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[Intervention Review]

Music-based therapeutic interventions for people with dementia

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ABSTRACT

Background

Dementia is a clinical syndrome with a number of different causes which is characterised by deterioration in cognitive, behavioural, social and emotional functions. Pharmacological interventions are available but have limited effect to treat many of the syndrome's features. Less research has been directed towards non-pharmacological treatments. In this review, we examined the evidence for effects of music-based interventions as a treatment.

Objectives

To assess the effects of music-based therapeutic interventions for people with dementia on emotional well-being including quality of life, mood disturbance or negative affect, behavioural problems, social behaviour, and cognition at the end of therapy and four or more weeks after the end of treatment.

Search methods

We searched [ALOIS](#), the Specialized Register of the Cochrane Dementia and Cognitive Improvement Group (CDCIG) on 14 April 2010 using the terms: music therapy, music, singing, sing, auditory stimulation. Additional searches were also carried out on 3 July 2015 in the major healthcare databases MEDLINE, Embase, psycINFO, CINAHL and LILACS; and in trial registers and grey literature sources. On 12 April 2016, we searched the major databases for new studies for future evaluation.

Selection criteria

We included randomized controlled trials of music-based therapeutic interventions (at least five sessions) for people with dementia that measured any of our outcomes of interest. Control groups either received usual care or other activities.

Data collection and analysis

Two reviewers worked independently to screen the retrieved studies against the inclusion criteria and then to extract data and assess methodological quality of the included studies. If necessary, we contacted trial authors to ask for additional data, including relevant subscales, or for other missing information. We pooled data using random-effects models.

Main results

We included 17 studies. Sixteen studies with a total of 620 participants contributed data to meta-analyses. Participants in the studies had dementia of varying degrees of severity, but all were resident in institutions. Five studies delivered an individual music intervention; in the others, the intervention was delivered to groups of participants. Most interventions involved both active and receptive musical elements. The methodological quality of the studies varied. All were at high risk of performance bias and some were at high risk of detection or other bias. At the end of treatment, we found low-quality evidence that music-based therapeutic interventions may have little or no effect on emotional well-being and quality of life (standardized mean difference, SMD 0.32, 95% CI -0.08 to 0.71; 6 studies, 181 participants), overall behaviour problems (SMD -0.20, 95% CI -0.56 to 0.17; 6 studies, 209 participants) and cognition (SMD 0.21, 95% CI -0.04 to 0.45; 6 studies, 257 participants). We found moderate-quality evidence that they reduce depressive symptoms (SMD -0.28, 95% CI -0.48 to -0.07; 9 studies, 376 participants), but do not decrease agitation or aggression (SMD -0.08, 95% CI -0.29 to 0.14; 12 studies, 515 participants). The quality of the evidence on anxiety and social behaviour was very low, so effects were very uncertain. The evidence for all long-term outcomes was also of very low quality.

Authors' conclusions

Providing people with dementia with at least five sessions of a music-based therapeutic intervention probably reduces depressive symptoms but has little or no effect on agitation or aggression. There may also be little or no effect on emotional well-being or quality of life, overall behavioural problems and cognition. We are uncertain about effects on anxiety or social behaviour, and about any long-term effects. Future studies should employ larger sample sizes, and include all important outcomes, in particular 'positive' outcomes such as emotional well-being and social outcomes. Future studies should also examine the duration of effects in relation to the overall duration of treatment and the number of sessions.

PLAIN LANGUAGE SUMMARY

Music-based therapeutic interventions for people with dementia

Background

People with dementia gradually develop difficulties with memory, thinking, language and daily activities. Dementia is often associated with emotional and behavioural problems and may lead to a reduction in a person's quality of life. In the later stages of dementia it may be difficult for people to communicate with words, but even when they can no longer speak they may still be able to hum or play along with music. Therapy involving music may therefore be especially suitable for people with dementia. Music therapists are specially qualified to work with individuals or groups of people, using music to try to help meet their physical, psychological and social needs. Other professionals may also be trained to provide similar treatments.

Purpose of this review

We wanted to see if we could find evidence that treatments based on music improve the emotional well-being and quality of life of people with dementia. We were also interested in evidence about their effects on emotional, behavioural, social or cognitive (e.g. thinking and remembering) problems in people with dementia.

