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a randomized controlled trial using mixed methods design

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MUSIC TO IMPROVE SLEEP IN ADULTS WITH DEPRESSION RELATED INSOMNIA: A RANDOMIZED CONTROLLED TRIAL USING MIXED METHODS DESIGN

BY
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CV

Helle Nystrup Lund is a music therapist and jazz pianist. Her work reflects a life-long interest in music, health and psychiatry. After working at the music therapy department at Aalborg University for 13 years, and establishing a private music therapy clinic, she continued her career in psychiatry in 2004. Her clinical work has covered a broad range of methods and patients from the intensive care units to out-patients in follow up treatment. Her therapeutic approach has a psychodynamic foundation and she is a certified cognitive therapist. She has a genuine interest in research at both national and international level. She has communicated her work at international conferences in psychiatry and music therapy for many years. She is co-inventor of the MusicStar app. Beside the four studies of her Ph.D. thesis, she has published in the area of music and health as well as disseminated her work publicly in radio and TV.

During the Ph.D. studies Helle has given oral presentations at the congress for Violence in psychiatry (Dublin, 2017), the European Music Therapy Congress (EMTC2019, Aalborg, 2019), Congress for Music in Psychiatry, Lausanne, Switzerland (HEMU2020) and for the national Danish network for psychiatrists working in depression (Copenhagen 2019). Additionally, she has provided poster presentations at European Psychiatric Association conferences in Firenze (EPA2017), Warsaw (EPA2019) and the Nordic Congress of Music Therapy in Stockholm (NMTC2019). Furthermore, she has joined the research network in music and public health, CREMAH and attended Nordic network meetings in Stockholm and Kristiansand.

ENGLISH SUMMARY

This dissertation investigated the effectiveness of music in improving sleep quality, depression and quality of life in depressed patients with sleep disturbances.

Background

Depression patients with sleep disturbances are in risk of relapse and worsening of symptoms due to poor sleep. Resolving sleep disturbances are difficult. While medication treatments include adverse effects as dependence, the first line non-pharmacological treatment, cognitive behavioral therapy, has limited availability and only partial focus on sleep and it is rejected by some patients.

Music intervention may take place in the home and does not require attendance in hospital clinics. The intervention has the potential to meet the needs of patients seeking alternatives to conventional treatments and offering potential treatment benefit without compliance to appointments.

Studies have shown calming effects of music listening at bedtime and improved sleep quality in populations with sleep disturbances. Still, there is little knowledge of the effect of music on sleep in depression-related sleep disturbances.

Method

The dissertation utilized a mixed methods study design comprising four studies.

STUDY I (Sound and music interventions in psychiatry at Aalborg University Hospital) was an overview article presenting the background for sound and music interventions in psychiatry at Aalborg University Hospital including pilot projects, literature, theoretical foundation and methodology. The study highlighted the development of the MusicStar app, playlists and log function.

STUDY II (Music to improve sleep quality in adults with depression-related insomnia: study protocol for a randomized controlled trial) presented the study protocol for a randomized controlled trial. We aimed to conduct a study investigating music intervention as a sleep aid for patients with depression and sleep disturbances. The investigation comprised adult outpatients in depression treatment with sleep disturbances divided in two groups; a music intervention group listening to bedtime music at minimum 30 minutes, and a waitlist-control group. The waitlist control group received treatment as usual and were offered the music intervention post treatment. The study protocol presented the methods and procedures to investigate sleep, depression symptoms and quality of life with questionnaires and actigraphy in a four-week period with a four week follow up period.

STUDY III (Music to improve sleep quality in adults with depression-related insomnia: randomized controlled trial) reported the results from the RCT described in Study II.

STUDY IV (Music, sleep and depression: An interview study) investigated patients' experiences of bedtime music listening in four weeks. Four participants from the study volunteered for an interview and their experiences were analyzed and reported in six themes; sleep and relaxation, distraction, mood, preference and technology.

Results

The RCT included 112 patients with depression and sleep disturbances of whom 102 patients completed. The music intervention group showed improved sleep quality and quality of life after four weeks of music listening compared to the control group. There were no changes in depression symptoms and objective sleep measures by actigraphy did not provide valid data. Log files from the MusicStar app showed that most participants adhered to music intervention but more frequently at other times than the bedtimes they indicated in questionnaires. Analysis of sleep duration pointed to prolonged nocturnal sleep by 18 minutes for the participants listening to music. The results suggest moderate effects of music on sleep quality and quality of life. Considering low attrition and absence of adverse effects, music intervention is suggested as a supplement to existing treatments improving sleep in depression.

The interview study reported patients' experiences of music highlighting effects of sleep and relaxation. The effects of music comprised distraction from inner stimuli, arousal regulation, positive influences on mood and support of bedtime habit formation. Three of four participants reported positive effects of music improving relaxation and sleep. One participant did not benefit from music intervention. The participant reported frustration and descending mood. She habitually listened to audiobooks with sleep inducing effects. The interviews pointed to the interplay of multiple underlying mechanisms for music to aid sleep, relaxation and wellbeing.

Conclusion

The studies add to the evidence base suggesting music as a non-pharmacological self-help intervention in treating sleep disturbances related to depression. The studies contribute to the understanding of the multiple effects of music and the interplay of underlying mechanisms of action.

DANSK RESUME

Denne afhandling havde til formål at undersøge effekten af musik til forbedring af søvnkvalitet for voksne psykiatripatienter med depressions-relaterede søvnproblemer.

Baggrund

For gruppen af patienter med unipolar depression er dårlig søvnkvalitet et ofte forekommende symptom, der forværrer tilstanden og forlænger sygdomsforløbet. Kliniske retningslinjer anbefaler ikke længere farmakologisk behandling af søvnforstyrrelser idet medicin kan være vanedannende og forbundet med bivirkninger. Kognitiv terapi anbefales som ikke-medicinsk behandling af søvnbesvær, men der er behov for at afsøge alternativer, da kognitive terapiforløb i depressionsbehandlingen kun omhandler søvn i begrænset omfang og ikke alle patienter ønsker denne terapi. Musik intervention kan tilbydes som supplement til den eksisterende behandling og der kræves ikke fremmøde idet musiklytning foregår i hjemmet. Denne behandlingsform kan potentielt tiltale en gruppe patienter som efterspørger alternativer til konventionelle behandlingsmetoder og hvor fremmødestabilitet ikke er en forudsætning for udbytte.

En række undersøgelser peger på at musik ved sengetid virker beroligende og kan forbedre søvnkvaliteten for en række målgrupper, men studierne er små og det vides ikke om musiklytning kan forbedre søvnen når søvnproblemerne er forbundet med depression.

Metode

Afhandlingen anvendte et mixed methods design og omfattede fire studier.

Studie I (Sound and music interventions in psychiatry at Aalborg University Hospital) var en oversigtsartikel der præsenterede baggrund for musikintervention i psykiatrien på Aalborg Universitetshospital, herunder pilotprojekter, litteratur på området, teori og metode. Desuden beskrev vi udviklingen af Musikstjernen (app), samt spillelister og logfunktion til dataindsamling omhandlende musikbrug.

Studie II (Music to improve sleep quality in adults with depression-related insomnia: study protocol for a randomized controlled trial) beskrev protokollen for et RCT-studie. Vi ville udføre et RCT med to forsøgsgrupper; en eksperimentalgruppe der lyttede til musik ved sengetid i minimum 30 minutter i 4 uger og en venteliste-kontrolgruppe, som fik standard behandling og tilbud om musiklytning efter forsøget. Målgruppen var voksne patienter mellem 18 og 65 år i ambulant behandling for depression og søvnproblemer. Vi undersøgte deltagernes søvn, depression og

livskvalitet med spørgeskemaer og accelerometer. Artiklen gjorde rede for forsøgsprocedurer og målemetoder, så forsøget kan gentages.

Studie III (Music to improve sleep quality in adults with depression-related insomnia: randomized controlled trial) afrapporterede resultater fra det randomiserede kontrollerede forsøg som beskrevet i studie 2.

Studie IV (Music, sleep and depression: An interview study) undersøgte fire forsøgsdeltageres erfaringer med musik til natten. Patienterne deltog i et interview med en ekstern forsker. Indholdet fra interviewene blev analyseret og grupperet i seks temaer som beskrev musikkens effekt; søvn/afslapning, afledning, humør, vaner, præferencer og teknologi.

Resultater

I alt 112 patienter deltog i RCT studiet hvoraf 102 gennemførte. Resultaterne viste at musiklytning i fire uger forbedrede søvnkvalitet og livskvalitet sammenlignet med en kontrolgruppe, mens musik ikke ændrede depressionssymptomerne. Resultaterne viste en moderat forbedring af søvnkvalitet og livskvalitet fra selvrapporterede spørgeskemaer mens accelerometer målinger ikke bidrog med valide resultater til undersøgelsen. Logfil analyser fra Musikstjerne-appen viste at de fleste deltagere havde lyttet til musik, men overvejende på andre tidspunkter end sengetiden som de havde angivet i spørgeskemaerne. Analyser af søvnvarighed viste at deltagerne der havde lyttet til musik, forlængede nattesøvnen med 18 minutter. Sammenholdt med et meget lavt frafald, deltagertilfredshed og fravær af bivirkninger, indikerede resultaterne at musik intervention kan supplere den aktuelle behandling til forbedring af søvn for voksne med depressions-relaterede søvnproblemer.

Interviewstudiet viste at tre af fire interviewdeltagere oplevede at musikintervention havde en positiv effekt på søvn og livskvalitet. Deltagerne beskrev musikkens beroligende virkning fysisk og mentalt, afledende funktion og musik støttede god søvnhygiejne for to deltagere. En deltager havde ikke udbytte af musiklytning og oplevede at musiklytning gav frustration og nedsat humør. Hun lyttede almindeligvis til lydbøger ved sengetid med positiv effekt. Interviewene pegede på et sammenspil af faktorer og psykologiske mekanismer som fandt sted ved musiklytning. Resultaterne bidrog til forklaring af musikkens sammensatte og til dels subjektivt betingede effekter.

Konklusion

Studierne bidrager til evidensgrundlaget for brug af musik som ikke-medicinsk selvhjælps-intervention til forbedring af søvn i depressionsbehandlingen, samt til forståelsen af faktorer og mekanismer der forklarer musikkens virkning.

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Finally, I am very thankful to the patients who gave consent to participate and made it possible to conduct this study. I send them my best wishes.

LIST OF STUDIES

This thesis is based on the following articles. In the text they are referred to by the number.

STUDY I

Lund HN, Bertelsen LR, & Bonde LO. Sound and music interventions in psychiatry at Aalborg University Hospital. *Sound Effects - An Interdisciplinary Journal of Sound and Sound Experience*, *6*(1), 48-68. (2016)

STUDY II

Lund HN, Pedersen IN, Johnsen SP, Heymann-Szlachcinska AM, Tuszewska M, Bizik G, Larsen JI, Kulhay E, Larsen A, Grønbech B, Østermark H, Borup H, Valentin JB, Mainz J. Music to improve sleep quality in adults with depression-related insomnia (MUSTAFI): study protocol for a randomized controlled trial. *Trials.* 21(1):305. (2020)

STUDY III

Lund HN, Pedersen IN, Heymann-Szlachcinska AM, Tuszewska M, Bizik G, Larsen JI, Kulhay E, Drago, A, Larsen A, Grønbech B, Østermark H, Borup H, Bertelsen, LR, Valentin JB, Mainz J. Johnsen SP, Music to improve sleep quality in adults with depression-related insomnia (MUSTAFI): randomized controlled trial. (2021) *In manuscript.*

STUDY IV

Lund HN, Hannibal NJ, MacDonald R, Mainz J, Pedersen IN. Music, depression and sleep: an interview study. *Psychology of music.* (2021)1-19.

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ABBREVIATIONS

ADHD	Attention Deficit Hyperactivity Disorder
CBT	Cognitive Behavioral Therapy
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
COPD	Chronic obstructive pulmonary disease
DSM	Diagnostic and Statistical Manual of Mental Disorders
ICD	International Classification of Diseases
ICU	Intensive Care Units
HAM-D	Hamilton Depression Rating Scale
MUSTAFI	MusicStar for Insomnia
PSQI	Pittsburgh Sleep Quality Index
QUAL	Qualitative
QUAN	Quantitative
REDCAP	Research Data Capture
RCT	Randomized Controlled Trial
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
WHO-5	World Health Organization Well-being index
WHOQOL-BREF	World Health Organization Quality of Life

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Tables

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COMPETING INTERESTS

The author is co-inventor of the MusicStar app and has economic interests due to ownership and sales of the app.

PREFACE

When working in intensive care psychiatry with severely disturbed and distressed patients, I was very welcomed by patients and caregivers. It seemed obvious to all that music had something to offer, either playing or listening, music encouraged ways to positively engage and socialize. Often, I met patients who were exhausted and extremely tired after long periods of malfunction. Communication was limited, sometimes distorted and aggressive. At appointments in the patients' room, I found myself sitting at the bed side listening to music with the patient lying in bed. This was a moment of ease, a time-out from troubles and pain and music listening did not demand much but to receive. Sometimes the patient fell asleep during the session. This situation caused some ambivalence for me sitting passive aside the sleeping patient. The music was simply doing the job and I only came to appreciate these moments when seeing the expression of relief in the nurses coming by for a safety check.

