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Impact of Individualised Music Listening Intervention on Persons with Dementia: A systematic review of randomised controlled trials

Abstract

Objective: To summarise the evidence regarding the impact of individualised music listening on persons with dementia.

Methods: Six electronic databases (CINAHL, Medline, ProQuest, PsycINFO, Music Periodicals and Cochrane) were searched up to July 2018 for randomised controlled trials (RCTs) evaluating the efficacy of individualised music listening compared to other music and non-music based interventions.

Results: Four studies were included. Results showed evidence of a positive impact of individualised music listening on behavioural and psychological symptoms of dementia (BPSDs) including agitation, anxiety and depression and physiological outcomes. Evidence for other outcomes such as cognitive function and quality of life was limited.

Conclusion: The limited evidence suggests individualised music listening has comparable efficacy to more resource-intensive interventions. However, there was a small number of RCTs and some outcomes were evaluated by a single study. This limits the conclusions drawn, warranting more RCTs evaluating other outcomes beyond the BPSDs.

Key words: Dementia, intervention, individualised music, older persons, systematic review

Introduction

Rationale

Along with the worldwide growth in the ageing population is an upsurge in the number of persons with dementia (PWDs) (1-3). Dementia is a chronic and progressive syndrome characterised by cognitive dysfunction and behavioural and psychological symptoms of dementia (BPSDs), which can include agitation, anxiety, depression, hallucination, and delusion, among others(4). Management strategies for dementia are mostly aimed at promoting quality of life by alleviating the disabling experience of the PWDs (4, 5). While there are medications that slow cognitive decline, their effectiveness is limited (4, 5). Psychotropic medications are predominantly used in the management of BPSDs (6, 7). However, evidence demonstrates modest benefits of psychotropic medication for management of PWDs and a range of adverse outcomes (8-10). With safety and efficacy

issues surrounding the use of medications for the management of dementia symptoms, non-pharmacologic interventions are promoted in dementia care (11, 12).

Music is one of the recommended and commonly used non-pharmacologic interventions for PWDs (13-16). The relative preservation of music memory in dementia and evidence demonstrating that PWDs are still able to enjoy music even in the late stage of cognitive impairment, provide a rationale for the development of music-based therapies and interventions (17-19). There are various applications of music including music therapy, music listening (individualised or music medicine), and general music based interventions (20). This review focuses on individualised music listening intervention that does not involve a relational component with a music therapist, attributing the therapeutic effect of the intervention on the music itself (20, 21). Although music medicine doesn't require the presence of a therapist (22), the selection of music is based on its structural characteristics to act on specific symptoms (20). With individualised music listening, music selection is based on the person's preferences as indicated by the person or his/her caregivers (20, 23). General music based interventions involve an assortment of activities which could include music listening and are usually administered in groups (20, 21).

There has been growing popularity of individualised music listening for PWDs. The results of several nonrandomised studies, conducted in various settings (e.g. residential care, home) with the intervention implemented by formal and informal caregivers, showed individualised music listening was effective on a number of outcomes, especially the BPSDs, for PWDs (24-29). Such interventions have also captured the media's interest, evidenced by the creation of a documentary titled *Alive Inside* which depicts the positive experiences of people with dementia who have been rejuvenated by listening to personalised music (30). Previous literature reviews on the use of pre-recorded music playlists (31) and music as a therapy (32) for PWDs found that positive effects were evident in therapist or non-therapist-led interventions as well as caregiver implemented interventions. Similarly, results from a meta-analysis suggested the higher likelihood of positive outcomes with music listening compared to music therapy (18). Being a relatively inexpensive intervention that does not require trained professionals for implementation (33), individualised music listening has a potential advantage over other resource-intensive interventions. However, the majority of published systematic literature reviews on music for PWDs are focused on music therapy or music based interventions delivered by a qualified professional, including both individualised and group interventions (16, 34-40). Although Vasionyte and Madison (18) evaluated the effects of different types of music interventions, there was no separate analysis for individualised music listening. One systematic review performed a separate evaluation of individualised

music listening during free time as a leisure activity, but excluded the studies that used music during caregiving routines (41). In addition, the aforementioned systematic reviews were not restricted to RCTs. This limits the strength of the conclusions drawn due to the weak methodological quality of most studies (18, 41). To our knowledge, this is the first systematic review of RCTs on individualised music listening implemented for various purposes and that evaluated a variety of outcomes for PWDs.