What we did

We searched for trials in which people with dementia were randomly allocated to a music-based treatment or to a comparison group, and in which any of the outcomes we were interested in were measured. The comparison groups might have had no special treatment, or might have been offered a different activity. The trials had to have offered at least five sessions of treatment because we thought fewer sessions than this were unlikely to have much effect. If we judged that the trials were similar enough, then we combined their results in order to estimate the effect of the treatment as accurately as possible.

What we found

We found seventeen trials to include in the review and we were able to combine results for at least some outcomes from 620 people. All of the people in the trials were living in care homes. People with all severities of dementia were included. Some trials compared music-based treatments with usual care, and some compared it with other activities, such as cooking or painting. The quality of the trials and how well they were reported varied, and this affected our confidence in the results. First, we looked at outcomes immediately after a course of therapy ended. From our results, we could be moderately confident that music-based treatments improve symptoms of depression, but do not help with agitated or aggressive behaviour. We were less confident in our results on emotional well-being including quality of life, overall behavioural problems, and cognition, but music-based treatments may have little or no effect on these outcomes. We had very little confidence in our results on anxiety and social interaction. Some studies also looked to see whether there were any lasting effects four weeks or more after treatment ended. However, there were few data and we were very uncertain about the results. Further trials are likely to have a significant impact on what we know about the effects of music-based treatments for people with dementia, and so continuing research is important.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Music-based therapeutic interventions compared to usual care or other activities for people with dementia: end of treatment effects

Patient or population: people with dementia (all resided in institutional settings)

Intervention: music-based therapeutic interventions

Comparison: usual care or other activities

Outcomes (end of treatment) measured with a variety of scales except for social behaviour	Anticipated absolute effects * (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)
	Score with music therapy compared with usual care or other activities		
Emotional well-being including quality of life	The score in the intervention group was 0.32 SDs higher (0.08 lower to 0.71 higher)	181 (6 RCTs)	⊕⊕○○ LOW ¹²
Mood disturbance or negative affect: depression	The score in the intervention group was 0.28 SDs lower (0.48 lower to 0.07 lower)	376 (9 RCTs)	⊕⊕⊕○ MODERATE ¹
Mood disturbance or negative affect: anxiety	The score in the intervention group was 0.50 SDs lower (0.84 lower to 0.16 lower)	365 (11 RCTs)	⊕○○○ VERY LOW ¹³⁵
Behavioural problems: agitation or aggression	The score in the intervention group was 0.08 SDs lower (0.29 lower to 0.14 higher)	515 (12 RCTs)	⊕⊕⊕○ MODERATE ¹
Behavioural problems: overall	The score in the intervention group was 0.20 SDs lower (0.56 lower to 0.17 higher)	209 (6 RCTs)	⊕⊕○○ LOW ¹²
Social behaviour: music vs other activities	The score in the intervention group was 0.54 SDs higher (0.06 higher to 1.02 higher)	70 (3 RCTs)	⊕○○○ VERY LOW ¹⁴
Cognition	The score in the intervention group was 0.21 SDs higher (0.04 lower to 0.45 higher)	257 (6 RCTs)	⊕⊕○○ LOW ¹²

* Interpretation of SMD: a difference of < 0.40 standard deviations can be regarded as a small effect, 0.40 to 0.70 a moderate effect, and > 0.70 a large effect.

CI: Confidence interval; SMD: standardised mean difference; SD: standard deviation

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low quality: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

¹ Risk of bias: no blinding of therapists and patients (not possible), and often no blinding of outcome assessment

² Imprecision: small number of participants and rather broad confidence interval

³ Inconsistency: more non-overlapping confidence intervals

⁴ Imprecision: very small number of participants and broad confidence interval

⁵ Publication bias: funnel plot is based on a limited number of studies but suggests there may be publication bias

BACKGROUND

Description of the condition

Dementia is a clinical syndrome characterised by progressive decline in cognitive functions. Dementia of the Alzheimer's type is the most common form of dementia, followed by vascular dementia, Lewy body dementia and frontotemporal dementia (ADI 2015).