It became evident that sleep was paramount to treatment progress, communication with health professionals and treatment adherence improved when the patient was rested. Playful activities came second to the basic need for rest and music listening enhanced relaxation and sleep. With the option to offer music therapy sessions to only a fraction of patients it seemed relevant to offer music beyond the limits of therapy sessions.

CHAPTER 1. INTRODUCTION

1.1. DEPRESSION

Depression is introduced including aetiology, symptoms and treatments followed by an introduction to music for health purposes, music in hospitals and music for sleep. A review of the literature leads to the aims of the thesis and overview of studies.

1.1.1. HISTORICAL VIEW

In ancient history depression (called melancholia) was caused by imbalanced body fluids or the anger of Gods. The Greek physician, Hippocrates (460-377 BCE) introduced medicine based on clinical observation and suggested what is known as lifestyle modifications (1). One of the first major publications on depression was the "Anatomy of Melancholy" by Robert Burton in 1621 (2). Coming forward to recent times, the present understanding of depression treatment evolved in the 1970's where a medical orientation came forward aiming to solve mental illness with medication based on neurophysiology and genetics. The treatment with anti-depressants became a new standard. In 1980, major depressive disorder was introduced in the DSM-III in USA and this definition is found in the ICD-10 classification used in clinical practice worldwide today (3). A brief historic encounter leads to the understanding of depression today.

Depression is a major threat to global health and one of the most common chronic diseases. WHO reports a prevalence of depressive disorders of 5% in Denmark and 4,4% globally (4). The prevalence of depression in adults (>18) is a growing concern (5). Health systems are required to improve efforts to respond to the burden of mental disorders including the epidemiological burden of depression (6). For many years reducing the burden of depression has been on the agenda in public health and the recognition of the burden of depression is widespread as it affects not only the individual but the society and the health services (7). Decreasing the level of burden require substantial increase in treatment coverage (6).

1.1.2. AETIOLOGY

There is not a common understanding of the etiology of depression, but many possible causes of depression are suggested ranging from generic, psychological, stress related, substance abuse related, to causes related to comorbidity (8). Recent research proposes neurobiological assessment of depression subtypes (9). Depression can occur at all ages and the symptoms have impact on emotional, psychological, physical and social functions. A twofold greater prevalence of depression is found in women (4).

1.1.3. SYMPTOMS

Symptoms of depression are defined in Hamilton Depression Rating Scale (HAM-D) including psychological, physiological, behavioral and cognitive changes: reduced mood, feelings of guilt, suicidal thoughts/impulse, insomnia, difficulties in work and activities, retardation, agitation, anxiety (psychic/somatic), loss of appetite, loss of libido (sexual interest), hypochondriasis, lack of insight and weight loss (8,10).

Sleep disturbances in depression are individual and include insomnia and hypersomnia characterized as excessive sleepiness (11). Oversleeping is common in hypersomnia, and the condition is evidenced by nighttime oversleeping or sleeping during daytime on a regular basis. This depression symptom is less frequent than insomnia. The insomnia symptoms are difficulties falling asleep at bedtime, difficulties maintaining sleep during the night caused by nightly awakenings and early morning wakefulness, waking up one or more hours before planned. The sleep disturbances of insomnia result in insufficient restorative sleep. Overall, poor sleep quality results in daytime sleepiness and reduced daytime functioning.

1.1.4. TREATMENT

Depression treatment most often includes medication. Danish national clinical guidelines for non-pharmacological treatment in depression recommend physical exercise, psychotherapy (CBT, psychodynamic short-term therapy and mindfulness) and supportive consultation (12). Among outpatients with depression, one third suffer from initial insomnia. Resolution of sleep disturbances in depression are important for full recovery and unfortunately insomnia is the most unresolved symptom when depression symptoms have been treated successfully with medication (11,13). A group of major drug classes treating insomnia include; Benzodiazepines (BZ), Benzodiazepines receptor agonists (BZRA), antidepressants, antipsychotics, antihistamines, Phyto therapeutics (for example valerian) and Melatonin (14). Hypnotic medication including benzodiazepines such as Eszopiclone may be prescribed after treating symptoms with serotonin reuptake inhibitors (13). Medication has a variety of side effects; hangover, nocturnal confusion, falls, rebound insomnia, tolerance and dependency. Hence, the treatment of insomnia in depression with medication is only recommended when CBT is ineffective or unavailable.

1.2. MUSIC ON PRESCRIPTION

1.2.1. MUSIC AND HEALTH

Prescribing music to improve health and wellbeing has been practiced since ancient times. Today the use of music for health purposes is practiced and reported from a great number of settings (15,16). Research in music and health is informed across the academic spectrum including humanistic, social and natural sciences (17). Research is required to establishing causal links between music and health to explain benefits of specific variables (music interventions) and for results to be included in the evidence base. The body of evidence is reported in mainly three domains; music psychology, music therapy and music and health (18).

Within the last two decades research publications in the field of music therapy and music medicine (see Table 1 and Figure 1) reflect a growing interest to investigate music intervention in research and in experimental settings replicating research designs from medical research (19).
Music therapists are encouraged to perform both objectivist and interpretivist research since all types of research are needed including research meeting the standards for inclusion in systematic reviews (20). Studies investigating music therapy include a music therapist and implies a relational therapeutic approach based on interpersonal communication models such as psychodynamic orientation. Music intervention studies investigating music on its own qualify to determine the effectiveness of the music. To this date, several systematic reviews made overarching definitions including music therapy and music intervention trials despite methodological discrepancies (21). The lack of clarity in research and the wish for distinguishing variables when investigating music interventions has been raised (22).

Music on prescription has emerged as a term used in publications as a part of the "Arts on Prescription" movement with roots in Great Britain and Scandinavia (16,23). Arts and health research has been documented in areas of: critical care and emergency medicine, dentistry, geriatric medicine, healthcare staff, neurology, obstetrics, gynecology, neonatology, oncology, pediatrics, palliative care, public health, psychiatry, rehabilitation medicine and surgery (16). Arts and health studies including music overlap with research in music intervention and music therapy. Still, they represent a separate field offering creative activities to fragile individuals or groups due to the general positive effects of music and arts on wellbeing. Focusing on music interventions in the health sector and hospitals, an overview of music and health interventions in hospitals in the Nordic countries has been published by Bonde (18) The essay concludes that there is a growing body of evidence from research studies, but evidence within specific areas is limited or missing (18). An overview of Cochrane reviews covering music therapy and music interventions in clinical settings comprising eight reviews include three from psychiatry covering autism spectrum disorder, schizophrenia and depression. The Cochrane review of music therapy for depression reports results indicating short term improvements of depression

symptoms, anxiety and level of functioning in adults based on music based interventions and music therapy (24).

An example of a randomized controlled trial investigating music therapy in the treatment of depression from Finland is reporting on effects of individual music therapy (25). The study concluded:

> "Individual music therapy combined with standard care is effective for depression among working-age people with depression. The results of this study along with the previous research indicate that music therapy with its specific qualities is a valuable enhancement to established treatment practices". (25)

Music therapy studies served as inspiration for this study. An example is this above mentioned RCT targeting the population of adults with depression and investigating use of music for reducing symptoms in depression. The RCT does not focus specifically on sleep and the method is a relational approach involving active playing and music activities other than music listening.

1.2.2. MUSIC INTERVENTION STUDIES

Music intervention studies have shown results indicating positive effects in the somatic field. A meta-analysis reviewed 72 RCTs concluding that music was effective in reducing postoperative pain and anxiety (26). The beneficial effects of music in reducing anxiety in somatic care indicated a regulatory effect which deserves investigation in other areas such as psychiatry and psychiatric diagnosis including anxiety symptoms.

There is a need for research to shed light on the cause of beneficial effects of music in clearly defined populations. In addition, the effect of music considering stimulating and sedative effects must equally be targeted and differentiated in research. Effects of music and the underlying mechanisms may be explained neuro-scientifically. A study investigating effects of music listening in depressed patients have shown increase of serotonin content of platelets from blood tests differing from controls (27). The serotonin content of platelets is linked to the serotonin content of central neurons. The findings point to the possibility that musical stimuli influence central neural serotonergic transmission (28). Since serotonin dysregulation is seen in the pathophysiology of depression these findings are highly relevant (29). A branch of research in music and health is placed within the field of psycho-endocrinology investigating psychophysiological effects of music and using markers such as cortisol, oxytocin, testosterone, endorphins and others. Another branch of research is the research investigating music-evoked emotions and emotion regulation through music. Studies found that; a) emotions evoked by music can change activity in central areas of emotional processing, b) musical emotion regulation is used strategically to

attaining affective goals, c) relaxation strategies (in adolescents) include processing of thoughts, experiences and emotions, distraction from internal processing, and induction, d) the process of affective self-regulation involves components including strategies, goals, tactics and mechanisms (30–33).

1.2.3. MUSIC IN HOSPITALS

Music interventions are investigated from psychological, emotional, cognitive, behavioral, physical and neuroscientific perspectives including participants from non-clinical and clinical populations. Music interventions studies may be categorized according to specific subcategories defined by the setting and the intervention method. Bonde divides music interventions in hospitals into six categories (18):

Table 1. Music in hospitals. Systematic overview: agents and interventions (34)

Music therapy is the specialised expertise in the use of musical experiences to treat both mental and somatic disorders. In the Nordic countries music therapy is practised in the healthcare system by university-trained music the- rapists (with a master degree), and the following tasks are typical: (1) treating patients with special needs one-to-one, (2) offering tailor-made interventions and activities for larger or smaller groups, (3) developing environmental therapeutic services, (4) advising and training staff in the use of music interventions and music medicine in the day-to-day running of the institution or hospital, (5) offering support services to the hospital/institution staff.

1. **Music medicine** is the use of music (recorded or live, often using specially designed sound systems) for the benefit of hospital patients, outpatients or citizens in specialised institutions, both in the treatment and rehabilitation phase and in palliative care. Many different agents are active in this field: composers develop special music for various purposes, such as music in ambulances. Professional musicians play for patients with an explicitly stated treatment goal, such as reducing anxiety or improving mood. Music medicine must always be administered in close consultation with doctors, nurses and trained music therapists.
2. **"Health musicians"** are most often professional musicians who use their advanced skills and commitment to create joy and improve quality of life for patients in hospitals and care centres through specially designed and personalised live performances. This is neither music therapy nor music medicine as it does not have an intended treatment component, yet it may have a therapeutic effect. The field is mainly self-regulating, and activities are currently expanding in parallel to the activities of hospital clowns, another non-treatment-oriented offer, so far financed 100 per cent by private funding.
3. **Music as health promotion.** Specially organised music experiences – in line with other cultural experiences – are included in 'culture on prescription' projects, among other things. In this field we are talking about authentic art experiences – not as treatment offered by therapists, but developed by the arts institutions, based on the documented fact that arts experiences can have a health-promoting function. In Aalborg the Nordjysk Centre for Culture and Health (NOCKS) operates an interdisciplinary and cross-sectoral research and development unit that initiates and documents new projects in this subfield.

5. **Music as a diversion/entertainment** in hospitals and institutions. More technological solutions are currently being developed such as commercial playlists and apps specifically aimed at adult hospital patients or people with dementia. The area is interesting in a health promotion context if specially composed music is included and/or if the choice of music is based on professional expertise on e.g. music for regulating arousal.
6. **Music pedagogy / music education.** Paediatric wards in larger hospitals may employ a music teacher or educator. Their work is framed by the primary school curriculum's objects clause and subject descriptions. But, of course, the situation and needs of the child or the young person in the hospital are obviously based on whether they are singing, playing or teaching music comprehension[1]

The studies performed in this project are categorized as music medicine. In this context music medicine is synonymous to music intervention. Still, when the music intervention is guided by a music therapist, it could be argued that the intervention also meets definitions of music therapy. To clarify the position of music medicine in the field of music and health, the model below illustrates the field (Figure 1).

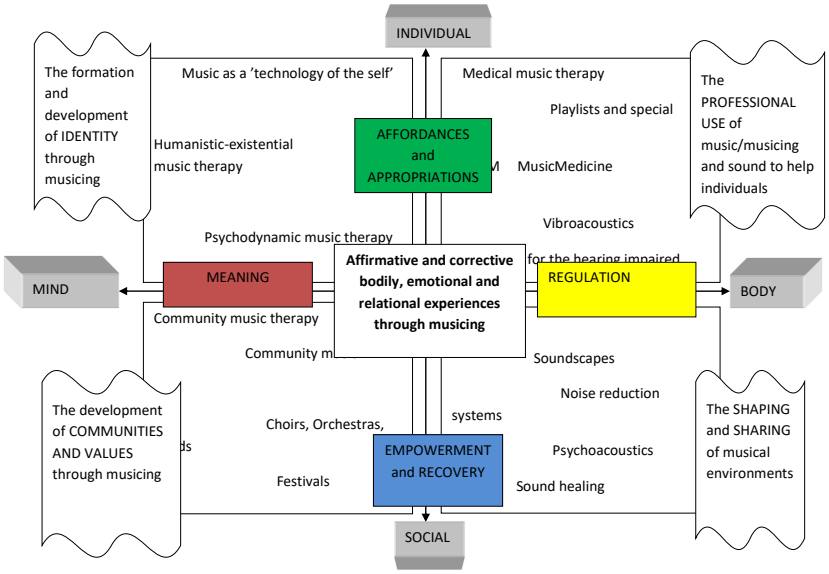


Figure 1. HEALTH MUSICING: A THEORETICAL MODEL (STUDY I)

Music medicine, playlists and special music is placed in the upper right field defined by the purpose of regulation and by the professional use of music and sound to help individuals. (Study I).

