements in insomnia severity, SE, SOL, nocturnal awakenings, WASO and TST (Zachariae et al., 2016). The positive findings in the current study are particularly encouraging given that previous CBT-based interventions in stroke and brain injury populations have been longer in duration (Ford et al., 2022; Nguyen et al., 2017).

Changes in wellbeing

In addition to improvements on sleep outcomes, the mindful-music listening intervention was found to improve mood with five of the six participants reporting clinically significant reduction in depressive symptoms and two in anxiety. Improvements were maintained at follow-up with one further participant reporting clinically significant reduction in anxiety at follow-up. In line with Ford et al. (2022), the findings for fatigue were mixed. Qualitatively, some participants reported that they were physically more active as the intervention progressed, which may have maintained or increased their level of fatigue. The current fatigue measure may therefore not capture fatigue accounting for change in activity levels.

Music listening

Most of the participants who demonstrated significant improvement in sleep outcomes post-intervention had music listening engagement rates of 55% or greater during the intervention phase indicating that regular listening is likely supportive of improvements. One of the

participants whose engagement was greater than 55% did not benefit from the intervention due to clinically severe anxiety affecting multiple aspects of everyday functioning not disclosed during screening. Although they were able to bring their focus to the present in the earlier intervention sessions, they reported that they were unable to focus on the music due to unrelated anxiety and worry when listening alone, describing that the music was "in the background". By contrast, those who benefitted from the intervention reported that they were able to focus on the music and return their attention back to it with ease if their mind wandered.

Listening duration did not appear to be strongly linked to outcome suggesting that frequency of listening may be more important than duration of listening. This may also suggest that mindful music-listening acts as a form of sleep hygiene, providing structure to pre-sleep routine. Systematic review of music listening interventions for sleep in the critically ill, however found that listening duration of >45 to ≤60 min was better at improving sleep quality than shorter listening durations (Chen et al., 2022).

The participants chose different genres of music based on their personal preference, but the pieces listened to tended to be slower in tempo. Participant 2 only had three weeks of music listening during the intervention phase due to a technical difficulty and needed some time to find music with a relaxing effect, hence they may not have been able to derive full benefit from the intervention.

Aside from higher engagement with music listening, those who showed greatest improvements across outcomes, also adhered to sleep hygiene guidance given. For example, participant 2 had an advance sleep phase but was unable to follow advice to get up if not able to fall back to sleep due to feeling they were up too early in the morning. Therefore, incorporating a sleep shifting phase prior to the intervention may therefore be beneficial to some individuals. Future SCED studies could also measure the degree of adherence to sleep hygiene guidance through a checklist.

Strengths, limitations, and future directions

This study represents a pragmatic realistic approach given that the inclusion criteria were broad, and the participants were recruited from a clinical service, with high levels of comorbidity. None of the participants were taking sleep medication on entering the study. Despite a clinical sample, the current study has a 100% completion rate compared to 83% reported in a post-stroke music listening study (Baylan et al., 2020b) and ~ 75% reported in the review of eCBT-I interventions in the general population (Zachariae et al., 2016). This study also benefits from the use of single case methodology as this allows greater control of non-intervention related factors such as time and detailed assessment of the pattern changes. In addition, the intervention has potential to offer a low-cost option for treating insomnia.

One of the limitations of this study is that the intervention combines two active components: sleep hygiene and mindful music-listening due to sleep hygiene being recommended in the clinical treatment guidelines making it difficult to disentangle their individual contribution to treatment effects. Visual analysis of the data suggests that for participants who benefitted from the intervention, changes occurred relatively quickly indicating that sleep hygiene likely plays a crucial part in improving sleep. However, although sleep hygiene is an important element of most non-pharmacological interventions for sleep, there is no evidence to support its effectiveness as a single-component or monotherapy for insomnia (Irish et al., 2015). Some of the participants reported that mindful music-listening supported their evening routine and helped calm their mind, indicating that mindful music-listening may have a dual role in supporting sleep. Further research would benefit from qualitative assessment of participants' experiences to aid the understanding of the contribution of the two components.

Another limitation of the current study is that the assessor was not blind to treatment phase, however assessment bias was reduced through participants recorded sleep diaries and objective assessment of sleep using an actiwatch. A further limitation is that this study did not assess the impact of the intervention on participants' bed partner sleep. Future studies should consider assessing changes given that both bed partners in the current study expressed that their sleep had also improved.