Dementia is a collective name for progressive degenerative brain syndromes which affect memory, thinking, behaviour and emotion (ADI 2015). Symptoms may include:

- loss of memory;
- difficulty in finding the right words or understanding what people are saying;
- difficulty in performing previously routine tasks;
- personality and mood changes.

Alzheimer's Disease International estimates that worldwide currently 46.8 million people are suffering from dementia; and that this figure will increase to 74.7 million by 2030 and to 131.5 million people by 2050 (ADI 2015).

Research is pursuing a variety of promising findings related to describing the causes of dementia and for the treatment of dementia. Pharmacological interventions are available but have limited ability to treat many of the syndrome's features. Little research has been directed towards non-pharmacological treatments.

As dementia is due to damage to the brain, one approach is to limit the extent and rate of progression of the pathological processes producing this damage. At present the scope of this approach is

limited and an equally important approach is to help people with dementia and their caregivers to cope with the syndrome's social and psychological manifestations. As well as trying to slow cognitive deterioration, care should aim to stimulate abilities, improve quality of life, and reduce problematic behaviours associated with dementia. The therapeutic use of music might achieve these aims.

Description of the intervention

Many treatments of dementia depend on the client's ability to communicate verbally. When the ability to speak or understand language has been lost, music might offer alternative opportunities for communication. People who cannot speak anymore may still be able to hum or play along with music.

Music therapy is defined by the World Federation of Music Therapy (WFMT) as "the professional use of music and its elements as an intervention in medical, educational, and everyday environments with individuals, groups, families, or communities who seek to optimize their quality of life and improve their physical, social, communicative, emotional, intellectual, and spiritual health and wellbeing". Research, practice, education, and clinical training in music therapy are based on professional standards according to cultural, social, and political contexts (WFMT, 2011). The American Music Therapy Association (AMTA) defines music therapy as "the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program" (AMTA). It describes assessment of the client, interventions ("including creating, singing, moving to, and/or listening to music"), benefits and research, and explains that music

therapy is used “within a therapeutic relationship to address physical, emotional, cognitive, and social needs of individuals”. We reviewed music-based interventions, which may share these therapeutic goals even if not provided by an accredited music therapist. Two main types of music therapy can be distinguished - receptive (or passive) and active music therapy - and these are often combined (Guetin 2013). Receptive music therapy consists of listening to music by the therapist who sings, plays or selects recorded music for the recipients. In active music therapy, recipients are actively involved in the music-making, by playing on small instruments for instance. The participants may be encouraged to participate in musical improvisation with instruments or voice, with dance, movement activities or singing.

Music may also be used in ways which are less obviously therapy or therapeutic, for example playing music during other activities such as meals or baths, or during physiotherapy or movement, or as part of an arts programme or other psychosocial interventions. ‘Music as therapy’ includes more narrowly defined music therapy provided by “a formally credentialed music major with a therapeutic emphasis” (Ing-Randolph 2015). In order to benefit people with dementia, those providing music-based interventions with a therapeutic goal may need to draw on the skills of both musicians and therapists to select and apply musical parameters adequately, tailored to a recipient’s individual needs and goals.

How the intervention might work

Music-based therapeutic interventions, including interventions provided by a certified music therapist, mostly consist of singing, listening, improvising or playing along on musical instruments. Music and singing may stimulate hemispheric specialization. Clinical observations indicate that singing critically depends upon right-hemisphere structures. By contrast, people suffering from aphasia due to left-hemisphere lesions often show strikingly preserved vocal music capabilities. Singing may be exploited to facilitate speech reconstruction when suffering from aphasia (Riecker 2000). Singing can further help the development of articulation, rhythm, and breath control. Singing in a group setting can improve social skills and foster a greater awareness of others. For those with dementia, singing may encourage reminiscence and discussions of the past, while reducing anxiety and fear. For individuals with compromised breathing, singing can improve oxygen saturation rates. For individuals who have difficulty speaking following a stroke, music may stimulate the language centres in the brain promoting the ability to sing. In sum, singing may improve a range of physical and psychosocial parameters (Clift 2016). Playing instruments may improve gross and fine motor coordination in individuals with motor impairments or neurological trauma related to a stroke, head injury or a disease process (Magee 2017; WFMT, 2010).