Objectives

This review aims to provide a summary of RCTs that explore the effectiveness of individualised music listening intervention for PWDs. The review aims to answer the question: What are the effects of individualised music listening intervention on PWDs? The authors considered the effects on the BPSDs, cognitive function, physiological outcomes and quality of life.

Methods

This review was developed in accordance to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement (see Appendix 1) (42). A review protocol has not been published.

Eligibility criteria

PICOS (participants, intervention, comparison, outcomes, study design)(43) is adopted to set the eligibility criteria.

Participants: Persons with a diagnosis of dementia.

Intervention: Individualised music listening based on the person's music preferences administered for various purposes (e.g. management of BPSDs, prior to care, leisure activity).

Comparison: Other types of music and non-music based therapy or interventions, usual care, and control conditions.

Outcomes: BPSDs including agitation, anxiety and depression, mood and emotion, cognitive function, physiological changes, and quality of life.

Study Design: Randomised trials with a control or comparator group.

Exclusion

Studies were excluded if the diagnosis of the participants was not specifically dementia. For the intervention, studies were excluded if they involved music listening that was not based on the person's preferences, active music therapy or interventions that combined music

listening with other activities in one session, music listening incorporating features of music medicine, and group music listening. Also excluded were studies that did not evaluate outcomes for PWDs and those that are published in non-English language.

Information sources

A literature search was conducted up to July 2018 through the following electronic databases: CINAHL, Medline, ProQuest, PsycINFO, Music Periodicals and the Cochrane databases including the Cochrane Central Register of Controlled Trials. The search strategy was developed with the assistance of an academic librarian. Search terms included “music” or “music therapy” combined with “dementia” or “Alzheimer*” or “lewy body” (see Appendix 2 for Medline search details). The search also included papers identified in the reference list of reviewed studies. No limitation was applied to publication date to include all relevant studies.

Study selection

One review author (MG) screened the titles and abstracts to determine the potential eligibility and relevance of the study. For those studies judged relevant or if relevance was unclear, full text articles were retrieved. Two other review authors (KI and SD) were then consulted to reach a consensus on the studies included in this review.

Data collection process

Data extracted from the full text articles included the citation, study design, setting, sample, dementia severity, the intervention and control or comparison conditions, duration of the intervention and frequency of implementation, outcomes and outcome measures, and results. One review author (MG) extracted data in consultation with the other review authors.

Risk of bias in individual studies

The Cochrane’s Collaboration tool for assessing risk of bias in randomised trials was used for the critical appraisal of included studies (44). The following domains were evaluated for each study: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias.

Risk of bias across studies

The quality of evidence was assessed across studies restricted to randomised controlled trial design.

Synthesis of results

Effects of the individualised music and other interventions on each of the outcomes evaluated were compared. The p value was used in evaluating the statistical significance of the results was set at $P < 0.05$.

Results

Study selection

A total of 2,904 articles were identified by electronic searching and 2 papers identified by hand-searching. After removing duplicates, 1,771 papers remained. Of these, 1,630 papers were excluded during the preliminary screening based on the title and abstract. Further data extraction of 141 full text articles excluded 135 papers based on the inclusion criteria.

Although six papers met the inclusion criteria, three papers were from the same research project as confirmed by the study author (45-47). Thus, a total of four studies were included in this review as shown in Figure 1.