2.7 Conclusions

Mindful music-listening, incorporating sleep hygiene, appears promising for improving insomnia symptoms with positive impact seen on several sleep outcomes and mood post-stroke. The findings for fatigue and daytime sleepiness were mixed. The findings are particularly encouraging given the shorter duration of the current intervention compared to CBT-I. Overall, this study provides preliminary data on its effectiveness and supports planning of a larger intervention trial to address sleep difficulties post-stoke using a non-pharmacological approach.

Funding

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Conflicts of interests

None

2.8 References

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Appendixes

1.1 PROSPERO registration

Music for sleep: An umbrella review of music-based interventions for sleep in adults

Citation

Satu Baylan, Maria Gardani, Kirsty Moore, Megan Montgomery, Jonathan Evans. Music for sleep: An umbrella review of music-based interventions for sleep in adults. PROSPERO 2023 CRD42023404788 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42023404788

Review question

What are the characteristics of music-based interventions aimed at improving sleep in adults?

What is the current evidence for supporting the effectiveness of music-based interventions in improving sleep in adults?

Searches

We will search the following databases:

Ovid (MEDLINE)

Ovid (Embase)

CINAHL (EBSCO host)

PsycINFO (EBSCO host)

Cochrane database of systematic review

Epistemonikos.org

Web of Science core collection

Restrictions: reviews published in English

Search strategy

https://www.crd.york.ac.uk/PROSPEROFILES/404788_STRATEGY_20230517.pdf

Types of study to be included

Systematic reviews with or without meta-analysis. We place no restriction on the type(s) of quantitative study designs of the included reviews. Where a previously published review has been updated (e.g. Cochrane Reviews), we will only include data from the most recently published review in our synthesis to avoid double counting included studies.

We will exclude reviews of qualitative studies. Where reviews includes both qualitative and quantitative studies, we will report the findings related to quantitative studies only.

Condition or domain being studied

Music based interventions for sleep in adults in any setting.

Sleep is essential to human health and wellbeing including cognitive and psychological functioning. Cognitive Behavioural Therapy (CBT) is the recommended treatment for insomnia but evidence other approaches to improve sleep in adults, with or without a sleep disorder is emerging. This umbrella review aims to synthesise evidence from existing reviews focused on music-based interventions for sleep.

Participants/population

Adults, aged 18 or over, with or without a diagnosed sleep disorder.

We will exclude reviews of pediatric populations. If the review includes studies of both children and adults, we will only report the findings related to adults.

Intervention(s), exposure(s)

We will include reviews focused on any types of music-based interventions for sleep (e.g. music therapy, music listening). We place no restrictions on intervention dose, duration, delivery method or person delivering the intervention.

We will exclude reviews focused on other non-pharmacological or psychological interventions for sleep that do not involve music as their focus, as well as reviews of pharmacological interventions and non-music based auditory stimulation (e.g. white noise).

Comparator(s)/control

We will include any type of comparator: treatment as usual, active psychological or pharmacological interventions, passive interventions (e.g waitlist control), no intervention.

Context

We place no restrictions on the setting or country.

Main outcome(s)

Change in subjective/objective sleep characteristics and/or insomnia symptoms, assessed using sleep diaries, standardised questionnaires or actigraphy.

Measures of effect

We place no restrictions on the measures of effect used in the included reviews.

Additional outcome(s)

We will describe other psychological outcome variables collected (e.g. change in depressive symptoms) but we will not draw conclusions based on these.

Measures of effect

We place no restrictions on the measures of effect used in the included reviews.

Data extraction (selection and coding)

Titles and abstracts generated from electronic database searches will be screened for relevance by two independent reviewers. Copies of full-text articles identified during the initial screening will be obtained and they will be assessed for inclusion by two reviewers. Disagreement will be resolved by discussion or by involving a third arbitrator if needed.

A study specific proforma will be created, piloted on two relevant papers and refined as necessary. We will extract data

on:

• Publication details (authors, year, reference details, possible conflicts of interest)

• Review type and focus (systematic review, meta-analysis including model used (random, fixed-effect); review aim/objective)

• Included study characteristics (number of included studies; types of included study designs, settings, countries, critical appraisal summary)

• Participant characteristics (number of participants, age range, gender, type of population/clinical group, comparison group)

• Comorbidity (where reported current/premorbid psychological, psychiatric or physical health problems, medication use)

• Music-based intervention characteristics (type of intervention, dose, duration, mode of delivery, person delivering intervention, music selection, music type, comparator)

• Outcome measures and outcomes (definition of sleep or sleep disorder, assessment method (e.g. actigraphy, questionnaire); name of instrument used; main results. For meta-analyses, effect estimates and 95% confidence intervals for the largest study in each meta-analysis, heterogeneity diagnostics, funnel plot asymmetry statistics.