Whereas cognitive functions decline during disease progression, receptivity to music may remain until the late phases of dementia

(Adridge 1996; Baird 2009; Cowles 2003). Even in the latest stage of the disease, they may remain responsive to music where other stimuli may no longer evoke a reaction (Norberg 1986). This may be related to musical memory regions in the brain being relatively spared in Alzheimer’s disease (Jacobsen 2015). Possibly, the fundamentals of language are musical, and precede lexical functions in language development (Adridge 1996). Listening to music itself may decrease stress hormones such as cortisol; and helps patients to cope with, for instance, pre-operative stress (Spintge 2000). Music therapy can bring relaxation and has a positive effect on enhancing communication and emotional well-being (Brotons 2000). Music therapy enables the recall of life experiences and the experience of emotions. Many important life events are accompanied by music; most of the time these ‘musical memories’ are stored for a longer time than the ones from the same period that were not accompanied by music (Broersen 1995; Baird 2009). If words are not recognized any longer, familiar music may provide a sense of safety and well-being, which in turn may decrease anxiety. Musical rhythm may help people with Alzheimer’s disease to organize time and space. Patients are able to experience group contact through musical communication with other participants, without having to speak. Owing to its non-verbal qualities, music-based interventions might help people with dementia at all levels of severity to cope with the effects of their illness.

Why it is important to do this review

In this review we examine current research literature to assess whether music-based therapeutic interventions, including music therapy, are an efficacious approach to the treatment of emotional, behavioural, social, and cognitive problems in people with dementia. We also investigate whether, in the absence of specific problems, these interventions have an effect on emotional well-being, including quality of life, or social behaviour in people with dementia. Quality of life is often an appropriate goal of care for people with dementia (ADI 2016), and it is important to assess evidence as to whether music-based therapeutic intervention can contribute to quality of life or related outcomes.

OBJECTIVES

To assess the effects of music-based therapeutic interventions for people with dementia on emotional well-being including quality of life, mood disturbance or negative affect, behavioural problems, social behaviour, and cognition at the end of therapy and four or more weeks after the end of treatment

METHODS

Criteria for considering studies for this review

Types of studies

We included both parallel and cross-over randomized controlled trials (RCTs).

Types of participants

We included people who were formally diagnosed as having any type of dementia according to DSM-IV or DSM-5, ICD-10 or other accepted diagnostic criteria. In order to be relevant to clinical practice, we also accepted a physician's diagnosis of dementia if no data on formal criteria such as DSM-IV, DSM-5 or comparable instruments were available. We included people living in diverse settings including in the community, hospitals or nursing homes and all severities of dementia. We did not use a criterion for age so as not to exclude studies in which some participants were below age 65.

Types of interventions

We included any music-based interventions, either active or receptive, delivered to individuals or groups. We required a minimum of five sessions in order to ensure that a therapeutic intervention could have taken place. We defined therapeutic music-based interventions as: therapy provided by a qualified music therapist, or interventions based on a therapeutic relationship and meeting at least two of the following criteria/indicators: (a) therapeutic objective which may include communication, relationships, learning, expression, mobilisation and other relevant therapeutic objectives; (b) music matches individual preferences; (c) active participation of the people with dementia using musical instruments or singing; (d) participants had a clinical indication for the intervention or were referred for the intervention by a clinician. We also required music to be a main element of the intervention (e.g. not merely moving with use of music). Simple participation in a choir would not meet our definition of a therapeutic intervention.

The music-based interventions could be compared with any other type of therapy or no therapy. Control groups could not receive any music-based therapeutic intervention (even if fewer sessions than the intervention group).

Types of outcome measures

- Emotional well-being, including quality of life and positive affect. Facial expressions (in the absence of interaction with the observer) may also indicate emotional well-being.
- Mood disturbance or negative affect: depression (depressive symptoms) or anxiety.
- Behavioural problems: agitation and/or aggression, overall behavioural problems or neuropsychiatric symptoms. (We

combined agitation and aggression outcomes consistent with the International Psychogeriatric Association consensus definition of agitation requiring presence of one of "excessive motor activity, verbal aggression, or physical aggression" (Cummings 2015)).