1.3. MUSIC FOR INSOMNIA

1.3.1. LULLABIES

Lullabies are known and used across cultures globally. The use of music to enhance sleep has been practiced by parents singing lullabies to help their infants to sleep in thousands of years. For infants, the voice of the parent has been central to the lullaby until recently where recordings of lullabies are more frequently used.

Considering the use of music by adults to improve sleep quality, music as a self-help sleep aid is commonly known and used and is documented in public health surveys (34,36). Nevertheless, pathological sleep disturbances are not commonly resolved with the use of music. The European guideline for the diagnosis and treatment of insomnia includes music therapy within a section on complementary medicine and concludes that the results from meta-reviews suggest a potential positive effect of music therapy (music intervention) for insomnia but the methodological quality of the studies is questionable. The guideline lists three meta-reviews comprising a total of 20 RCT's (37–39). The reviews suggest positive effects of music, but the guideline does not recommend music for insomnia due to the lack of methodological consistency in the studies (14).

1.3.2. SLEEP ASSESSMENT

Trials investigating the effect of music on sleep have focused on different populations. A literature review based on studies evaluating outcomes with PSQI comprised groups of elderly (40,41), students (42), traumatized refugees (43) and depressed outpatients (44).
The sleep-inducing effects of music have also been studied in primary insomnia (38,45,46). Instruments used to evaluate effects of music in sleep comprise self-report questionnaires such as Richards-Campbell Sleep Quality Questionnaire, Jenkins Sleep Scale, Synder-Halpern Sleep Scale, Glasgow Sleep effort scale, Visual Analogue scale of subjective responses and instruments for objective measures as actigraphy and polysomnography.

The dose of music required has been investigated in trials. One study found that a single exposure to music at bedtime did not show effect in a group of female students (47). On the other end, a study investigating music listening in elderly in a three-month period reported continuous improvements of sleep over time with the largest effect after the first month and a slightly decreasing effect at the following time points (48). A literature review investigating the dose-effect relationship in studies assessing sleep with PSQI showed increase in sleep quality with increased exposure to music in the six included studies. The findings were consistent across study populations, music genres offered, duration and frequency of music intervention (49). The duration of

music listening ranged from 30 to 60 minutes. The review suggested that music exposure beyond 3 weeks continue to improve sleep quality. In addition, the study points out that counterproductive sleep associations and anxious wakeful thoughts due to frustration of sleeping problems may lead to hyperarousal. The state of hyperarousal further prevents sleep initiation and this vicious circle may be broken by music listening normalizing the state of arousal. Music may create new constructive sleep associations enhancing relaxation and sleep. The review points to the fact that forming new associations at bedtime, is a psychological change process requiring time for settlement (49). This point is important although limited to targeting problems of sleep initiation.

Three systematic reviews of music for insomnia published in 2009 (37), 2014 (21) and 2015 (50) all point to a heterogenic evidence base. The most recent review suggested that music listening may improve sleep quality in populations with insomnia symptoms. The review included studies measuring sleep with PSQI and the effect size was reported to be one standard deviation in favor of music intervention compared to controls. None of the studies reported negative adverse effects. The quality of the evidence from the five included studies was moderate and the need for investigating the effectiveness of music in clinical populations was raised (50).

1.4. LITERATURE

A literature review was conducted in order to identify studies investigating the use of music in improving sleep in depression-related insomnia. A search was performed with a focus on three main themes; depression, music and sleep. The search was performed in Cinahl, Psych Info, Pubmed, Embase and Scopus and yielded a total of 984 titles. The titles listed in the search results were assessed using Mendeley in an initial screening for relevance. The search strategy is described in Appendix A.

Studies within populations of children, youth and elderly were excluded. Studies investigating music interventions in improving sleep quality in adults without depression and/or sleep disorder were excluded. This yielded one trial by Deshmukh et al investigating sleep in depression (44).

Including music intervention trials for insomnia within all populations and utilizing PSQI for assessment yielded nine trials. One trial (51) was excluded as the intervention included listening to live music and a writing assignment in addition to music listening at bedtime. Three trials were excluded as the intervention included relaxation instructions (52,53) and sleep hygiene education (48) and one trial was retracted by the authors (54). The four remaining trials supporting the rationale for this study are listed in Table 2.

1.4.1. LITERATURE TABLE

Table 2. Music intervention and Sleep Trials using PSQI. Deshmukh (44), *Shum* (40), *Harmat* (42), *Jespersen* (43).

Author, year	***Study type, Population, music intervention, control condition***	***Results Effect sizes PSQI**, 95%CI***	***Intervention period/ duration per session***
Deshmukh et al, 2009	RCT, 2-arm, Depressed insomniac adult outpatients (N=50) Indian raga, medication control.	2.9 [not reported]	45 days 45 min.
Shum et al, 2014	RCT, 2-arm, elderly (N=60) Relaxation music, control*.	-3.60 [-4.87 - -2.33]	45 days 40 min.
Harmat et al, 2008	RCT, 3-arm, students with sleep complaints (N=94) Classical music, audiobook and control*.	-2.63 [-3.63 - -1.63]	21 days 45 min.
Jespersen et al, 2012	Quasi-RCT, 2-arm, (N=15) Traumatized refugees, relaxation music, pillow control	0.78 [-3.97 - 2.41]	21 days 60 min.

Note: *= no intervention ** = Pittsburgh Sleep Quality Index

The literature search highlighted an existing field of music and sleep research with a lack of studies investigating effects of music in depression related insomnia. The literature review underlined the relevance of research in this domain.

1.5. AIMS AND HYPOTHESES

The objectives of the PhD project:

1. To examine the efficacy of a music intervention in improving sleep quality, symptoms of depression and quality of life in adults with depression-related insomnia.

2. To investigate patients' experiences of music listening at bedtime.

Study I
Sound and music interventions in psychiatry at Aalborg University Hospital
The first study aimed to report the development of the sound and music milieu in psychiatry at Aalborg University Hospital outlining music intervention solutions and challenges. The overview included reporting of music intervention pilot projects, documentation of the field, the theory-driven development of new music equipment and the novel method of data collection.

Study II
Music to improve sleep in adults with depression-related insomnia (MUSTAFI): study protocol for a randomized controlled trial
The aim of the second study was to create a study protocol to investigate the efficacy of music listening on sleep quality, depression and quality of life in adults with depression-related insomnia through a randomized controlled trial.

It was hypothesized that self-administered use of the MusicStar app combined with a sound pillow can serve as a sleep aid in reducing depression-related sleep disturbances.

Study III
Music to improve sleep in adults with depression-related insomnia: randomized controlled trial
The aim of the third study was to report on the trial of the efficacy of music listening on sleep quality, depression symptoms and quality of life in adults with depression-related insomnia.

Study IV
Music, sleep and depression: An interview study
The fourth study aimed to examine patients' experiences through an interview study. The objective was to gain knowledge of the underlying mechanisms related to music listening at bedtime from examples, improving the understanding of the effects of music intervention.

CHAPTER 2. METHODS

This section includes a description of the research design, the background summarizing STUDY I and materials used in STUDY II, III and STUDY IV.

2.1. MIXED METHODS DESIGN

Utilizing qualitative and quantitative methods in a mixed methods research design is an approach integrating multiple forms of evidence (55). Approaching a research questions from different perspectives have relevance when addressing a multi-facetted research aim (51, 52). Study designs using mixed methods have been used in music intervention studies (55). This study is conducted in an explanatory sequential design giving priority to a larger quantitative study and using a qualitative study to explore subjective experiences possibly explaining quantitative outcomes.

While Study I served as a prelude to the main investigation, Study II and Study III provided the quantitative data from the trial and Study IV provided the qualitative data from the interview study. The explanatory sequential design is seen in the figure below:

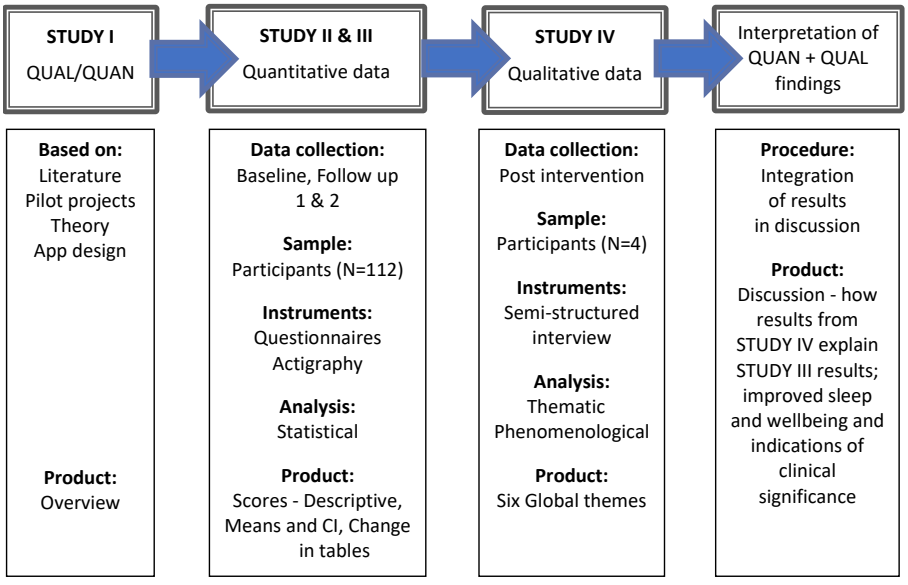


Figure 2. Explanatory sequential design based on Burns and Masko's figure in Music Therapy Research (58)

Aiming to reach out to an audience of health professionals in psychiatry focusing on objectivist research, the RCT (STUDY II and STUDY III) is reported in publications of the trial. The outreach to communities investigating effects of music from a humanities-based interdisciplinary stand, explains the reporting of the qualitative findings (STUDY I and STUDY IV). The objectivist and interpretivist studies were published separately (STUDY III and STUDY IV). Hence, the publications did not merge quantitative and qualitative findings. In the discussion section the quantitative and qualitative findings are merged.

2.2. MUSIC INTERVENTION (STUDY I)

Music intervention in health care is a relatively new field and the use of relaxing music in psychiatry at Aalborg University Hospital has previously been documented sparsely in pilot projects and mostly in Danish (59).

The method included a narrative approach, describing and discussing the background including relevant empirical studies. The innovation process of the MusicStar app based on the national project 'Reduction of Restraint in Psychiatry' was documented (STUDY I).

The method of music intervention grew from a music therapy practice where music listening was part of individual and group treatment by music therapists. Subsequently, several pilot projects initiated by music therapists aimed at qualifying health professionals to offering music to patients and changing the role of the music therapists from being clinicians facilitating music therapy to a guiding role instructing nurses in facilitating music intervention as a therapeutic tool for arousal regulation, reduction of anxiety and sleep support (STUDY I).
In the North Denmark Region several projects introduced sound and music in health care improving the sound environment. The recent projects and studies have been inspired from the pioneering work of chief physician Per Thorgaard (60).
Sound equipment and technological solutions have changed over time influencing music listening practices, from portable cd players, music pillows, hard pillow speakers, and mp3 players to Maysound Music Players (designed for health care), computers with portable speakers and tablets. New software including the MusicStar has added modern technical solutions to sound distribution (STUDY I).
Practices of music selection were shaped by music therapists selecting music for individual therapy and music listening groups. In recent times, the professional selection of music changed for an individual patient-selection of music for music therapy, partly due to the easy access to online music libraries.

Music listening is an activity associated with pleasure (61). As patients across diagnosis and individual problems share feelings of hopelessness and chaos, music listening can offer a break from pain, worries, suicidal thoughts and from hearing voices. (59). From a neuropsychological perspective music has the ability to be processed by the amygdala by-passing cognitive appraisal in an almost direct emotional processing (29). An initial positive attitude towards music can be helpful for the patient making a constructive choice of music listening in contrast to destructive choices and coping strategies with substantial side-effects leading to hospitalization. Patient-centered treatment including increased attention to the responsibility of the patient to being actively engaged in treatment and recovery process is on the political agenda and included in multidisciplinary clinical practice in psychiatry. The recent projects aim to empower patients acknowledging the patients wish for control and agency and supporting the choice of music according to individual needs (STUDY I). A review of the effectiveness of music listening in reducing depressive symptoms in adults (62) emphasized the importance of individual choice of music from an available music collection for effectiveness and concluded that all types of music may be used. Based on the studies included in the review the authors suggested that effects of music in reducing depressive symptoms augment with increased exposure to music.