Where a review is believed to include usable data but these have not been included in the publication, we will attempt to contact the authors for further information.

Risk of bias (quality) assessment

To assess the quality of the included reviews, we will use the Assessment of Multiple Systematic Reviews (AMSTAR 2). Ratings will be performed by two reviewers. Discrepancies will be resolved by discussion or by involving a third arbitrator, if required.

Strategy for data synthesis [1 change]

We will describe sample and intervention characteristics of the included systematic review both in tabular and narrative formats.

We will extract, and provide a tabular and narrative synthesis of the main outcomes and findings of the included reviews using the format used in the original review. For meta-analytic reviews, we will extract report effect estimates with 95% confidence intervals and provide a narrative summary of these.

We will provide and tabular and narrative synthesise the quality of included reviews using the AMSTAR 2 rating tool.

Analysis of subgroups or subsets

Where possible, we will describe and synthesis evidence separately for clinical and non-clinical populations (e.g. individuals with sleep disorder vs without sleep disorder; individuals with neurological/psychological disorder vs. healthy adults).

Contact details for further information

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NHS Greater Glasgow and Clyde

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Ms Kirsty Moore. University of Glasgow / NHS Greater Glasgow and Clyde

Ms Megan Montgomery. University of Glasgow

Professor Jonathan Evans. University of Glasgow

Type and method of review

Review of reviews, Systematic review

Anticipated or actual start date

23 February 2023

Anticipated completion date

29 December 2023

Funding sources/sponsors

None

Grant number(s)

State the funder, grant or award number and the date of award

Not applicable

Conflicts of interest

Language

English

Country

Scotland

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Adult; Humans; Music; Music Therapy; Sleep

Date of registration in PROSPERO

30 May 2023

Date of first submission

17 May 2023

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions

30 May 2023

1.2 Search strategy for Ovid Medline

1. exp Music/
2. exp Music Therapy/
3. music*.mp.
4. listen*.mp.
5. 1 or 2 or 3 or 4
6. exp Sleep/
7. exp Sleep Wake Disorders/
8. exp "Sleep Initiation and Maintenance Disorders"/
9. exp Sleep Quality/
10. sleep*.mp.
11. insomnia*.mp.
12. bed*.mp.
13. Pittsburgh sleep quality index.mp.
14. psqi.mp.
15. 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
16. Meta-Analysis as Topic/
17. meta analy$.tw.
18. metaanaly$.tw.
19. Meta-Analysis/
20. (systematic adj (review$1 or overview$1)).tw.
21. exp Review Literature as Topic/
22. 16 or 17 or 18 or 19 or 20 or 21
23. cochrane.ab.
24. embase.ab.
25. (psychlit or psyclit).ab.
26. (psychinfo or psycinfo).ab.
27. (cinahl or cinhal).ab.
28. science citation index.ab.
29. bids.ab.
30. cancerlit.ab.
31. 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32. reference list$.ab.
33. bibliograph$.ab.
34. hand-search$.ab.
35. relevant journals.ab.
36. manual search$.ab.
37. 32 or 33 or 34 or 35 or 36
38. selection criteria.ab.
39. data extraction.ab.
40. 38 or 39
41. Review/
42. 40 and 41
43. Comment/
44. Letter/
45. Editorial/
46. animal/
47. 44 or 45 or 46
48. 22 or 31 or 37 or 42
49. 48 not 47
50. 5 and 15 and 49

1.3 Excluded full-texts with reasons

Conference proceeding

De Niet, G., Tiemens, B., Lendemeijer, B., Hutschemaekers, G. (2008). Music, a sound way to sleep? *Journal of Sleep Research*, 17, 248-248.

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Literature review / Review not meeting systematic review criteria

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Dickson, G. T., & Schubert, E. (2020). Music on Prescription to Aid Sleep Quality: A Literature Review. *Frontiers in psychology*, 11, 1695.