- Social behaviour, such as (verbal) interaction.
- Cognition.
- Any other adverse effects.

For these outcomes, we accepted all assessment tools used in the primary studies. Outcomes were assessed at the end of treatment (a minimum of five sessions), irrespective of the duration and number of sessions in excess of four. If there was evidence of no different effect over time, then reported outcomes could include earlier assessments. We also looked for outcomes a minimum of four weeks after the treatment ended in order to assess long-term effects.

Primary outcomes

The protocol did not prioritise outcomes. We prioritised the outcomes related to emotions (emotional well-being including quality of life, and mood disturbance or negative affect) as being of critical importance because these outcomes (e.g. depression) are closely related to quality of life of people with dementia (Banerjee 2009; Beerens 2014). Depression and anxiety are also prevalent and rather persistent during the course of the dementia (van der Linde 2016; Zhao 2016). We further prioritised behavioural problems because these affect relationships and caregiver burden (e.g. van der Linde 2012); and some may also be indicators of distress.

Secondary outcomes

Social behaviour and cognition were important but secondary outcomes, as the benefit for the participants themselves was not as obvious as for outcomes more closely related to their quality of life.

Search methods for identification of studies

We searched ALOIS, the Cochrane Dementia and Cognitive Improvement Group's Specialized Register. The search terms used were: music therapy, music, singing, sing, auditory stimulation. ALOIS is maintained by the Trials Search Co-ordinator for CD-CIG and contains studies in the areas of dementia prevention, dementia treatment and cognitive enhancement in the healthy. Details of the search strategies used for the retrieval of reports of trials from the healthcare databases, the Cochrane Central Register of Controlled Trials (CENTRAL) and conference proceedings can be viewed in the 'Methods used in reviews' section within the editorial information about the [Dementia and Cognitive Improvement Group](#). To view a list of all sources searched for ALOIS see [About ALOIS](#) on the ALOIS web site.

We performed additional searches in each of the sources listed above to cover the timeframe from the last searches performed for ALOIS to 3 July 2015. The search strategies for the above described databases are presented in Appendix 1.

In addition, we searched [Geronlit/Dimdi](#), [Research Index](#), [Carl Uncover/Ingenta](#), [Musica](#) and [Cairrs](#) in January 2006 and June 2010, with the following search terms: music therapy, music, singing, dance, dementia, alzheimer. We also searched on these dates specific music therapy databases, as made available by the University of Witten-Herdecke on www.musictherapyworld.de, based in Germany. We checked the reference lists of all relevant articles and a clinical librarian conducted a forward search from key articles using SciSearch. In addition, conference proceedings of European and World Music Therapy conferences on www.musictherapyworld.de and European music therapy journals, such as the [Nordic Journal of Music Therapy](#), the [British Journal of Music Therapy](#) the [Musiktherapeutische Umschau](#) and the Dutch [Tijdschrift voor Vaktherapie](#) were hand searched to find music therapy studies (RCTs) for people with dementia, in January 2006, June 2010, and July 2015. A new database search was performed on 12 April 2016 to identify new studies published after 3 July 2015. Potentially eligible new studies (based on abstract review with two independent reviewers) were included under [Characteristics of studies awaiting classification](#).

Data collection and analysis

Selection of studies

Two review authors independently assessed publications for eligibility by checking the title and, if available, the abstract. If any doubt existed as to an article's relevance they retrieved and assessed the full article.

Data extraction and management

Two reviewers extracted and cross-checked outcome data independently of each other. They discussed any discrepancies or difficulties with a third reviewer. We reviewed articles in English, French, German and Dutch and searched for Cochrane collaborators to assess articles in other languages. We emailed authors for additional information when unclear (for example, about the type of control group or setting); and for additional data if that would help inclusion of the study data in meta-analyses (for example, if estimates from graphical presentation were imprecise, SDs were lacking, or item-level data if items of global tools represented relevant outcomes).

We first extracted data on the design (RCT), population (dementia diagnosis), the criteria for music therapy, outcomes and timing of outcome assessment, to evaluate eligibility of the study. Of the

eligible studies, we subsequently recorded the following characteristics.