Study characteristics

The included studies were randomised trials with a control or comparison group conducted in Canada, Italy, Japan and Spain. The study setting was heterogeneous: residential care, specialised dementia complex, dementia hospital, group homes, activity centres, and inpatient centres. Participants were PWDs aged 65 years and older. Severity of cognitive impairment was from mild to very severe. The number of participants ranged from 21 (47) to 120 (48). Only one study specified the type of dementia (Alzheimer's' Disease) (49).

The studies included a music listening intervention based on the person's preferences. As the included studies had participants in the severe to very severe stage of dementia, information about music preferences were determined from the PWDs where possible (48, 49) and/or their family members (45-47, 49, 50) or from formal and informal caregivers (48) who have knowledge about the music preferences of the PWD. Music was played through a compact disc (CD) player or a computer in the participant's room, in a private/quiet room or a familiar area. Trained professionals (45-47) and a research assistant (50) delivered the intervention. In one study, it was stated only that the participants passively listened to their preferred music (49) while in another study the music therapist prepared the music playlist but the participants listened to the music without interaction with the therapist (48). The prescribed duration of the intervention was 30 minutes in three studies (45-49) and 10 minutes in one study (50). Except for one study wherein the participants were randomly exposed to each of the three treatments (50), the intervention was implemented either once

(49) or twice a week (45-48) for 10 weeks in two studies (48, 49) and 16 weeks in another study (45-47). However, in one paper, the outcomes presented were evaluated only in the first 12 weeks (47). The details of each study are summarised in Table 1.

An assortment of measures was used to evaluate outcomes. The BPSDs in general were evaluated using the Neuropsychiatric Inventory (48) and the Behavioural Pathology in Alzheimer's Disease (49). Specific BPSDs were evaluated using the Cohen-Mansfield Agitation Inventory for agitation (45, 48, 50), the Rating Anxiety in Dementia scale for anxiety (45), and the Cornell Scale Depression in Dementia for depression (45, 48). In one study, mood and behaviour were also assessed using the Interact scale (47). Cognitive function was assessed using the Severe Mini Mental State Examination (45) while dementia severity was determined using the Bedford Alzheimer Severity Scale (45). Other outcome measures include the Cornell Brown Scale – Quality of Life in Dementia (48) to evaluate quality of life and the Faces Scale to assess emotion (49). The physiological outcomes were evaluated using the heart rate (47), oxygen saturation (47), autonomic nerve index (49) and salivary chromogranin A (46).

Risk of bias within studies

The included studies were randomised controlled trials employing random sequence generation. The allocation concealment was unclear for all studies as details were not clearly reported. All studies were at high risk of bias based on not blinding participants or personnel, due to the nature of the intervention. For the blinding of outcome assessment, the ratings were mixed: two studies were at low risk (48, 49), one was at high risk (50) and one was unclear (45-47). Three studies were at low risk for incomplete data (48-50) while one study was rated unclear due to the lack of description as to how the authors managed missing data (45-47). All of the included studies were rated unclear for the selective outcome reporting as there was no published protocol paper for reference on further details about the study outcomes. The Risk of Bias assessment is summarised in Table 2.

Results of Individual Studies

Behavioural and Psychological Symptoms of Dementia (BPSDs)

Two studies evaluated the impact of individualised music listening on BPSDs in general (48, 49). In a study of 120 PWDs (48), participants were randomised to standard care) alone and standard care with either music therapy or listening to music. The activities for the standard care included educational, occupational and physical activities, with no music exposure. All groups showed improvement in behavioural symptoms (delusion, anxiety, and disinhibition;

$p \leq 0.001$) with no significant differences between groups. In another study (49), 39 PWDs were assigned to music intervention groups (passive or interactive) or a no-music control group. Participants in the passive group listened to their preferred music while the interactive group participants engaged in interactive activities guided by a music facilitator. BPSDs associated with affective disturbance and anxieties and phobias ($p < 0.025$) were reduced in the passive group. Five Behavioural Pathology in Alzheimer's Disease (BEHAVE-AD) items were reduced in the interactive group including affective disturbance, anxieties and phobias, paranoid and delusional ideation, aggressiveness and activity disturbance ($p < 0.025$). Activity and affective disturbance were increased in the control group ($p < 0.025$). However, three weeks post intervention, BPSDs had significantly increased in both the passive and interactive groups ($p < 0.025$) while the control group showed no changes ($p = 0.025$).