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Meghani, N., Tracy, M. F., Hadidi, N. N., & Lindquist, R. (2017). Part I: The Effects of Music for the Symptom Management of Anxiety, Pain, and Insomnia in Critically ill Patients: An Integrative Review of Current Literature. *Dimensions of critical care nursing: DCCN*, 36(4), 234–243.

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Skingley, A., Vella-Burrows, T. (2010). Therapeutic effects of music and singing for older people. *Nursing standard (Royal College of Nursing (Great Britain)*: 1987, 24(19), 35–41.

Pre-registration

Bissonnette, J., Dumont, E., Pinard, A-M., Landry, M., Rainville, P., Ogez, D. (2022). Hypnosis and music interventions for pain, anxiety, sleep, and well-being in palliative care: a systematic review and meta-analysis, *medRxiv* 2022.01.20.22269568

Previous version of updated review

Jespersen KV, Koenig J, Jennum P, Vuust P. Music for insomnia in adults. (2015). *Cochrane Database of Systematic Reviews*, Issue 8. Art. No.: CD010459.

Review commentary

Andrews, L, SPQ (Renal). (2016) Music for Insomnia in Adults. *Clinical Nurse Specialist* 30(4), 198-199.

Wrong language
Zhu, B., Li X. (2013). Effect of music therapy on sleep quality: a meta-analysis. *Journal of Nursing Science*, 28(21), 80-83

Wrong outcome
Bissonnette, J., Dumont, E., Pinard, A. M., Landry, M., Rainville, P., & Ogez, D. (2022). Hypnosis and music interventions for anxiety, pain, sleep and well-being in palliative care: systematic review and meta-analysis. *BMJ supportive & palliative care*, bmjspcare-2022-003551. Advance online publication.

de Jong JC, Maroda AJ, Camacho M, Chen PG. (2020). The Impact of Playing a Musical Instrument on Obstructive Sleep Apnea: A Systematic Review. *Annals of Otology, Rhinology & Laryngology*, 129(9), 924-929.

1.4 Review level AMSTAR 2 risk of bias ratings

	AMSTAR 2 checklist item																
Author, year	**Q1**	**Q2***	**Q3**	**Q4***	**Q5**	**Q6**	**Q7**	**Q8**	**Q9***	**Q10**	**Q11***	**Q12**	**Q13***	**Q14**	**Q15***	**Q16**	Critical weakness
Chen2022	Yes	Yes	No	No	Yes	Yes	No	Partial Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	1
Chen 2021	Yes	No	Yes	No	No	No	No	Partial Yes	Yes	No	Yes	No	No	No	No	Yes	4
deNiet 2009	No	No	No	No	No	No	No	Yes	Partial yes	No	Yes	Yes	Yes	Yes	Yes	Yes	2
Fang 2023	Yes	Partial Yes	Yes	Partial Yes	Yes	Yes	No	Partial Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	0
Feng 2018	Yes	No	Yes	Partial Yes	No	Yes	No	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	2
Gassner 2022	Yes	No	No	No	Yes	Yes	No	Yes	Yes	No	No meta-analysis conducted	No meta-analysis conducted	Yes	No	No meta-analysis conducted	Yes	2
Huang 2020	Yes	No	No	Partial Yes	Yes	Yes	No	Partial Yes	Yes	No	No meta-analysis conducted	No meta-analysis conducted	Yes	Yes	No meta-analysis conducted	Yes	1
Jespersen 2022	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	0
Kakar 2021	Yes	Yes	No	Partial Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	1
Mu 2022	No	No	No	No	Yes	No	No	No	No	No	No meta-analysis conducted	No meta-analysis conducted	Yes	Yes	No meta-analysis conducted	Yes	3
Petrovsky 2021	No	No	No	No	Yes	Yes	No	Yes	Yes	No	No meta-analysis conducted	No meta-analysis conducted	No	Yes	No meta-analysis conducted	Yes	3
Tang 2022	Yes	Yes	No	Partial Yes	Yes	Yes	No	Partial Yes	Yes	No	Yes	No	Yes	No	No	Yes	1
vanderWeijden 2020	Yes	Yes	Yes	Partial Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes	Yes	Yes	2
Wang 2021	Yes	No	Yes	Partial Yes	Yes	Yes	No	Yes	Yes	No	No	No	No	Yes	No	Yes	4
Wang 2014	No	No	Yes	Partial Yes	Yes	No	Yes	No	Partial yes	No	No	No	No	Yes	Yes	Yes	3
Yang 2021	Yes	No	Yes	Partial Yes	Yes	Yes	No	Partial Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	1

* critical domain

2.1 Study protocol

Available via Open Science Framework:
https://osf.io/4hmnz/?view_only=4b5c98df53e7424da65f9c890d596011

2.2 Ethical approval

Revised sg 16/02/23 at applicants request to alter internal reference number and remove superseded version of protocol.