- Data collection period.
- Setting: nursing home, residential home, hospital, ambulatory care, other.
- Participant characteristics: age, sex, severity and type of the dementia.
- Number of participants included, randomized and lost to follow up.
- Type, frequency and duration of active interventions and control interventions.
- Description of activities in the control group if not usual care.
- Outcomes: type of outcome measures about emotional well-being, emotional problems (mood disturbance or negative affect), problematic or challenging behaviours (in general; and more specifically, agitation or aggression), social behaviours and cognition. Whether outcomes were being referred to as primary or secondary outcomes.
- Timing of outcome measurement including the long term, after treatment ended.
- Research hypotheses if specified, and a description of the results.
- Any methodological problems and comments.
- Funding sources.
- A 'Risk of bias' assessment (below).

For each study, we extracted relevant outcome data, i.e. means, standard deviations and number of participants in each group for continuous data and numbers with each outcome in each group for dichotomous data. If needed or helpful, we contacted authors for clarification; or for data, such as from relevant subscales.

Assessment of risk of bias in included studies

Two reviewers (neither of whom was an author on any of the studies that they assessed) independently of each other assessed included studies for risk of bias according to the guidelines in the *Cochrane Handbook for Systematic Reviews of Interventions*, and using the 'Risk of bias' assessment tool ([Higgins 2011](#)). They looked at the following elements of study quality: selection bias (random sequence generation, allocation concealment); performance bias (blinding of participants and personnel); detection bias (blinding of outcome assessment); attrition bias (incomplete outcome data); reporting bias (selective reporting); and other potential threats to validity. They assessed performance, detection and attrition bias for each outcome.

Measures of treatment effect

We used the risk ratio to summarize any effects on dichotomous outcome variables and the mean difference (or if different instru-

ments or scales were used, the standardised mean difference) for continuous variables.

Unit of analysis issues

Only participant-level outcomes were considered, and all were continuous measures. For cross-over trials, we extracted data for the first period only because of the likelihood of carry-over.

Dealing with missing data

We considered if there were missing outcome data, with reasons reported, for example due to participants who moved or died, and how these were dealt with (exclusion of cases for analyses or were dealt with otherwise).

Assessment of heterogeneity

We interpreted I^2 according to criteria in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011: chapter 9.5.2). Further, a low P value for the Chi^2 statistic indicated heterogeneity of intervention effects, which we evaluated against the combined 'usual care' and 'other activities' control groups. Because of small numbers of participants and studies for most outcomes, a non-significant P value was not decisive in the evaluation of consistency, and we also considered overlap of confidence intervals in the forest plots.

Assessment of reporting biases

Selective outcome reporting is covered by the risk of bias assessment, and for this we searched the articles about included studies and related articles for references to study protocols and trial registrations. If available, we compared with outcomes and prioritisation of outcomes in the article. If no research protocol was available, risk of reporting bias was set to either unclear, or high when appropriate. To detect possible publication bias, we examined funnel plots for outcomes with at least 10 studies available.

Data synthesis

We included studies about all eligible interventions in similar groups of people in different stages of dementia, and we pooled the results of studies that examined effects on the same seven outcomes. We discriminated between effects at the end of treatment, and long-term effects (a minimum of four weeks after treatment ended). In case of clinically homogeneous studies, results would have been combined using a fixed-effect model. In case of statistical heterogeneity (assessed by visual inspection of the forest plots) and the availability of at least five studies, a random-effects model was used.

We were interested in both usual care and other activity-control interventions because usual practice with regard to activities offered

is variable, and the question as to whether music-based therapeutic interventions should be introduced and the question as to whether they are superior to other activities are both relevant in practice. We presented data by type of control intervention: usual care or other activities. A control group with other activities controls for increased social contact and stimulation. However, it is unclear whether this increases or decreases contrast with the music-based intervention group for different outcomes (e.g. agitation, anxiety). We therefore analysed effects against all control groups as planned in the protocol, but for purposes of possible hypothesis generation we present forest plots by subgroup.

With probable selective outcome reporting, we ran the analyses for the reported outcomes while omitting the particular study, to evaluate change and direction of change of the estimate.