Agitation

Specific BPSDs were also evaluated. For agitation, results from two studies showed positive effects of the individualised music listening (45, 50). Hicks-Moore and Robinson (50) compared the effectiveness of listening to favourite music and/or hand massage in reducing agitation. Thirty-two PWDs were randomly assigned to one of three treatment groups (hand massage, favourite music, and a combination of hand massage and favourite music) and nine to the control group. For all of the three treatment types, there was a significant reduction in verbally agitated behaviours ($p = 0.001$) and non-aggressive agitation ($p < 0.001$). The combined treatment of favourite music and hand massage failed to demonstrate a significant reduction in agitation compared to each single treatment. The control group demonstrated significantly higher agitation scores than each treatment group. Sanchez, Maseda (45) compared the multisensory stimulation environment (MSSE) with individualised music listening in a study of 22 PWDs. Improvement in agitation was noted for both groups between pre, mid and post intervention ($p = 0.031$) and at follow up ($p = 0.032$) with no significant differences between groups. In the study of Raglio, Bellandi (48), the analysis of Neuropsychiatric Inventory (NPI) subscales did not support the significant effects of preferred music listening on agitation.

Anxiety and Depression

Another outcome evaluated from the study of Sanchez, Maseda (45) was anxiety. During the intervention, only the MSSE group showed reduction in anxiety. However, during follow up, the anxiety scores improved for both MSSE and individualised music group ($p = 0.013$) with no significant differences between groups. Results of the NPI subscale analysis in another study (48) showed significant improvement overtime in some of the behavioural symptoms including anxiety for all treated groups.

In the study of Sanchez, Maseda (45) there was worsening of the Cornell Scale for Depression in Dementia (CSDD) scores during the intervention for the individualised music group while the scores remained stable in the MSSE group. During the follow up period, the CSDD scores of both individualised music and MSSE participants improved with no significant differences between groups ($p=0.021$) (45). The CSDD scores of the participants from the study of Raglio, Bellandi (48) improved for all groups ($p = 0.001$).

Physiological Outcomes

Physiological outcomes were evaluated in two studies (45-47, 49). In one of the articles from the study comparing individualised music with MSSE (46), the effects of the interventions on the salivary chromogranin A (sCgA) as a biomarker of psychological stress was reported. Results showed no significant differences in the sCgA levels before and after each MSSE and individualised music sessions. In another article from the same study reporting the results for the biomedical parameters (47), participants from both groups demonstrated a reduction in heart rate ($p=0.013$) and an increase in oxygen saturation ($p=0.011$) from before to after each session with no significant differences between groups. Sakamoto, Ando (49) also evaluated the short-term effects of passive and interactive music interventions on parasympathetic nerve activity. Participants from both groups showed parasympathetic versus sympathetic nerve activity dominance ($p<0.01$) indicating reduced stress and increased relaxation. The improvement however was greater in the interactive group.

Mood and emotion

Effects of the interventions on mood and emotions were evaluated in two studies (47, 49). During the intervention, MSSE group participants were noted to be more observant ($p=0.044$) while the individualised music group participants were more relaxed ($p=0.003$) (47). Ten minutes after each session, participants from both MSSE and individualised music were more happy/content ($p<0.001$), talked more spontaneously ($p=0.009$), related to people better ($p=0.002$), were more attentive/focused on their environment ($p<0.001$), enjoyed themselves more ($p=0.003$), were less bored/inactive ($p=0.004$), and were more relaxed/content ($p=0.003$) (47). Similarly, in the study by Sakamoto, Ando (49), analysis of the Faces Scale revealed that participants who passively listened to their preferred music were in a more comfortable mood after the intervention ($p<0.01$) while participants who engaged in interactive activities showed even greater improvement in emotional state ($p<0.01$).