NHS
Health Research Authority

East Midlands - Derby Research Ethics Committee
Equinox House
City Link
Nottingham
NG2 4LA

14 February 2023

Professor Jonathan Evans
Professor of Clinical Neuropsychology
University of Glasgow
Mental Health & Wellbeing
Academic Centre
Gartnavel Royal Hospital
G12 0XH

Dear Professor Evans

Study title:	**Mindful music-listening as a tool to improve sleep post-stroke: A single case experimental design study**
REC reference:	**23/EM/0033**
Protocol number:	**N/A**
IRAS project ID:	**312921**

Thank you for your letter of 10 February 2023, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation on 13 February 2023.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants

4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:
https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

Revised sg 16/02/23 at applicants request to alter internal reference number and remove superseded version of protocol.

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Revised sg 16/02/23 at applicants request to alter internal reference number and remove superseded version of protocol.

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]		10 February 2023
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Indemnity UoG - Clinical Trials - 2022-2023 Client Information Letter]		20 July 2022
GP/consultant information sheets or letters [IRAS312921 GN22ST470_GP letter V1.1 02112022]	V1.1	02 November 2022
GP/consultant information sheets or letters [IRAS312921 GN22ST470_Recruiting clinician information V1.1]	V1.1	10 February 2023
GP/consultant information sheets or letters [Recruiting clinician information]	V1.1 tracked	10 February 2023
Interview schedules or topic guides for participants [IRAS312921 GN22ST470_Mindful music listening summary V1.0]	V1.0	25 November 2022
Interview schedules or topic guides for participants [IRAS312921 GN22ST470_Intervention manual researcher copy Musas_Final]	V1.0	25 November 2022
Interview schedules or topic guides for participants [IRAS312921 GN22ST470_Using an IPod_Musas]	V1.0	25 November 2022
Interview schedules or topic guides for participants [IRAS312921 GN22ST470_Sleep problems after stroke]		
Interview schedules or topic guides for participants [IRAS312921 GN22ST470 AA leaflet_Stroke Psychology]		
Interview schedules or topic guides for participants [IRAS312921 GN22ST470_Intervention manual researcher copy Musas_Final]	V1.1	10 February 2023
Interview schedules or topic guides for participants [Intervention manual]	V1.1 tracked	10 February 2023
IRAS Application Form [IRAS_Form_23122022]		23 December 2022
IRAS Checklist XML [Checklist_13022023]		13 February 2023
Other [Response to REC provisional opinion]		10 February 2023
Participant consent form [IRAS312921 GN22ST470 Consent form MUSAS V1.2]	1.2	14 February 2023
Participant consent form [IRAS312921 GN22ST470 Consent form MUSAS V1.2 tracked]	1.2 tracked	14 February 2023
Participant information sheet (PIS) [IRAS312921 GN22ST470 PIS MUSAS V1.1 15122022]	V1.2	10 February 2023
Participant information sheet (PIS) [PIS V1.2 tracked]	V1.2 tracked	10 February 2023
Protocol [IRAS312921 GN22ST470 Research Governance Protocol Musas V1.1 15122022]	1.2	10 February 2023
Research protocol or project proposal [IRAS312921 GN22ST470 Research Governance Protocol Musas V1.1 15122022]	V1.2 tracked	10 February 2023
Sample diary card/patient card [IRAS312921 GN22ST470_Music listening diary V1.0 27102022]	V1.0	27 October 2022
Sample diary card/patient card [IRAS312921 GN22ST470_Sleep diary V1.0 27102022]	V1.0	27 October 2022
Summary CV for Chief Investigator (CI) [CV_Evans]		22 April 2022
Summary CV for student [CV_Baylan]		27 October 2022
Summary CV for supervisor (student research) [CV_Gardani_Collaborator]		31 October 2022
Summary CV for supervisor (student research) [CV_Irvine_Local lead clinician]		01 November 2022
Validated questionnaire [IRAS312921 GN22ST470_GAD7]		

Revised sg 16/02/23 at applicants request to alter internal reference number and remove superseded version of protocol.