2.2.2. PILOT PROJECTS

The aim of the project was to prepare the ground for a systematic application of sound and music interventions in hospitals. The project was based on pilot studies conducted primarily in psychiatry. One project investigated the implementation of special playlists and sound equipment in daily routines and patient care by health professionals supervised by music therapists (59). The equipment consisted of sound pillows and portable mp3 players. The music was selected, and playlists were developed based on theoretical and empirical research in music medicine and music therapy. Other projects tested sound equipment and music in different settings. Schou conducted a pilot study investigating guided relaxation with music in improving relaxation, alleviating pain and reducing anxiety in patients in a coronary unit. Four playlists were developed and named according to style including classical, easy listening, Musicure and jazz. Analysis of patient preferences concluded a priority of easy listening, while classical and Musicure shared a second priority leaving jazz as the least preferred playlist. Thorgaard implemented music listening in postanesthetic care (60) and in ambulances in the North Denmark region.
During playlist development the rationale for music selection was discussed and influenced by the debate on expert-selected versus patient-selected music (63,64).

In Denmark, several music medicine studies were conducted offering the specially composed Musicure series as the only music available. While results suggested positive outcomes in projects investigating music intervention comparing Musicure

to no music or treatment as usual, projects including choice of music and including patients preferences were more effective than expert selected music only and these preliminary findings found support in literature (62).

In 2012, music pillows and mp3 players with music selections compiled by music therapists were available to patients in psychiatric in-patient units at Aalborg University Hospital. In this process, music therapists identified the challenge to balance the wish for a varied repertoire of music and accommodating a broad spectrum of preferences while aiming for functional simplicity. See Table 3. An interview study of nurses with experience of using the sound equipment in patient care was performed (59). The interviews were subject to thematic analysis and five themes were identified: feasibility, varied use, three main aims, technical difficulties and 'the music therapists are the experts'.
The three main aims of music reported were distraction, relaxation and sleep support. Importantly, the study reported challenges in handling the sound equipment including difficulties in operating the mp3 player, navigating in playlists and lack of knowledge of music available. The study led to further refinement of the playlists forming the basis of the playlists in the MusicStar app.

Table 3. Overview of playlists from the early stages of the project. (STUDY I)

Playlists (30 minutes)	Playlists (60 minutes)
Easy Listening (K. Norge, M. Rowland)	Easy Listening (K. Norge)
Classical (mixed repertoire)	Classical (Bach, Beethoven, Mozart,
MusiCure (N. Eje)	Vivaldi, Chopin)
Rock for relaxation (mixed repertoire)	Pop (J. Johnson)
	Relaxation ('Quiet Please')
	Celtic folk music (The Kells)
	Soul (S. Indrio, J. Gurevitsch)

While small scale pilot projects in the North Denmark Region made a basis for a systematic application of sound and music interventions in the hospital environment, music in healthcare experienced increasing attention internationally. The Danish white book entitled 'Music interventions in Health Care' marked an increasing attention to the field from a neuroscientific perspective (19). In 2015, a public health study investigating the association between self-rated health and active use of music in daily life and the association between use of/ understanding of music as a potential

health factor and self-reported health reported that half of the adult Danish population use music to regulate mood and energy (34).

2.2.3. THEORETICAL BASIS

The original categorization of playlists according to genres changed due to a new theory of music classification introduced by Wärje and Bonde in 2014 (65). The taxonomy of music divides music in three distinctive groups; a) Supportive music b) Mixed supportive/Challenging Music c) Challenging Music. Music is categorized according to degree of stimuli and each group has three subcategories. The subcategories of 'Supportive Music' are; 1) The supportive and safe field 2) The supportive and opening field 3) The supportive and exploring field. These categories described as 'fields' are independent of musical style or genre and the three supportive subcategories are categorized by predictable tempo, often slow, melodic and harmonic simplicity, sparse orchestration and a high degree of predictability in all musical parameters (65).

The taxonomy of music served as inspiration in designing the MusicStar as the approach to music categorization across genres was appropriate to selecting calm music for the purpose of relaxation, sleep and distraction in psychiatric hospital units. The taxonomy of music within the subcategory of supportive music was reflected in three colors; blue, green and red. (STUDY I). The color codes illustrate a continuum of stimuli as seen in Figure 3.

Figure 3. The continuum of musical stimuli and color codes. (66)

2.2.4. DEVELOPMENT

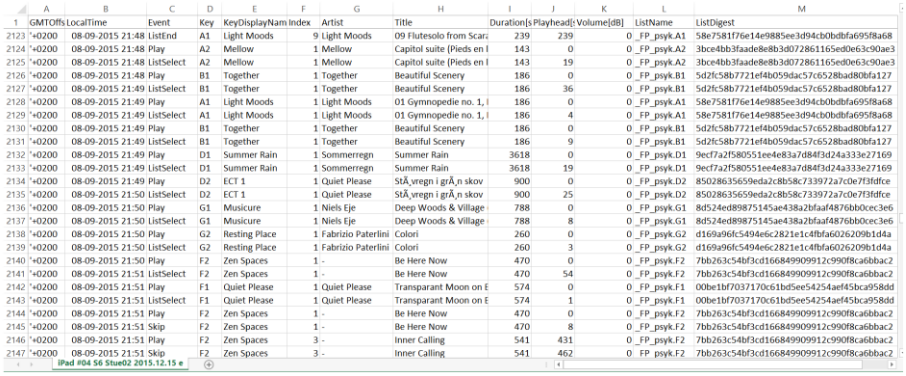
A national Danish political initiative to reducing coercion in psychiatry funded a project building on the knowledge from the pilot projects in psychiatry at Aalborg University Hospital (67). The project aimed at a further implementation of music intervention for relaxation, arousal regulation and stress reduction potentially

introducing music in de-escalating interventions for highly aroused patients in intensive care. Hence, improving existing sound solutions and meeting requirements for implementation in intensive care psychiatry was paramount. This resulted in the design of an app giving access to a larger selection of playlists. The MusicStar was developed by music therapists Bertelsen and Lund (STUDY I). A total of 12 sound systems were distributed in individual patient rooms in two intensive care units. Design requirements included robustness aiming at preventing destructive use including self-harm or violence against health professionals.

The user interface of the MusicStar is shaped as a star consisting of 16 colour coded triangles. The triangles contain expert-curated playlists. The colours allow identification of a playlist without association to genre (STUDY I).

Figure 4. The MusicStar app.

The app has a built-in log function for research purposes. The log function provides data enabling data collection including date, time, duration and music preferences. User patterns and profiles may be collected from a single user to entire units. An example of log file print in Figure 5.



	A	B	C	D	E	F	G	H	I	J	K	L	M
1	GMTOffs	LocalTime	Event	Key	KeyDisplayNam	Index	Artist	Title	Duration[s	Playhead[s	Volume[dB]	ListName	ListDigest
2123	'+0200	08-09-2015 21:48	ListEnd	A1	Light Moods	9	Light Moods	09 Flutesolo from Scar	239	239	0	FP_psyk.A1	58e7581f76e14e9885ee3d94cb0bdbfa695f8a68
2124	'+0200	08-09-2015 21:48	Play	A2	Mellow	1	Mellow	Capitol suite (Pieds en l	143	0	0	FP_psyk.A2	3bce4bb3faade8e8b3d07286116 5ed0e63c90ae3
2125	'+0200	08-09-2015 21:48	ListSelect	A2	Mellow	1	Mellow	Capitol suite (Pieds en l	143	19	0	FP_psyk.A2	3bce4bb3faade8e8b3d07286116 5ed0e63c90ae3
2126	'+0200	08-09-2015 21:48	Play	B1	Together	1	Together	Beautiful Scenery	186	0	0	FP_psyk.B1	5d2fc58b7721ef4b059dac57c6528bad80bfa127
2127	'+0200	08-09-2015 21:49	ListSelect	B1	Together	1	Together	Beautiful Scenery	186	36	0	FP_psyk.B1	5d2fc58b7721ef4b059dac57c6528bad80bfa127
2128	'+0200	08-09-2015 21:49	Play	A1	Light Moods	1	Light Moods	01 Gymnopedie no. 1,	186	0	0	FP_psyk.A1	58e7581f76e14e9885ee3d94cb0bdbfa695f8a68
2129	'+0200	08-09-2015 21:49	ListSelect	A1	Light Moods	1	Light Moods	01 Gymnopedie no. 1,	186	4	0	FP_psyk.A1	58e7581f76e14e9885ee3d94cb0bdbfa695f8a68
2130	'+0200	08-09-2015 21:49	Play	B1	Together	1	Together	Beautiful Scenery	186	0	0	FP_psyk.B1	5d2fc58b7721ef4b059dac57c6528bad80bfa127
2131	'+0200	08-09-2015 21:49	ListSelect	B1	Together	1	Together	Beautiful Scenery	186	9	0	FP_psyk.B1	5d2fc58b7721ef4b059dac57c6528bad80bfa127
2132	'+0200	08-09-2015 21:49	Play	D1	Summer Rain	1	Sommerregn	Summer Rain	3618	0	0	FP_psyk.D1	9ecf7a2f580551ee4e83a7d84f3d24a333e27169
2133	'+0200	08-09-2015 21:49	ListSelect	D1	Summer Rain	1	Sommerregn	Summer Rain	3618	19	0	FP_psyk.D1	9ecf7a2f580551ee4e83a7d84f3d24a333e27169
2134	'+0200	08-09-2015 21:49	Play	D2	ECT 1	1	Quiet Please	StÃ¸vregn i grÃ¸n skov	900	0	0	FP_psyk.D2	85028635659eda2c8b58c733972a7c0e7f3fdfce
2135	'+0200	08-09-2015 21:50	ListSelect	D2	ECT 1	1	Quiet Please	StÃ¸vregn i grÃ¸n skov	900	25	0	FP_psyk.D2	85028635659eda2c8b58c733972a7c0e7f3fdfce
2136	'+0200	08-09-2015 21:50	Play	G1	Musicure	1	Niels Eje	Deep Woods & Village	788	0	0	FP_psyk.G1	8d524ed89875145ae438a2bfaaf4876bb0cec3e6
2137	'+0200	08-09-2015 21:50	ListSelect	G1	Musicure	1	Niels Eje	Deep Woods & Village	788	8	0	FP_psyk.G1	8d524ed89875145ae438a2bfaaf4876bb0cec3e6
2138	'+0200	08-09-2015 21:50	Play	G2	Resting Place	1	Fabrizio Paterlini	Colori	260	0	0	FP_psyk.G2	d169a96fc5494e6c2821e1c4fbfa6026209b1d4a
2139	'+0200	08-09-2015 21:50	ListSelect	G2	Resting Place	1	Fabrizio Paterlini	Colori	260	3	0	FP_psyk.G2	d169a96fc5494e6c2821e1c4fbfa6026209b1d4a
2140	'+0200	08-09-2015 21:50	Play	F2	Zen Spaces	1	-	Be Here Now	470	0	0	FP_psyk.F2	7bb263c54bf3cd166849909912c990f8ca6bbac2
2141	'+0200	08-09-2015 21:51	ListSelect	F2	Zen Spaces	1	-	Be Here Now	470	54	0	FP_psyk.F2	7bb263c54bf3cd166849909912c990f8ca6bbac2
2142	'+0200	08-09-2015 21:51	Play	F1	Quiet Please	1	Quiet Please	Transparant Moon on E	574	0	0	FP_psyk.F1	00be1bf7037170c61bd5ee54254aef45bca958dd
2143	'+0200	08-09-2015 21:51	ListSelect	F1	Quiet Please	1	Quiet Please	Transparant Moon on E	574	1	0	FP_psyk.F1	00be1bf7037170c61bd5ee54254aef45bca958dd
2144	'+0200	08-09-2015 21:51	Play	F2	Zen Spaces	1	-	Be Here Now	470	0	0	FP_psyk.F2	7bb263c54bf3cd166849909912c990f8ca6bbac2
2145	'+0200	08-09-2015 21:51	Skip	F2	Zen Spaces	1	-	Be Here Now	470	8	0	FP_psyk.F2	7bb263c54bf3cd166849909912c990f8ca6bbac2
2146	'+0200	08-09-2015 21:51	Play	F2	Zen Spaces	3	-	Inner Calling	541	431	0	FP_psyk.F2	7bb263c54bf3cd166849909912c990f8ca6bbac2
2147	'+0200	08-09-2015 21:51	Skip	F2	Zen Spaces	3	-	Inner Calling	541	462	0	FP_psyk.F2	7bb263c54bf3cd166849909912c990f8ca6bbac2

iPad #04 S6 Stue02 2015.12.15 e

Figure 5. Example of a log file print. (STUDY I)

Log data provides information guiding future revisions of playlists. Log files with data of music user profiles may be connected to data from patient journals in investigation of the effect of music intervention on wellbeing, medication and restraint in future research. Findings combined with cost-benefit analyses will provide useful information for decision-makers in psychiatry.

2.2.5. PERSPECTIVES

Based on pilot projects, challenges to music intervention were identified and solved with new technology offering safer, more robust music equipment including an app; MusicStar, comprising sixteen curated playlists and a log function. The study fostered novel and genuine technology development within sound equipment in the healthcare sector. STUDY I suggested further experimental research in music medicine in domains such as music intervention effects on sleep quality, brain waves or ANS responses.

Transition

Based on results from Study I, an experimental research project was initiated. Of the three main aims of music intervention identified (distraction, relaxation, sleep) the objective was to investigate the efficacy of music intervention as a sleep aid in the population of adults with depression and sleep disturbances. A randomized controlled trial and an interview study in an explanatory mixed methods research design was formulated.