Other outcomes

In the article of Sanchez, Maseda (45), the effects of MSSE and individualised music on dementia severity and cognitive function were reported. For the dementia severity, only the MMSE group showed some improvement during the pre-, mid-, and post-intervention assessments. However, during the follow-up period, both MSSE and individualised music group demonstrated worsening of dementia (45). The cognitive status of the participants from both groups declined during the trial (45). In addition to BPSDs, Raglio, Bellandi (48) included the evaluation of quality of life (QoL) of the PWDs. Improvement in the QoL was noted ($p=0.01$) for all treated groups with no significant differences between groups.

Risk of bias across studies

Due to the restriction of the eligibility criteria to RCTs and the intervention to individualised music listening, there were only four studies included in this review. Thus, some of the outcomes were evaluated by a single study. Also, three of the included studies had a sample size of less than 50. The small number of eligible studies and the small sample size of included studies limit the conclusions that can be drawn about the interventions and outcomes evaluated.

Discussion

Summary of Evidence

Consistent with previous reviews (16, 18, 35, 38, 41), BPSDs were commonly evaluated outcomes in the included studies. The result of this systematic review supports the promising impact of individualised music listening on a number of BPSDs. These include verbally agitated behaviour (50), non-aggressive behaviours (50), delusion (48), disinhibition (48), anxiety (45, 48, 49), phobias (49), affective disturbance (49) and depression (45, 48). Individualised music listening interventions also had positive short-term effects on mood and emotion (47, 49). Interestingly, in the study that compared music therapy with music listening and standard care (48), no significant differences were noted between groups. This is in contrast with the findings from previous reviews which demonstrated the superiority of music therapy over other interventions in the reduction of BPSDs (37, 51). Raglio, Bellandi (48) delineated some factors that may have contributed to this including the large number of dropouts and the outcome measurement used.

In this review, results of some outcomes varied between studies. For agitation, the two studies that used Cohen-Mansfield Agitation Inventory (CMAI) as a measurement tool showed positive effects of individualised music (45, 50) while another study that used the

global NPI did not support this positive outcome for the music listening group (48). Raglio, Bellandi (48) contended that compared to music therapy where the PWD's interaction with a music therapist could possibly contribute to treatment efficacy, the therapeutic effect of music listening is mainly from the music exposure itself. For anxiety, two studies reported improvement in anxiety in all study groups including the music listening (48, 49). However, in another study, the individualised music group failed to show improvement in anxiety during the intervention but showed improvement during the follow up period (45). For depression, CSDD scores for all groups including music listening improved in one study (48) but worsened during the intervention period then improved at follow up in another study (45). Likewise, for the physiological outcomes, positive effects of individualised music listening were demonstrated in two studies such as decreased heart rate, increased oxygen saturation (47) and parasympathetic nerve activity dominance (49). However, evaluation of the salivary chromogranin A (sCgA) levels failed to demonstrate beneficial effects for both the individualised music and the comparison group (MSSE) (46).

Cognitive function, dementia severity (45) and quality of life (48) were evaluated by a single study. Results showed decline in cognitive function and worsening of dementia severity for the individualised music group (45). This is consistent with the findings from previous reviews of music based therapy and interventions where significant effects on cognitive function were not demonstrated (36, 37). The minimal effectiveness of treatments could be attributed the irreversible and progressive nature of cognitive disabilities associated with dementia (4). For the quality of life of PWDs, improvement was noted over time in all treated groups (48).