Validated questionnaire [IRAS312921 GN22ST470_PHQ9]		
Validated questionnaire [IRAS312921 GN22ST470_ESS]		
Validated questionnaire [IRAS312921 GN22ST470_Fatigue Severity Scale (FSS)]		
Validated questionnaire [IRAS312921 GN22ST470_Sleep Condition Indicator (SCI)]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 312921 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Mrs Janet Mallett
Chair

Email:derby.rec@hra.nhs.uk

Enclosures:

After ethical review guidance for sponsors and investigators –
Non CTIMP Standard Conditions of Approval]

Copy to: Dr Colette Montgomery Sardar,

2.3 Greater Glasgow and Clyde management approval

Coordinator: Mr Graeme Piper
Telephone Number: 0141 314 0222
E-Mail: Graeme.Piper@ggc.scot.nhs.uk
Website: https://www.nhsggc.org.uk/about-us/professional-support-sites/research-innovation/

Research & Innovation
Dykebar Hospital, Ward 11
Grahamston Road
Paisley, PA2 7DE
Scotland, UK

17 February 2023

Dr Satu Baylan
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
G51 4TF

NHS GG&C Board Approval

Dear Dr Baylan

Study Title:	Mindful music-listening as a tool to improve sleep post-stroke: A single case experimental design study
Principal Investigator:	Dr Satu Baylan
GG&C HB site	NHSGGC Stroke Service Facilities (Queen Elizabeth University Hospital, Royal Alexandra Hospital, Glasgow Royal Infirmary, Stobhill Hospital, Inverclyde Royal Hospital, West Glasgow Ambulatory Care Hospital)
Sponsor	NHS Greater Glasgow and Clyde
R&I reference:	GN22ST470
REC reference:	23/EM/0033
Protocol no: (including version and date)	V1.2 10.02.2023

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file. Researchers must follow NHS GG&C local policies, including incident reporting.

2. **For all studies** the following information is required during their lifespan.
   a. First study participant should be recruited within 30 days of approval date.

b. Recruitment Numbers on a monthly basis
c. Any change to local research team staff should be notified to R&I team
d. Any amendments – Substantial or Non Substantial
e. Notification of Trial/study end including final recruitment figures
f. Final Report & Copies of Publications/Abstracts
g. You must work in accordance with the current NHS GG&C COVID19 guidelines and principles.

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

Mr Graeme Piper
Research Co-ordinator

2.4 Participant information sheet

Participant Information Sheet

Music for Sleep after Stroke

You are being invited to take part in a research study. Before you decide whether to participate, it is important that you understand why the research is being done and what it will involve. Please take time to read this information carefully and discuss it with others if you wish. If you would like more information, please ask. You do not have to decide immediately.

1. What is the purpose of this study?

People can experience a number of difficulties after having a stroke, including difficulties with **sleep.** These can include **difficulties falling asleep, staying asleep, not being able to get back to sleep or waking up too early in the morning**. When these difficulties are present for at least three nights a week, over a period of at least three months, this is referred to as **insomnia**. Cognitive Behavioural Therapy for Insomnia (CBT-I) is recommended as the non-medication approach for treating insomnia, however this has been poorly researched in individuals with stroke. Both music-based and mindfulness-based interventions have been shown to improve insomnia symptoms or sleep quality. **Combining a music listening intervention and a mindfulness-based intervention** may therefore increase the benefit that could be gained from either alone. We have developed a combined **mindful music-listening intervention** that has been shown to be acceptable and enjoyable to individuals following stroke. We now want to see if it can be used to improve sleep, mood and fatigue post-stroke. Our aim is to use our findings to **inform clinical treatments for people with stroke.**

2. Why have I been invited to participate?

You are being invited to take part because you have had a stroke more than three months ago.

3. Do I have to take part?

No, you can decide whether to participate. Even if you decide to take part, you are free to withdraw at any time and without giving a reason by contacting a member of the study team. This would not affect your current or future treatment.

4. What does taking part involve?

If you decide to take part, you will be asked to sign a consent form to show you have agreed to participate. You will be given information on **sleep hygiene** (things you can do that may help you sleep better), followed by a **5-week mindful music-listening intervention** and a follow-up visit. You will be asked to complete brief questionnaires before, at the end of the intervention and at follow-up. You will also be given an **actiwatch** to wear on your wrist for the duration of the study. The actiwatch records motion and light and will provide us with information about your sleep/wake pattern.