2.3. MUSTAFI : PROTOCOL (STUDY II)

This study aimed to create a study protocol of a trial assessing the effectiveness of music intervention in improving sleep quality, reducing depression symptoms and improving quality of life in adults with depression-related insomnia. The outcome was the protocol of a single center randomized controlled trial in a two-arm parallel group.

The protocol was registered in clinicaltrials.gov ID NCT03676491. The study received approval from the North Denmark Region Committee on Health Research Ethics on 5 September 2017; N-20170055 case number 58691. Additional applications approved 15 March 2018, 17 october 2018 and 13 March 2020 case number 73255. A yearly report of adverse events and unintended effects of the trial was obtained by the local ethics Committee. Registration by the Danish Data protection Agency; ID 2017-236.

2.3.1. PARTICIPANTS

Participants were recruited from an outpatient unit for depression in psychiatry at Aalborg University Hospital. The study included adult patients aged 18-65 in treatment for depression with a diagnosis of unipolar depression, F32 or F33, according to ICD-10 Classification and sleeping problems identified by the Hamilton Depression Rating Scale (HAM-D17) by a score of at least two in one item, or at least 3 in total in three items (question 4, 5 and 6). The patient was eligible when in stabilized pharmacological treatment and having completed a minimum of four weeks of treatment. Patients were required to follow national guidelines for depression including medication, psychotherapy and psycho education. Patients were excluded if they had psychotic episodes, substance misuse or sentence to treatment by law. Furthermore, patients with restless legs syndrome, obstructive sleep apnoe or other organic sleep disorders were excluded. Functional hearing loss and dislike of music was also reason for exclusion (STUDY II).

The patients with depression and insomnia in outpatient treatment were a heterogeneous group. Some participants were referred directly to the hospital from private practice with moderate or severe symptoms of depression, others were referred from an inpatient unit and in recovery and others were diagnosed in previous hospital treatment and in treatment for a recurrent depression. All participants continued receiving treatment as usual while taking part in the study.

2.3.2. MUSIC INTERVENTION

Participants in the music intervention group used the MusicStar app in combination with a sound pillow. The principal investigator gave instructions to the participants in the experimental group on the use of the sound pillow and the sound equipment including the MusicStar app. The sound pillow should be placed in the bed and the MusicStar (installed on an iPad mini4) placed close by for easy access. Participants were required to listen to music from the MusicStar for at least 30 minutes at bedtime every night in four weeks with an option to listen to music during the night and in the early morning hours. The participants were instructed to listen in advance to the playlists and selecting music according to preferences and the intention to sleep. At the baseline appointment the instructions were followed by hands-on tests of equipment including how to adjust the volume (STUDY II).
Participants wore an accelerometer to monitor sleep (by arm movement) during the eight-week period. It was worn as a wrist bracelet constantly or at night. The accelerometer data was collected after 4 and 8 weeks.

The participants in the waitlist control group were asked to continue normal routines at bedtime and no further instructions were given. The use of music at bedtime was reported and included in demographic data (Table 4).

The schedule was reported in the SPIRIT flow chart (Figure 6).

STUDY PERIOD							
	Enrolment	Allocation	Post-allocation				*Follow Up*
TIME	$-t_1$	0	*Week 1-2*	*Week 3-4*	*Week 5-6*	*Week 7-8*	*Week 9*
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
Music			X	X			
Control			X	X	X	X	
ASSESSMENTS:							
PSQI, WHO-5, WHOQOL-BREF, HAM-D17			X		X		X
Actigraphy					X		X
Log files MusicStar					X		

Figure 6. Schedule of enrolment, interventions, and assessments MUSTAFI. (Recommendations for Interventional Trials, SPIRIT flow chart, adapted from STUDY II). PSQI: Pittsburg Sleep Quality Index, WHO-5: World Health Organization-5, WHOQOL-BREF: World Health Organization Quality of Life BRIEF, HAM-D17: Hamilton Depression Rating Scale.

2.3.3. RANDOMIZATION

Patients were randomized using computer-generated block randomization (random block sizes 2-8) using stratification of age, i.e., under 30 years/30 years and above. A program named Redcap (Research Electronic Data Capture) hosted at Aalborg University Hospital was used to allocate patients in a 1:1 ratio of waitlist control group (standard care) to music intervention (68).

Once the randomization had taken place the participant was included in the study and baseline data was collected. Data was entered utilizing double entry verification.

2.3.4. OUTCOME MEASURES

The study outcomes included subjective and objective sleep measures, measures of depression symptoms and of quality of life. Data gathered by questionnaires and medical status was collected at baseline, at four weeks and at eight weeks. Demographic information was collected at baseline.

The primary outcome measure was the Pittsburgh Sleep Quality Index (PSQI), the endpoint defined as change of subjective sleep quality from baseline at four weeks. Statistically significant change indicating treatment benefit after the intervention period.

The secondary outcome measures included objective sleep measures using actigraphy. Symptoms of depression was assessed with the Hamilton Depression Rating Scale (HAM-D17) and quality of life was assessed with WHO-5 and WHOQOL-BREF questionnaires collecting data on psychological wellbeing including mood, vitality and interests (WHO-5) and physical/psychological health, social engagement and environment (WHOQOL-BREF).

The secondary endpoints were change from baseline at 4 and 8 weeks.

Pittsburgh Sleep Quality Index (PSQI)

The PSQI questionnaire was used to assess sleep quality of participants as it refers to sleep habits and disturbances within the last month. Domains including subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, daytime dysfunctions and use of anti-depressants form the seven subscales summed for the global score ranging from 0 to 21 with sub scores ranging from 0 to 3. The predictive validity for PSQI in psychiatric populations has been demonstrated (69,70).

Hamilton Depression Rating Scale (HAM-D17)

The HAM-D17 was used to assess depression. It is a well-established questionnaire for assessing depression including sleep disturbances. Seventeen items cover the depressive state, unspecific stress and arousal symptoms, suicidal thoughts and lack of insight. The total score ranking from 0 to 52 graduates the severity in four categories from minimal to severe depression. The psychiatrist, nurse or research leader performed the rating using a rating sheet in combination with a guide to the questions. The HAM-D17 is validated and refers to the last three days (10,71).

The 5-item World Health Organization Well-Being Index (WHO-5)

This short questionnaire containing five questions was used to self-report subjective psychological well-being. It is a widely used assessment tool measuring subjective quality of life based on positive mood, vitality and general interests. The respondent answers how the five statements apply considering the last two weeks. The items are scored from 0-5 and the total sum indicates the state of well-being. WHO-5 is validated as a measure of depression severity (72).

The World Health Organization Quality of Life BREF (WHOQOL-BREF)

The WHOQOL-BREF is a 26-item questionnaire for self-report of physical health, psychological health, social relationships and environment. The participants answered the questions on a 5-point Likert scale. A higher score indicating higher subjective experience of quality of life. The questionnaire has been validated for use by sick and well respondents (73).

Actigraphy

The wrist worn accelerometer with on board memory (Axivity Ax3, Newcastle upon Tyne, UK) was used to measure arm movement at night. The measurement range was set to +/- 8G with a sampling frequency of 25 Hz. A genereric algorithm providing a sleep analysis provided data on sleep duration and has been validated for sleep assessment (74).

The MusicStar app

The music intervention was delivered utilizing a music app designed by Bertelsen and Lund. The app contains 16 playlists of calm music in a self-explanatory user interface visually represented in the shape of a colored star. Music has been selected by music therapists and it is organized according to stimuli and by color-coding. A log function registers the use of music, including time and duration allowing for objective report of compliance and treatment adherence. (STUDY II)

Sample size

Based on a previous study, the mean decrease in Pittsburgh Sleep Quality Index (PSQI) scale was 3.04 (SD2) points for the music intervention group and 2.04 (SD1.67) points for the waitlist control group after four weeks. Using the Satterwaite's two-sample *t* test with a total of 100 patients (n=50 per group) the power was estimated to be 76% at a confidence level of 5% (STUDY II).

The sample consisted of 112 adults with unipolar depression aged 18-65. Recruitment began in May 2018 and continued until October 2020. The recruitment was slowed

down during the Covid-19 pandemic and lock down in the spring of 2020. A total of ten participants dropped out before completion (9%) while 102 participants completed the eight-week period.

2.3.5. STATISTICAL ANALYSIS

The intention-to-treat principle was used for analyses performed using STATA (StataCorp. 2021. *Stata Statistical Software: Release 17*. College Station, TX: StataCorp LLC). STATA software was utilized to perform data analysis and the $P < 0.005$ gave indication of statistical significance. A descriptive analysis of patient characteristics was performed comparing groups using F-tests and chi-squared tests. Data was analyzed using mixed effects linear regression with subject specific random effects. We compared the groups on outcome measures at three timepoints; baseline, four weeks and eight weeks. Age and gender were added as covariates in all regression analyses. Results from baseline were compared with results from four-week and eight-week follow up using Repeated measures of variance (RM-ANOVA) to explain the relation between groups.

Transition
The protocol reported the research design using a randomized controlled trial as a method investigating if music intervention was effective in treating insomnia in depression. Investigating how and why the music intervention was effective or not, was explored through a qualitative study utilizing interviews of participants. The method used in STUDY IV is reported in the following section.

2.4. MUSTAFI: INTERVIEW (STUDY IV)

To gain knowledge of the underlying mechanisms and possible benefits of music intervention, we examined experiences of music listening through an interview study of participants. The study design utilized a qualitative thematic analysis (75) using phenomenological methods applied as microanalysis of interview data (76).

2.4.1. PARTICIPANTS

The participants comprised four adults (3 women, 1 man) aged 23 to 62 who, at time of study, were patients receiving treatment for unipolar depression in an outpatient unit in the department of psychiatry at Aalborg University Hospital. The participants

had moderate or severe sleep disturbances including difficulties falling asleep or maintaining sleep. The Hamilton Depression Rating Scale (HAM-D17) identified the sleeping problems by a score of at least 2 in one item, or at least 3 in total for the three items (sleep items 4-6).

We recruited participants from the RCT for a post intervention individual semi-structured interview. The wish for diversity (age and sex) had to be moderated due to slow recruitment and few volunteers, resulting in inclusion of those who volunteered.

Inclusion criteria was completion of the music intervention period regardless of outcome and ability to communicate personal experience in an interview format. We included four interviews for thematic analysis (75). More women than men were recruited for the trial resulting in only one male participant.

2.4.2. INTERVIEW

An independent researcher carried out interviews in a time frame of one month after the music intervention period. Interviews were conducted in Danish at individual appointments at the hospital. The mean length of the interview was 42 minutes. The interview guide is found in Appendix B. The interviewer was provided with a tablet with the MusicStar app in order to help participants recall the playlists and play extracts. The interviews were audio recorded and the analysis of the interviews followed the systematic seven step procedure of Phenomenological Microanalysis as reported by McFerran and Grocke (76).

2.4.3. MICRO ANALYSIS

In the first step, interviews were fully verbatim transcribed and checked for accuracy by the research leader. In the second step, *Identifying Key Statements*, the research leader and a second researcher read the transcripts independently and noted key statements for the research questions (Appendix B). Statements answering directly to the research questions were included as well as statements on how music listening as prescribed had had an effect during the intervention period. We included suggestions on future improvement of music listening and audio equipment, but statements of the effect of other music or sound during the intervention period were excluded. Other themes than indicated in the research questions were excluded as well as statements of the future use of other means than music (other audio) (STUDY IV).

Inclusion of two researchers selecting key statements aimed at reducing potential researcher bias. The interrater agreement was 93%. Disagreements were resolved after discussion between the two researchers. The third step named *Creation of Structural Meaning Units* involved categorization of the key statements were using headings

guided by statements on the effects of the music during the intervention period. For example; "Sleeping problems related to loneliness" was removed because it represented an individual theme. "Selecting music for the brain" was subsumed into the category "Selection of music (structural musical features)" and "Change of habits – no screen" was subsumed into the category "Change of habits and behaviour". The fourth step, *Creating Experienced Meaning Units*, involved a revision of categories and titles. The third and fourth step were merged in the working process. The fifth step, *Developing the individual distilled essence*, implied writing a short narrative summarizing the participant experience. The sixth step, *Identifying Collective Themes*, implied creation of global themes based on commonalities of themes subdivided into common, significant and individual themes. In total sixteen collective themes were included. From these, six overarching themes emerged. The conclusions from each theme were summarized in step seven, *Creating Global meaning Units and the Final distilled essence,* the result of the analysis (STUDY IV).

Transition

The research methods have been described. First, the quantitative method consisting of a randomized controlled trial in a two-arm design was presented. The participants, music intervention, measures, sample size and plan for analysis was included in this section. Second, the qualitative research method was presented with an overview of the seven steps of thematic analysis in a microanalysis of interview data.

CHAPTER 3. RESULTS

This section includes summaries of results from the four studies.