Regarding the duration and frequency of the implementation, three of the included studies administered the interventions for 30 minutes weekly or biweekly. One study had the shortest duration with 10 minutes each of the three treatments (hand massage, favourite music, and combined favourite music and hand massage) (50). Although the optimal dosage of the intervention to achieve therapeutic effects remains unclear (16, 40, 52), it must be noted that the long term effects of the interventions were not evaluated in this study, with assessments performed 10 minutes before, immediately after and 1 hour post intervention (50).

Considering the harrowing impact of BPSDs on PWDs and their family and caregiver (53), results of this systematic review demonstrating the promising impact of individualised music on some BPSDs is valuable. Even though the benefits of the other interventions were greater or better compared to individualised music for some outcomes (45, 49),

individualised music listening requires minimal resources compared to these interventions. The authors of the study involving MSSE stressed that the greater economic investment involved in MSSE must be taken into consideration when individualised music interventions may be as effective (47). In addition, Bellelli, Raglio (54) highlighted that from a cost-effective perspective, it is important to also consider the economic sustainability of an intervention (54). Another important consideration is the ease of administering the intervention so it can be implemented in various settings without requiring the presence of professionally trained facilitators such as music therapists (40). Blackburn and Bradshaw (52) posited that it remains unclear whether involvement of a music therapist in the delivery of a music intervention is crucial for its success. With the guidelines recommending the involvement of family and carers in the management of BPSDs and the use of non-pharmacologic interventions that are tailored to the individual's preferences (11, 12), this relatively safe, simple and inexpensive intervention could be of great value.

Limitations of this review

Limitations include only literature found in the electronic databases searched (n=6), the language of publication (English), and the small number of studies that met the inclusion criteria. Some of the outcomes were evaluated by a single study (e.g. cognitive function, dementia severity, quality of life), limiting the conclusions drawn about these outcomes. Due to the heterogeneity of the population with PWDs in the mild to very severe stages of cognitive impairment, it is not possible to conclude which dementia severity would benefit most from the individualised music.

Conclusion

This systematic review supports the promising impact of individualised music listening intervention on a number of short-term and long-term BPSDs and physiological outcomes for PWDs. Three of the included studies demonstrated positive short-term or immediate outcomes for the individualised music listening intervention (46, 47, 49, 50). Although most of the long-term outcomes were heterogeneous, there was consistent evidence in favour of the beneficial effects of individualised music listening. The efficacy of individualised music listening was comparable to other interventions requiring more resources. While the individualised music listening intervention did not have a positive effect on cognitive function and dementia severity, these outcomes were evaluated in a single study only (45). Overall, the findings from this review must be interpreted with caution due to the small number of RCTs that evaluated individualised music listening. In agreement with the recommendations from previous reviews on music based therapy and interventions, there is a need for more

rigorously conducted studies that explore the impact of individualised music listening on other outcomes apart from BPSDs. Additionally, with individualised music listening's potential for large-scale implementation in various settings, future studies should take into consideration the evaluation of the economic aspect (51, 54) as well as the processes and contextual issues involved for its sustained implementation (55, 56).

Impact Statement

Policy Impact Statement: Managing agitation, anxiety and depression in persons with dementia can be resource intensive in terms of time and economic investment. Limited evidence from this review shows that individualised music interventions are effective, low cost interventions that could be used as a first-line measure in residential aged care.

Practice Impact Statement: Limited evidence from this systematic review indicates that individualised music interventions for persons with dementia have a positive impact on agitation, anxiety, depression, and emotion. Individualised music interventions are not resource-intensive and could be considered as an option to help manage behavioural symptoms and improve mood of persons with dementia.