Visit / Activity	1	2	3	4	5	6	7	8
Questionnaires								
Sleep intervention								
Actiwatch								
Diaries								

Questionnaires

At the first visit, we will ask you to complete short questionnaires assessing your **sleep, mood and fatigue**. You will be asked to complete these same questionnaires again at the final intervention visit, and three weeks after the end of the intervention to assess change.

Mindful music-listening intervention for sleep

After your first appointment, **you will** be randomly allocated to **start the intervention after 7, 11 or 15 days**. The random allocation is important for the scientific quality of the study as this will allow us to assess whether any changes in your sleep are a result of the intervention, rather than some other non-relevant factor.

At the start of the intervention, you will be given information on sleep hygiene, and we will explore your music preferences. This visit will last approximately 45 minutes. At the second intervention visit, you will be introduced to the concept of mindful music-listening and supported to select listening material based on your personal music preferences using Spotify (or equivalent with free subscription provided for the duration of the study). This and subsequent visits will be up to 30 minutes long. Throughout the intervention phase, you will be asked to **listen to your material for 30 minutes before bedtime each day** using a mobile device (an iPod can be provided for the duration of the study for participants who do not have access to a suitable device), and to keep a short daily diary of time spent listening. The intervention visits can be completed in person or remotely via video-calling or telephone based on individual preference.

5. What are the possible benefits and disadvantages of taking part?

There may be no direct benefit to you. Your participation may help us understand whether mindful music-listening can improve sleep after stroke. Based on previous research, you may also find the intervention enjoyable or relaxing. You will receive no payment for taking part. Where a physical or mental disability prevents you from attending study appointments at a NHS/university facility, the study team may be able support you with travel costs. Please enquire with the research team.

We do not expect there to be any risks or disadvantages in taking part. You will be able to access all your usual treatment and care.

6. Will my GP be informed?

If you are happy for your GP to be contacted, we will send them a letter informing them of your participation. If you would prefer your GP not to be informed, you can let us know.

7. Will my taking part be kept confidential?

All information during this study will be kept **strictly confidential** and accessible only to the study team**.** NHS research governance staff may also require access to the data for auditing purposes only. We will be collecting and storing identifiable information from you (such as name and contact details). Your identifiable data will be held separately from your study data (such as questionnaires), which will be **anonymised and referred to using an ID code**.

In addition to duty of confidentiality, the research team has a **duty of care.** This means that if information emerges during the study that leads us to believe that you or another person might be at risk of harm (e.g., imminent risk to life), we may need to pass this information to your clinical care team, before we are able to seek your consent.

8. What will happen to my data?

NHS Greater Glasgow and Clyde (NHS GG&C) is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NHS GG&C will keep identifiable information about you for up to one year after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you decide to withdraw from the study or are withdrawn by the study team (e.g. due to significant illness preventing participation or loss of capacity), we will keep the information about you that we have already obtained. To safeguard your rights, we **will use the minimum personally-identifiable information possible**.

You can find out more about how we use your information https://www.hra.nhs.uk/information-about-patients/ or by contacting NHS GG&C Information Governance Department. Tel: 0141 355 2059 Email: data.protection@ggc.scot.nhs.uk

The University of Glasgow will be the data processor for this study. Researchers from the University of Glasgow collect, store and process all personal and research data in accordance with the General Data Protection Regulation (2018). **The research data will be stored in archiving facilities in line with the University of Glasgow retention policy of up to 10 years.** After this period, further retention may be agreed or your data will be securely destroyed in accordance with the relevant standard procedures.

Your identifiable information might be shared with people who check that the study is done properly on behalf of the Sponsor. Your data will form part of the study results that will be published in scientific journal journals, presentations, and Doctorate in Clinical Psychology thesis. Your name will not appear in any publication. You can opt-in to receiving a brief summary of the study findings.

9. Who is conducting and funding the research?

The research is conducted by **Dr Satu Baylan,** Trainee Clinical Psychologist, NHS Greater Glasgow and Clyde (GGC) and University of Glasgow. She is supervised by **Professor Jonathan Evans,** Institute of Mental Health & Wellbeing with support from **Dr Maria Gardani,** University of Edinburgh and **Dr Bruce Irvine**, NHS GGC Community Stroke Team. Funding for the study is provided by the University of Glasgow Doctorate in Clinical Psychology Programme.