3.1. OVERVIEW (STUDY I)

The study provided documentation of the development of music intervention practices in psychiatry at Aalborg University Hospital. Pilot projects identified problems with existing sound equipment and the developmental process of the MusicStar app was highlighted. The challenges of selecting music repertoire according to the needs of the patients were identified and the rationale for the present solutions were presented underlining accessibility and intuitive non-genre-based music selection. An interview study highlighted three aims for music interventions in psychiatric settings; distraction, relaxation and sleep support. Metatheoretical perspectives were highlighted; music therapy and music medicine originate from different paradigms while a pragmatic approach enabled the merging of a humanistic foundation with a post-positivistic approach to music intervention. Study I underlined clinical, technical, musical and theoretical considerations shaping the direction for music interventions in psychiatry.

3.2. MUSTAFI: PROTOCOL (STUDY II)

The protocol study reported the trial design including objectives and methods; eligibility criteria for participants, description of interventions with specific instructions and specification of primary and secondary outcomes. The study reported recruitment procedures including oral and written information to potential participants followed by initial screening of sleep disturbance severity, the process of obtaining informed consent and procedures ensuring patients' rights, securing data and keeping documents in a safe locked place. The study reported the use of Research Electronic data capture (Redcap) hosted at Aalborg University Hospital for data collection utilizing computer generated block randomization and stratification of 120 participants according to age separating groups at 30 years of age and in a 1:1 allocation ratio. The statistical methods were reported using the intention to treat principle and analysis was performed using RM Anova. An eight-week period was defined and illustrated in a participant flow diagram comprising a four-week intervention period and a four week follow up with three test points; at baseline, at four weeks and at eight weeks follow up.

3.3. MUSTAFI : RCT (STUDY III)

A randomized controlled trial was performed and reported following the guidelines of the revised Consolidated Standards of Reporting Trials (CONSORT). Participants in the music intervention group and the waitlist controls are seen in the study flow diagram.

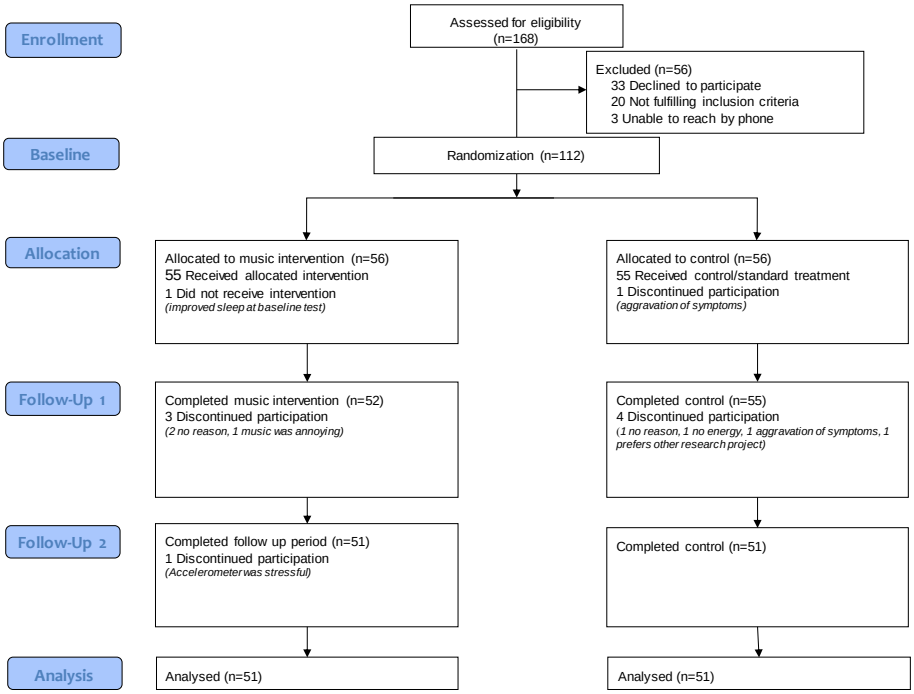


Figure 6. Flow diagram of MUSTAFI participants. (STUDY III)

Demographic and clinical data at baseline:

Table 1

Sociodemographic and clinical Characteristics of Participants at Baseline

Baseline	Music intervention (N=55)	Wait-list control (N=56)	Missing	
	n (%)	*n (%)*	Music	Control
Age				
Median	28	27	n = 1	n = 0
Below 30	31 (56)	31 (55)	n = 0	n = 0
30 and above	24 (44)	25 (45)	n = 0	n = 0
Sex				
Female	38 (69)	39 (70)	n = 1	n = 0
Etnicity				
Danish	50 (93)	47 (84)	n = 1	n = 0
Other	3 (6)	8 (14)	n = 0	n = 0
Unknown	1 (2)	1 (2)	n = 0	n = 0
Marital status				
Single/Divorced/widow	21 (38)	38 (68)	n = 0	n = 0
Partner	34 (62)	18 (32)	n = 0	n = 1
Children (living at home)				
None	44 (80)	40 (71)	n = 0	n = 0
0-6 years old	5 (9)	5 (9)	n = 0	n = 0
6-13 years old	7 (13)	6 (11)	n = 0	n = 0
Teenagers	5 (9)	8 (14)	n = 0	n = 0
Work position				
Working	7 (13)	6(11)	n = 1	n = 0
Sick leave	21 (39)	19 (34)	n = 0	n = 0
Sick leave, part time	3 (6)	1 (2)	n = 0	n = 0
Not working	11 (20)	7 (13)	n = 0	n = 0
Student	9 (17)	20 (36)	n = 0	n = 0
Early retirement	3 (6)	3 (5)	n = 0	n = 0
Highest educational level				
Middle school	10 (18)	19 (35)	n = 0	n = 1
High school	20 (36)	9 (16)	n = 0	n = 0
College	7 (13)	6 (11)	n = 0	n = 0
Shorter higher education	3 (5)	5 (9)	n = 0	n = 0
Longer higher education	11 (20)	13 (24)	n = 0	n = 0
University/postgraduate Degree	3 (5)	2 (4)	n = 0	n = 0
Other education	1(2)	1(2)	n = 0	n = 0
Alcohol (subjective)				
Less than 7/14 units per week (women/men)	53 (96)	53 (96)	n = 0	n = 0
More than 7/14 units per week(women/men)	2 (4)	3 (5)	n = 0	n = 0

ICD 10 Diagnosis				
F32	29(53)	31(56)	n = 0	n = 2
F33	26(47)	24(44)	n = 0	n = 0
Months since recent depression diagnosis	4.3	4.1	n = 2	n = 3
Months since first depression diagnosis	6.5	10.3	n = 4	n = 9
Comorbidity* (diagnosed)	13(12)	15(13)		
Medication				
Antidepressants	47(42)	52(46)	n = 0	n = 0
Antipsychotics	27(24)	30(27)	n = 0	n = 0
Mood stabilizers	3(3)	13(12)	n = 0	n = 0
Other**	15(13)	19(17)	n = 0	n = 0
Music listening at bedtime				
Never	30 (59)	25 (48)	n = 0	n = 0
Rarely	10 (19)	16 (31)	n = 0	n = 0
Sometimes	6 (12)	6 (12)	n = 0	n = 0
Often	5 (10)	4 (8)	n = 0	n = 0
Always	1 (2)	0 (0)	n = 0	n = 0

Note. N = 112 (n = 56 for each condition). The mean age of participants was 34 years.
*= Diagnosis include PTSD, ADHD, ADD, Autism Spectrum Disorder, Anxiety and others.
**= Other medication: Melatonin, Benzodiazepines, Phenergan, Methylphenidate (Ritalin), Atomoxetine (Strattea)

Of 112 included participants, 48 changed medication during the project period (24/24), 32 had doses increase and/or added medication including new pharma (15/17), 5 had doses decrease and/or removal of medication (4/1), 11 had various medication changes during the period (5/6). 7 participants did not receive pharmacological treatment for depression during the project (5/2).

Table 5. Adaptation from Table 2 STUDY III. Means and standardized Mean difference at Baseline, week 4 and week 8, Confidence Intervals. Change from baseline at four and eight weeks. Sleep duration = PSQI subscore.

	Music		**Waitlist control**		**Change scores**	
Outcomes	Mean	95%CI	Mean	95%CI	Mean	95%CI
PSQI						
Baseline	14.3	13.6 - 15.0	14.6	13.8 - 15.4		
Week 4	11.6	10.6 - 12.5	13.9	12.9 - 14.8	**2.1***	1.0 - 3.3
Week 8	12.5	11.5 - 13.5	12.8	11.7 - 13.9	0.9	-1.1 - 1.4
HAM-D17						
Baseline	17.6	16.3 - 19.0	17.2	15.9 - 18.5		
Week 4	15.1	13.6 - 16.6	15.5	14.0 – 17.0	0.9	-1.0 - 2.8
Week 8	15.1	13.5 - 16.7	15.1	13.3 - 16.8	0.6	-1.3 - 2.6
WHOQOL-BREF						
Baseline	72.4	70.2 - 74.7	75.8	73.0 - 78.6		
Week 4	76.2	74.2 - 78.3	77.6	74.8 - 80.4	-2.3	-5.3 - 0.6
Week 8	73.8	71.2 - 76.4	77.0	74.0 - 80.0	-0.4	-3.5 - 2.6
WHO-5						
Baseline	25.1	22.2 - 28.2	29.7	25.8 - 33.6		
Week 4	36.5	32.4 - 40.5	32.7	28.6 - 36.7	**-8.4***	-14.0 - -2.7
Week 8	32.5	28.1 - 37.0	34.4	29.5 - 39.4	-2.8	-8.6 - 2.9
Sleep duration						
Baseline	6.2	5.7 - 6.6	5.9	5.4 - 6.3		
Week 4	6.5	6.1 - 6.9	5.7	5.3 - 6.1	-0.6	-1.2 - -0.5
Week 8	6.3	5.8 - 6.8	6.2	5.8 - 6.6	0.1	-0.5 - 0.7

Note * : Numbers in bold indicate statistical significance.

The results showed a significant reduction in global PSQI scores indicating improved sleep quality from baseline at four weeks in the music intervention group. At eight weeks the global PSQI scores in the two groups were similar.

The HAM-D17 scores indicated light to moderate depression at baseline, with decrease at four weeks indicating minor improvement in depression symptoms for both groups, but not any differences between groups at the two follow up tests.

The quality of life as measured with WHO-QOL-BREF showed global increasing scores for the music intervention group indicating improved quality of life from baseline at four weeks, but this did not reach statistical significance. The scores for the music intervention group decreased from four weeks at eight weeks indicating diminished quality of life when omitting music. WHO-5 wellbeing scores showed increase from baseline at four weeks and decrease at eight weeks. For the music intervention group the change score at four weeks reached statistical significance indicating improved wellbeing. The WHO-5 wellbeing scores increased by 33% at four weeks.

The PSQI subscore of sleep duration indicated poor sleep at baseline and indication of increased sleep duration by 18 minutes at four weeks.

Treatment fidelity

Strategies to enhance adherence to protocol was oral instructions during consultations and telephone calls reaching out to fragile participants. The sound pillow emphasized horizontal music listening as it was placed in the bed. MusicStar Logfile data was available from 84% of participants (n=46). Missing data was due to technical issues. The average of strict adherence to protocol (27 nights/30 min. at indicated bedtime) was 39%. The average adherence to protocol (27 nights/self-administered exposure) was 67%.

3.4. MUSTAFI : INTERVIEW (STUDY IV)

The four participants evaluated the music intervention in a semi-structured interview guided by interview questions (see Appendix B). The participants were anonymized and named Mona, Louis, Tina and Alice.

Tina, 23 years old, reported depression, anxiety and stress. Habitual music for sleep: often.

Mona, 23 years old, reported depression. Habitual music for sleep: sometimes.

Louis, 24 years old, reported depression. Habitual music for sleep: always.

Alice, 61 years old, reported depression and Chronic obstructive pulmonary disease (COPD). Habitual music for sleep: never.

The results from the interview study were reported in themes: sleep and relaxation, distraction, mood, habits, preference and technology.

Sleep and relaxation: Music was reported as a relaxing stimulus promoting sleep. Statements did not separate relaxation from sleep, indicating a strong relationship between relaxation and sleep. Sleep quality was defined and characterized by problems of sleep initiation, nightly awakenings and early morning awakenings. Two participants experienced improved relaxation and sleep quality including improved daytime restedness and longer periods of continuous sleep indicating fewer nightly awakenings. One participant reported fewer nightmares and two participants reported reductions of time to sleep onset.

> “Yes, during the time I used the app, I slept better than I did before” (Mona)

The perception of sleep-inducing effects of music were individual and included positive physical effects, feelings of wellness and mental effects of the music including an effect characterized as peace of mind. One participant did not benefit from music listening and reported that listening to audiobooks at night was more effective.

The exposure to music was individual from the use at bedtime to continuous use during the night.

Distraction: Distraction was discussed in depth by three participants and played a significant role.

> "If you start to focus on what's happening in the music, that is, you try to figure it out. Then you remove many running thoughts. It is extremely calming". (Louis)

Music listening distracted from thoughts, ruminations, anxiety and physical restlessness.

Mood: Mood changes towards positive moods were reported by two participants. Improving mood may increase wellbeing and counteract symptom of decreased mood in depression.

> "It can give you a complete sense of happiness…It has really been good, not the first week, right, you must get used to it and finding out what kind of music to listen to. But then, I was really looking forward to listening to the music, because it would give me peace of mind". (Alice)

Alice reported improved mood and wellness in addition to improved sleep and relaxation. Tina reported music to cause frustration resulting in a negative mood.