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Individualised Music Intervention in Dementia

Table 1. Summary of Included Randomised Controlled Trials in Systematic Review of Impact of Individualised Music Listening Intervention on Persons with Dementia

Citation	Design	Setting	Sample and severity of cognitive impairment	Intervention	Duration and Frequency	Outcomes	Measure	Results
Hicks-Moore & Robinson 2008	Experimental 3x3 repeated measures design	Special care units in three nursing homes (Canada)	41 PWDs (mild to moderate)	Treatment: Hand massage (HM), Favourite music (FM) and HM + FM (HMFM) Control: Usual care	10 minutes	Agitation	CMAI	TG: Reduction in verbally agitated ($p=0.001$) and non-aggressive behaviours ($p<0.001$) CG: higher agitation scores($p<0.001$)
Maseda et al 2018	RCT	Specialised dementia Gerontological Complex (Spain)	21 PWDs (severe to very severe)	MSSE and individualised music	Two 30-minute weekly sessions for 16 weeks. However, the outcomes evaluated were only from the first 12 weeks.	Mood, behaviour and biomedical parameters	Interact scale, HR, SpO2	Improvement in mood and behaviour, decrease in HR ($p=0.013$), and increase in SpO2 ($p=0.011$) for both groups.
Raglio et al 2015	RCT	Nine institutions (Italy)	120 PWDs (moderate to severe)	Standard Care (SC) alone, SC + Music Therapy and SC + Listening to Music (LtM)	Music Therapy and LtM: 30 minutes biweekly for 10 weeks.	BPSDs, QoL	NPI, CSDD, CMAI, CBS-QoL	All groups showed reduction in NPI global score ($p<0.001$), CSDD ($p=0.001$), and CBS-QoL ($p=0.01$)
Sakamoto, Ando & Tsutou 2013	RCT	Group homes and a special dementia hospital (Japan)	39 PWDs (severe)	Treatment: interactive and passive music group control group: silent environment	30 minutes weekly for 10 weeks.	BPSDs	Faces Scale, Autonomic Nerve Index, BEHAVE-AD, Videotape of participants' behaviours	TG (passive and interactive): parasympathetic nerve activity dominance ($p<0.01$), improvement in emotional state ($p<0.01$); reduction in BEHAVE-AD items ($p<0.025$) CG: increase in affective and activity disturbance ($p<0.025$)
Sanchez et al 2016	RCT	Specialised dementia Gerontological Complex (Spain)	22 PWDs (severe to very severe)	MSSE and individualised music	Two 30-minute weekly sessions for 16 weeks.	Agitation, mood, anxiety, cognitive function, and dementia severity	CMAI, CSDD, RAID, SMMSE, BANS-S	Improvement in agitation for both groups between pre, mid and post intervention ($p=0.031$) and at follow up ($p=0.032$).

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Valdiglesias et al 2017	RCT	Specialised dementia Gerontological Complex (Spain)	22 PWDs (severe or very severe)	MSSE and individualised music	Two 30-minute weekly sessions for 16 weeks.	Changes in Salivary Chromogranin A (sCgA)	sCgA	No significant differences in the sCgA levels for both groups.
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Abbreviations: RCT: randomised controlled trial; PWDs: persons with dementia; MSSE: multisensory stimulation environment; HR: heart rate; SpO2: oxygen saturation; BPSDs: behavioural and psychological symptoms of dementia; QoL: quality of life; NPI: neuropsychiatric inventory; CSDD: Cornell Scale Depression in Dementia; CMAI: Cohen-Mansfield Agitation Inventory; CBS-QoL: Cornell Brown Scale- quality of life in dementia; TG: treatment group; CG: control group

Table 2. Risk of bias summary

Citation	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessors	Incomplete outcome data	Selective outcome reporting
Hicks-Moore & Robinsion 2008	Low	Unclear	High	High	Low	Unclear
Maseda et al 2018	Low	Unclear	High	Unclear	Unclear	Unclear
Sanchez et al 2016	Low	Unclear	High	Unclear	Unclear	Unclear
Valdiglesias et al 2017	Low	Unclear	High	Unclear	Unclear	Unclear
Raglio et al 2015	Low	Unclear	High	Low	Low	Unclear
Sakamoto et al 2013	Low	Unclear	High	Low	Low	Unclear