10. Who has reviewed the study?

The study has been reviewed by the NHS HRA East Midlands - Derby Research Ethics Committee.

11. Contact for Further Information

Dr Satu Baylan **Email:** Omitted from electronic copy

Prof Jonathan Evans **Tel:** 01412113978 **Email:** jonathan.evans@glasgow.ac.uk

Thank you for taking the time to read this information sheet. If you have any questions or would like some more information, please contact a member of the research team.

If you would like to discuss the study with someone **not** closely linked to the study, please contact: Dr Jessica Fish, University of Glasgow on 0141 211 3917 or Jessica.Fish@glasgow.ac.uk.

Assent to Contact Form

I agree to being contacted by researchers regarding the study entitled « **Music for Sleep after Stroke.** I understand that they will be in contact to discuss the study with me but I am under no obligation to take part. I agree to pass on the following contact details. I understand that if I would like to participate in the study, I will be asked to sign a Consent Form.

Name: _____

Telephone number: _____

Address (including postcode): _____

_____

Email address_____

Please return to Dr Satu Baylan by

(1) Email at

Omitted from electronic copy

OR

(2) Post at
Satu Baylan,
Neuropsychology Rehabilitation Service,
Major Trauma Ward 1C,
Queen Elizabeth University Hospital,
Glasgow G51 4TF

2.5 Consent form

University of Glasgow | College of Medical, Veterinary & Life Sciences

NHS Greater Glasgow and Clyde

Participant Identification Number:

CONSENT FORM

Music for Sleep after Stroke

Satu Baylan, Email Omitted from electronic copy

The University of Edinburgh

Please initial box

1. I confirm that I have read the information sheet dated 10/02/2023 (version 1.2) for the above study. I have had the opportunity to consider the information, ask questions and had these answered. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I agree to the way my data will be collected and processed and that data will be stored for up to 10 years in University facilities in accordance with relevant Data Protection policies and regulations. ☐
4. I understand that all data and information I provide will be kept confidential, and will be seen only by the research team and regulators whose job it is to check the work of researchers. ☐
5. I understand that if I withdraw from the study, my data collected up to that point will be retained and used for the remainder of the study. ☐
6. I understand that sections of my medical notes may be looked at by the research team where it is relevant to my taking part in the research. I give my permission for the research team to have access to my records. ☐
7. I agree to my GP being informed of my participation in the study. Yes / No (please select)
8. I wish to be informed of the results of the study Yes / No (please select)
   If Yes, I wish to be informed using the following method (please complete details for preferred method)
   1. Email _____
   2. Post _____ Postcode _____
3. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person seeking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file

Version 1.2 14/02/2023

2.6 Key study procedures and outcomes schedule

Visit	**1** Baseline	**2** Intervention Session 1 (7,11 or 15 days following baseline)	**3** Intervention Session 2	**4** Intervention Session 3	**5** Intervention Session 4	**6** intervention Session 5	**7** End of intervention (one week following visit 6 (allowance + 2 weeks)	**8** Follow-up (3 weeks after end of intervention, allowance +3 weeks)
Consent								
Sleep diary								
Sleep hygiene								
Music-listening + diary								
Actigraphy								
SCI								
ESS								
PHQ-9								
GAD-7								
FSS								

2.6 Sleep diary

Sleep diary

Start date ____/_____/_____

	Day 1 _____	Day 2 _____	Day 3 _____	Day 3 _____	Day 4 _____	Day 5 _____	Day 6 _____	Day 7 _____
Evening								
Time I went to bed at	pm/am	pm/am	pm/am	pm/am	pm/am	pm/am	pm/am	pm/am
Time taken to fall asleep	mins	mins	mins	mins	mins	mins	mins	mins
Morning								
Time I woke up	am/pm	am/pm	am/pm	am/pm	am/pm	am/pm	am/pm	am/pm
Time I got out of bed	am/pm	am/pm	am/pm	am/pm	am/pm	am/pm	am/pm	am/pm
When I woke up, I felt: 1 Refreshed 2 Somewhat refreshed 3 Fatigued	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
During the night								
Number of times I woke up								
Total time I spent awake during the night	mins	mins	mins	mins	mins	mins	mins	mins
What disturbed my sleep (e.g. noise, light, temperature, pain, stress, need to use toilet)								
Total sleep								
How much sleep did I get in total (hrs, mins)								

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