Habits: Music at bedtime implied attention to bedtime habits and bedtime sleep hygiene. Mona and Alice reported positive effects of music and change of habits.

> "It (music listening) has changed my behavior, so I don't lie with my cell phone anymore, which is a good thing". (Mona)

Music had a positive effect on sleep hygiene except for participants who were experienced bedtime music listeners for whom bedtime habits did not change.

Preference: The participants searched for relaxing music, the rationale for selecting music was specific and individual. While Alice chose music for a psychological

purpose (peace of mind), Mona selected music for a physical effect (physical wellness).

> "I chose music according to physical sensations. Some of the playlists were better some days than others, and it may have something to do with physical restlessness". (Mona)

Participants listened to music with different objectives and rationale. Alice changed her listening mode when listening to music for sleep. She introduced a supportive regulating thought, conditioning the bedtime situation with positive reinforcement.

The process of music listening involving music and the individual was in one case characterized as a static one-way receptive process and in another case as a dynamic interactive process adjusting musical stimuli to individual needs ad hoc.

Music preferences was discussed as playlist preferences rather than preferences of music pieces. The rejected playlists were perceived with reactions of stress and irritation and the participants described disliked music as disturbing, interrupting, annoying and noisy. Playlist preferences included sleep music favorites varying from one to four playlists. Playlists from the blue segment of the MusicStar was common favorite playlists. The blue playlists contain the least stimuli, slowest tempo, little melodic and harmonic change, predictable rhythmic structure and the music is performed by small ensembles.

Technology:

The listening experience was affected by frequency, duration and volume. The options to adjust the music were appreciated and adjusting the volume to an individual low level was paramount.

> "I thought it should be a lot louder for me than it should, actually. It must be like floating, passing by my ear, calmly, quietly. I can hear it, but it's not in a way that it is so loud that you, like, now you get what's happening here". (Alice)

The music selection was important to participants. Mona and louis reported the music in the MusicStar was similar to their normal preferred bedtime music. Tina missed music of her personal preference.

> "I hoped that I might find something a little bit more (appealing to) me". (Tina).

The color groups of the playlists, the music selection and the app design were evaluated positively by three participants. The evaluation of the sound pillow was

mixed; the sound quality ranged from low to good, the sound distribution had the advantage of distributing the sound locally not disturbing a partner in bed. For Alice the sound from the sound pillow created a sensation of a protective bonnet supporting distancing to exterior sounds.

In conclusion, themes and subthemes were visualized in a theme map (Fig. 7.) The theme map illustrated the complexity of themes, subthemes and interrelated strategies, mechanisms and outcomes.

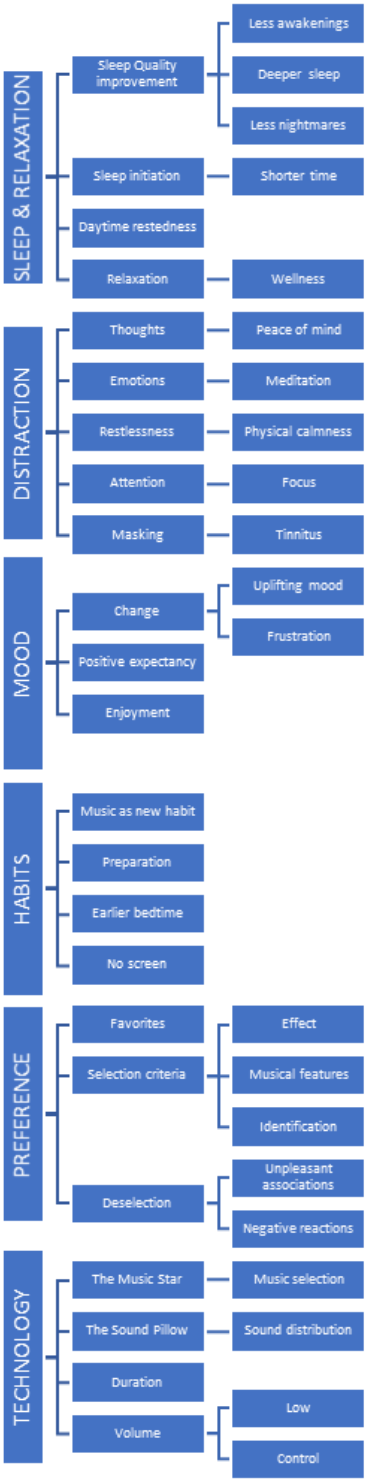


Figure 7. Theme map (STUDY IV)

Results

Three of four participants evaluated the music intervention effective in improving sleep and relaxation while one participant did not benefit from music intervention. Music enhanced acceleration of sleep initiation and reduced nightly awakenings, positive effects were both psychological and physiological. Relaxation was enhanced by music listening providing distraction from thoughts and physical restlessness and in one case distracting from tinnitus. The musical features of selected music were highlighted as beneficial.

Two participants experienced positive mood changes and positive effects of improved sleep hygiene in relation to bedtime routines. Activities were stopped earlier, including turning off screens and preparations for bed were initiated at an earlier time. A psychological mechanism was highlighted playing a part in habit formation showing evaluative conditioning as music was linked to good sleep and positive thoughts of sleep reduced sleep-inhibiting anxiety. In this case, a conditioned stimulus (music) was repeatedly connected to an unconditioned stimulus (falling asleep) resulting in a positive healthy association enabling music to act sleep-reinforcing. Calm and predictable music played at low volume was reported to enhance relaxation and sleep, while duration and frequency of music listening at night was individual. Three of four participants gave positive evaluations of the playlists and reported favorites. The rationale for choice of music was individual and the wish for familiarity and non-familiarity was equally emphasized suggesting most benefit from a varied repertoire of music and nature soundtracks.

CHAPTER 4. DISCUSSION

This section discusses main findings including strengths and limitations. Findings from the RCT and the interview study are merged, and the results are discussed in comparison with relevant literature.

4.1. DISCUSSION OF MAIN FINDINGS

The objectives of this thesis were to examine the efficacy of a music intervention in improving sleep quality, symptoms of depression and quality of life in adults with depression-related insomnia. Furthermore, the thesis aimed to investigate patients' experiences of music listening at bedtime.

Results from the RCT showed that music intervention was effective in improving sleep quality, confirming the hypothesis that self-administered use of the MusicStar app combined with a sound pillow can serve as a sleep-aid in reducing depression-related insomnia.
The results showed a statistically significant difference in sleep quality at four weeks comparing the intervention group with controls. The effect size was 2 standard deviations in favor of music intervention indicating a large effect size. A sub-analysis indicated improved nocturnal sleep duration of 18 minutes when listening to music and pointed to a benefit from music considering duration of sleep while other outcomes such as sleep initiation and nightly awakenings were not reported. This study does not contribute with evidence to specific variables of sleep quality.
Results from assessments of depression symptoms did not show differences between the music intervention group and controls at any time. Results suggest that depression symptoms persisted. As sleep quality improvements were moderate, they did not affect the individual regarding depression symptoms within the four-week intervention period. The mean global PSQI scores decreased but they were still far from the scores of normal sleepers scoring up to 5 points on the sleep scale ranging from 0-21 (higher scores indicating more severe sleep disturbances). At all tests, the mean scores in both groups were above 10 points indicating severe insomnia. Results from assessments of quality of life and wellbeing showed improved well-being and improved quality of life at four weeks. Improved psychological well-being assessed with the WHO-5 questionnaire reached statistical significance and the WHOQOL-BREF scores showed the same tendency but not reaching statistical significance. These results point to rejection of the hypothesis that music may reduce depression symptoms but confirm the hypothesis that music has positive effect on quality of life and wellbeing.

The results from objective sleep assessment with actigraphy did not point to differences between groups. The improvements of sleep quality, quality of life and wellbeing were therefore solely based on self-report. The aim to include objective and subjective sleep data providing thorough evidence for the efficacy of music in improving sleep quality was not met. Still, the positive effects of music on sleep, quality of life and wellbeing were clear. Considering the symptoms of reduced mood and negative emotions in depression, improved wellbeing and quality of life from listening to music may positively affect the depressed individual improving mood and regulating emotion, but this remains hypothetic.

The group of patients volunteering to take part in the trial showed initial motivation to test an unconventional treatment modality and to music listening. This group of patients may not be representative for the population of adults with depression-related insomnia. Assuming that benefit from music interventions increase with motivation, the results of the trial should be seen in the light of this.

4.2. STRENGHTS AND LIMITATIONS

A major limitation was a lack of a systematic review of the literature considering music for depression-related insomnia. A systematic literature search was included in the thesis with a table listing relevant trials. The search revealed few trials confirming the need for research.

STUDY I
The main strength of Study I was the synthetization of results from music intervention pilot studies outlining the background, identifying relevant literature and methodology, and highlighting the design of the MusicStar app. Clinical, technical, musical and theoretical perspectives were presented. The conclusions from Study I pointed towards sleep and using the MusicStar app in relation to sleep. The limitation of Study I was the preliminary nature of results.

STUDY II and STUDY III
The main strength of Study II was the rigorous study protocol in adherence with scientific norms (CONSORT) minimizing flaws using standardized outcome measures to assess sleep quality, depression symptoms and quality of life. The research procedure was described in detail including sample size calculation, randomization procedures and plan for statistical analysis. Detailed report of the music intervention and listening instructions were included.

A music intervention was investigated through a RCT. The trial had a large sample with adequate power (76%) which was a considerable strength. External validity was achieved due to low attrition reducing the risk of selection bias.
This is the first study to include a longer non-music follow up period after the music intervention, assessing long term treatment gains. Adding a second post treatment

follow up test showing decrease in sleep quality and wellbeing after an additional four-week period without music underlined the ad hoc effect of music. Comparing results at four weeks and eight weeks indicated that changes in sleep and wellbeing were caused by the music intervention and not by time or other treatment gains. Still, the findings should be interpreted with caution. The improvements of sleep quality were moderate, participants reported a continuum of high scores at all time points of PSQI assessments.
Blinding participants was not possible which may influence self-ratings causing a Hawthorne effect. A major limitation was the lack of objective data from actigraphy to inform the study. Adherence to protocol was reported based on log files from the MusicStar app adding objective data in reports of treatment fidelity. Results showed that a minority of participants followed the listening instructions according to the self-reported bedtime. This could indicate unrealised treatment potential and possible increased benefits with increased and correct exposure to music. Bedtimes for depressive insomniacs are possibly varying (rather changing than fixed) and indications of fixed bedtimes listed in questionnaires were not reflecting reality which may also explain that log files did not show exposure to music at the indicated bedtimes.

The years of suffering from insomnia were not investigated. Future research should investigate the aetiology of sleep disturbances to target the group for whom music intervention is suggested to be most effective. A strength of the trial was registration of medication showing equal distribution between groups. However, medication changes during the trial were inevitable.

STUDY IV

The study aimed to reveal impacts of music for sleep from participants experiences. The Theme map (Fig. 7) underlined the complexity of underlying mechanisms when addressing the effects of music within themes of sleep & relaxation, distraction, mood, habits, preference and technology.

This study findings were in line with studies pointing to effects of music related to habit formation and evaluative conditioning (49), studies pointing to arousal regulating effects of music (31) (46), mood increasing effects of music (30), and distraction effects. Participant testimonials revealed that music distracted from thoughts and depression-related worries. Preference and familiarity showed contradicting results in favour of familiarity and non-familiarity. Selecting and adjusting music for individual needs emphasizing agency and control were suggested to have psychological impact enhancing positive expectation. A dynamic interactive process during self-assessment and self-prescription of music, adjusting the dose and forming habits was suggested to have positive impact on outcomes.

This study pointed to the technology delivering the music as an under-reported and perhaps underestimated parameter with potential influence on outcome. In addition to the discussion of the impact of preferences and familiarity, the study pointed to a discussion of the impact of technology. The study pointed to advantages of an app design providing easy access to music selected by music therapists potentially improving user satisfaction and enhancing positive expectation.

A major limitation was the small sample of participants in STUDY IV which did not allow generalizations. The small sample was not representative for the population. The study allowed for the voice of participants unfolding examples of complex interplay between music, sleep, depression symptoms, relaxation and wellbeing.

4.3. DISCUSSION OF MIXED METHODS

The mixed methods design in an explanatory sequential design (Fig. 2) demonstrated research procedures from objectivist and interpretivist paradigms. STUDY III and STUDY IV provided two separate data sets requiring two types of analysis. Assessing sleep, depression and quality of life with questionnaires and actigraphy in the trial and assessing patient experiences with questions in a semi-structured interview provided knowledge of different research methodologies. Reporting results from statistical analysis and from qualitative thematic analysis provided findings from two separate stands. In the following section, quantitative and qualitative results are merged.

The results from the RCT showing improved sleep quality in reduced global PSQI scores were reflected in the interviews of participants within the theme of Sleep & Relaxation. The results from the trial pointing to an increase of sleep duration were not reported as prolonged sleep by participants, but the improvements of sleep quality were defined as shortening of sleep initiation, less nightly awakenings, deeper sleep and less nightmares (Fig. 7). The increase of sleep duration from listening to music at bedtime reported in the PSQI sub-analysis in the trial may be caused by increased relaxation and wellbeing shortening sleep initiation. However, the testimonials suggest effects of music beyond sleep onset and throughout the night. The relaxing effects of music were highlighted by participants possibly leading to deeper sleep and less nightly awakenings. This was reflected in the descending global PSQI scores indicating sleep quality improvements. Deeper sleep at night may be reflected in the global PSQI scores but not necessarily in the sleep duration scores.

Assessing depression symptoms, the trial did not reveal any differences between groups. In the interviews, depression did not emerge separately as a theme. The distracting effect of music was emphasized by participants reporting distraction from unwanted thoughts, emotions and physical restlessness. Negative thoughts and emotions and physical restlessness are common depression symptoms. In the light of

the absence of changes in depression symptoms found in the trial, the participant statements lead to suggest that music distracted from depression symptoms considering negative thoughts and emotions rather than alleviated the depression symptoms.

The results of the RCT showed improved quality of life from bedtime music listening. The results indicated clinically significant improvements as scores improved by 33% at four weeks. In the interviews, quality of life was not a separate theme. Within the theme of sleep and relaxation quality of life and wellbeing was included as relaxing effects of music were leading to increased wellbeing. Wellbeing was also reflected in mood and enjoyment of music listening. The close relationship between enjoyment of music, improved mood, wellbeing and relaxation was underlined in quotes from participants. The results from the RCT pointing to improved quality of life were clearly reflected in the participant testimonials.

While results from the trial (STUDY III) suggested moderate effects of music listening for the population, the findings from the interview study (STUDY IV) showed examples of individual and varying outcomes. The effects of music reported by the four participants pointed to a spectrum of outcomes from no benefit to clinically significant benefit.

Improved sleep, wellbeing, mood, and improved feeling of restedness were outcomes indicated by interviewees except one participant who indicated no sleep quality improvements and negative reactions of frustration and worsening of mood. While it was not possible to generalize from the small sample, these examples demonstrated that effects of music were individual. A negative evaluation of the music intervention from one participant led to suggest that music intervention is not beneficial to all. The spectrum of individual responses and varying outcomes reported in the interviews lead to hypothesize that music intervention has better effect for patients with motivation for using music as a sleep aid.

4.4. COMPARISONS WITH LITERATURE

The evidence base supporting the use of music for improving sleep quality is based on trials measuring sleep from self-reports (50). Trials indicating efficacy of music interventions with objective measures of sleep quality may add to the evidence base, although this trial did not provide results from objective measures. Sleep trials have combined subjective and objective outcomes (46,77).

A trial investigating music for insomnia disorder used sleep questionnaires (Insomnia Severity Index and Pittsburgh Sleep Quality Index) as primary outcomes and polysomnography and actigraphy to measure objective sleep as secondary outcomes (46). The objective measures from polysomnography and actigraphy showed no differences between groups while self-reports of sleep perception and quality of life

showed significant effects in the music intervention group after a four-week music intervention. The three-armed trial included an audio-book control group in addition to ordinary controls. Two studies with audiobook controls showed better effects of music than audiobooks (46,78). Contradicting to this, the interview study (STUDY IV) provided one example in favor of audiobooks to music. Still, the examples did not allow for conclusions.

One explanation for moderate positive results was suggested to be the severity of insomnia symptoms which may limit the effect of music. The above-mentioned trial included participants with a mean global PSQI score above 10 at baseline. The insomnia severity was also reflected in high PSQI scores in this trial comprising depression patients (STUDY III). Studies have suggested that more difficult sleep disturbances are more difficult to resolve with music (46,49). The suggestion that higher PSQI scores require more than four weeks of music intervention to lead to better sleep has been proposed (49). A review investigating dose-response relationships of music interventions and sleep quality showed decrease of sleep disturbances with increase of music exposure across studies (49). This trial showed that improvements in sleep quality and quality of life declined when music exposure was stopped. The comorbid presentation of depression and insomnia symptoms may influence prognosis for normalization of sleep by music. It is unknown if the prognosis is worsened by comorbidity. The apparent short-term effects of music in improving sleep have been partly explained with the time consuming process of habit formation when integrating music in bed time routines (49). This argument implied that habit impacted the effect of music positively. In the interview study, music listening at bedtime was reported to support healthy bedtime habits. The dose-response relationship regarding an accumulative effect was not possible to report in this trial (STUDY III) as assessments were limited to four and eight weeks as opposed to weekly assessments (40,43,54,78,79).

Adherence to protocol has been reported based on subjective report and methods have developed. In 2012, a trial reported adherence to protocol pointing to instructions of the use of cassette tapes and instructions to horizontal placement in bed in a quiet room (44). In 2018, a trial reported adherence to protocol from self-reports indicating use of music intervention at least 5 days a week by percentage of the sample (46). To the knowledge of the author, this study is the first music and sleep study to report adherence to protocol based on objective log data.

A remaining question is how music induces sleep. A review identified six researcher proposed reasons for music to improving sleep quality (80). They were identified in existing literature and comprised; relaxation, distraction, entrainment, masking, enjoyment and expectations. The reasons were evaluated for support in music and sleep trials. Masking was identified as supporting sleep, while relaxation, enjoyment and distraction showed mixed levels of support. Expectation and entrainment had less clear support in the trials of investigation. The interview study (STUDY IV) provided

examples of patient proposed effects of music and comprised; sleep and relaxation, distraction, mood and arousal regulation and support of healthy sleep habits. Further investigation may allow for identification of reasons for music aiding sleep. This will help researchers explain results from music and sleep trials.

CHAPTER 5. CONCLUSIONS

This thesis examined the efficacy of a music intervention in improving sleep quality, symptoms of depression and quality of life in adults with depression-related insomnia. The results of the trial indicated improved sleep and quality of life while there was no indication of improvements in depression symptoms. The study had a large sample and low attrition indicating patient interest in music intervention. Indications of moderate adherence to protocol suggested unresolved treatment potential.

Investigation of patients' experiences of music listening at bedtime unfolded examples of the influences of music on sleep and relaxation. Music distracted from inner stimuli, affected mood and arousal and supported the formation of sleep habits. The testimonials highlighted multiple underlying mechanisms of the effects of music demonstrating a complex interplay of music, sleep and wellbeing.

The four studies of the thesis were carried out in an explanatory mixed methods design. Complementary qualitative data from interviews underlined the diversity of influences of music and examples of individual experiences were utilized in discussion of outcomes from the trial. The RCT and the interview study contributed to the evidence-base of music intervention as sleep-aid in depression-related insomnia.

In summary, this thesis adds to the evidence base supporting music intervention as a safe and low-cost sleep aid in depression-related insomnia.

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APPENDICES

APPENDIX A LITERATURE SEARCH

Search history, updated 31 May 2021:

Cinahl:

Search ID#	Search Terms	Search Options	Last Run Via	Results
S20	S14 AND S19	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	149
S19	S15 OR S16 OR S17 OR S18	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	88,539

S18	Sleep*	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	79,429
S17	insomnia*	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	12,197
S16	(MH "Sleep Disorders+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database -	40,830

			CINAHL with Full Text	
S15	(MH "Sleep+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	27,498
S14	S3 AND S13	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	1,486
S13	S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search	47,835

	S10 OR S11 OR S12		Screen - Advanced Search Database - CINAHL with Full Text	
S12	AB songs	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	1,380
S11	TI songs	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	1,168

S10	AB song	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	1,380
S9	TI song	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	1,168
S8	sounds	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database -	28,590

			CINAHL with Full Text	
S7	sound	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	28,590
S6	(MH "Sound")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	2,264
S5	music	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search	19,405

			Screen - Advanced Search Database - CINAHL with Full Text	
S4	(MH "Music") OR (MH "Music Therapy")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	15,903
S3	S1 OR S2	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	194,054

S2	depress*	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	193,980
S1	(MH "Depression+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL with Full Text	118,219

Embase:

No.	Query	Results	Date
#11	('depression'/exp OR depress*:ti,ab,kw) AND ('music'/exp OR (music:ti,ab OR	566	31 May 2021

	song:ti,ab OR songs:ti,ab OR sound*:ti,ab)) AND ('sleep'/exp OR 'sleep disorder'/exp OR (sleep*:ti,ab OR insomnia*:ti,ab))		
#10	'sleep'/exp OR 'sleep disorder'/exp OR (sleep*:ti,ab OR insomnia*:ti,ab)	458449	31 May 2021
#9	sleep*:ti,ab OR insomnia*:ti,ab	315149	31 May 2021
#8	'sleep disorder'/exp	280465	31 May 2021
#7	'sleep'/exp	257425	31 May 2021
#6	'music'/exp OR (music:ti,ab OR song:ti,ab OR songs:ti,ab OR sound*:ti,ab)	160493	31 May 2021
#5	music:ti,ab OR song:ti,ab OR songs:ti,ab OR sound*:ti,ab	154188	31 May 2021
#4	'music'/exp	19735	31 May 2021
#3	'depression'/exp OR depress*:ti,ab,kw	845322	31 May 2021
#2	depress*:ti,ab,kw	669211	31 May 2021
#1	'depression'/exp	531053	31 May 2021

Psych info:

((IndexTermsFilt: ("Major Depression") OR IndexTermsFilt: ("Anaclitic Depression") OR IndexTermsFilt: ("Dysthymic Disorder") OR IndexTermsFilt: ("Endogenous Depression") OR IndexTermsFilt: ("Late Life Depression") OR IndexTermsFilt: ("Postpartum Depression") OR IndexTermsFilt: ("Reactive Depression") OR IndexTermsFilt: ("Recurrent Depression") OR IndexTermsFilt: ("Treatment Resistant Depression")) OR (Any Field: (depress*))) AND ((title: (song)) OR (Any Field: (music)) OR (IndexTermsFilt: ("Music") OR IndexTermsFilt: ("Musical Instruments") OR IndexTermsFilt: ("Rock Music") OR IndexTermsFilt: ("Music Therapy")) OR (title: (songs)) OR (abstract: (song)) OR (abstract: (songs)) OR (Any Field: (sound)) OR (Any Field: (sounds))) AND ((Any Field: (Sleep*)) OR (Any Field: (insomnia*)) OR (IndexTermsFilt: ("Sleep") OR IndexTermsFilt: ("Dreaming") OR IndexTermsFilt: ("Napping") OR IndexTermsFilt: ("NREM Sleep") OR IndexTermsFilt: ("REM Sleep") OR IndexTermsFilt: ("Sleep Onset") OR IndexTermsFilt: ("Sleep Quality") OR IndexTermsFilt: ("Snoring") OR IndexTermsFilt: ("Insomnia") OR IndexTermsFilt: ("Sleep Wake Disorders") OR IndexTermsFilt: ("Hypersomnia") OR IndexTermsFilt: ("Insomnia") OR IndexTermsFilt: ("Narcolepsy") OR IndexTermsFilt: ("Parasomnias") OR IndexTermsFilt: ("Sleep Apnea") OR IndexTermsFilt: ("Sleepwalking")))

Pubmed:

Search: ((((depress*[tw]) OR ("Depressive Disorder"[Mesh])) OR ("Depression"[Mesh])) AND (("Music"[Mesh] OR "Music Therapy"[Mesh]) OR (music[tw] OR song[tiab] OR songs[tiab] OR Sound[tw] OR sounds[tw]))) AND ((("Sleep Initiation and Maintenance Disorders"[Mesh]) OR (insomnia*[tw] OR sleep*[tw])) OR ("Sleep"[Mesh]))

Scopus:

TITLE-ABSKEY

(depress* AND (music OR song OR songs OR sound) AND (sleep OR insomnia))

APPENDIX B INTERVIEW QUESTIONS

Questions for a semi-structured interview

Semi structured means that the interview starts with the written questions. The interview situation may bring new themes and new questions into the conversation. The interview ends when the interviewer believes that the theme has been elaborated and the 14 questions have been answered.

The interview is audio recorded and transcribed.

Theme: The quality of sleep of the participant, the experience of the music, the sound pillow and of The Music Star.

1. Has music listening had an influence on you and your sleep? If yes, how and when? (Did the music make a difference when falling asleep, in the middle of the night, in the early morning hours?)

2. Has music listening made a difference regarding bedtime routines and have you changed any behaviours when listening to music at bedtime?

3. Has music listening influenced you in other ways than in relation to sleep? If yes, how? (Has music listening had an influence on your mood, your energy or made you relax?)
4. Has music listening affected negative or running thoughts, or restlessness? If yes, describe how.

5. Additional remarks or comments concerning the music and the effect.

6. Describe which music in The Music Star that seemed to work best. What seemed to work, when and how?
7. What do you think about the music selection and the colour codes in The Music Star?
8. Do you think there was enough music to choose from? If yes, why? If no, what did you miss?
9. How will you describe the music in The Music Star in comparison with the music you listen to usually?
10. Would it have made a difference for the effect of the music listening if you had been listening to your own music, instead of The Music Star? If yes, describe in detail the difference you think it would make.
11. How long should the music play before there was an effect?
12. What is your opinion on the sound pillow (comfort, sound quality and sound experience)?
13. Further comments concerning the sound equipment? Satisfaction/Dissatisfaction.
14. Supplementary comments regarding your participation in the research project.

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