Sensitivity analysis

Post hoc, we performed a series of sensitivity analyses because there are different possible criteria as to what constitutes music therapy, and because funding related to music therapy potentially involves an intellectual conflict of interest. We first reran all analyses on end-of-treatment effects with studies in which the intervention was probably or definitely (when mentioned explicitly) delivered by a professional music therapist only. Second, we restricted these analyses to studies definitely delivered by a music therapist. Third, we restricted the analyses to studies definitely delivered by a music therapist and with no potential conflict of interest related to funding or no reported funding source.

Presentation of results and 'Summary of findings' table

We used GRADE methods to rate the quality of evidence (high, moderate or low) behind each effect estimate in the review (Guyatt 2011). This rating refers to our level of confidence that the estimate reflects the true effect, taking account of risk of bias in the included studies, inconsistency between studies, imprecision in the effect estimate, indirectness in addressing our review question and the risk of publication bias. We produced 'Summary of findings' tables for end-of-treatment and long-term outcome comparisons to show the effect estimate and the quantity and quality of the supporting evidence for outcomes for which more studies were available. The summary of findings was generated with Review Manager 5 (RevMan 5) data imported into the GradePro Guideline Development Tool (2015).

RESULTS

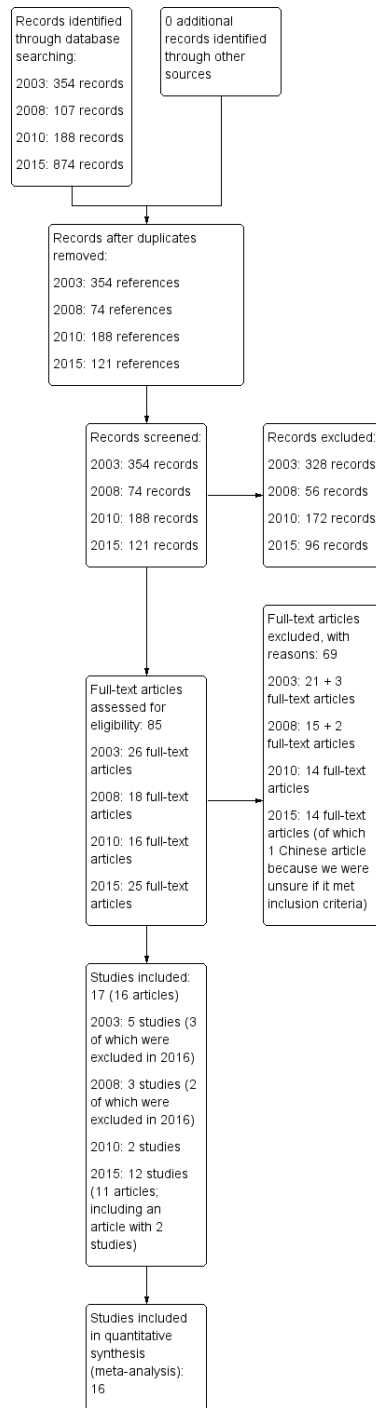
Description of studies

Results of the search

The total number of included studies was 17. For the first version of this review (Vink 2003), we identified 354 references related to music-based interventions and dementia (Figure 1). Of those, 254 were discarded as they did not refer to a research study or were identified as anecdotal or reports of case studies on the basis of their abstracts. Hard copies were obtained for the remaining 100 studies. We then discarded a further 74 studies as they involved participant series or case studies. A total of 26 studies remained in 2003 of which five met the criteria for inclusion at that time (Groene 1993; Lord 1993; Clark 1998; Brotons 2000; Gerdner 2000). In 2008 an additional eighteen studies were reviewed, of which three studies met the criteria at that time (Sung 2006; Svansdottir 2006; Raglio 2008). For the update of 2010 we retrieved a total of 188 references of possible relevance. After a first assessment 16 references remained which were further assessed, of which two studies met the criteria of this review (Guétin

2009; Raglio 2010b). In total, 10 studies were included in the previous update. In 2015, due to clarified criteria for eligibility of interventions, randomization, and more stringent application of criteria for analyses of outcomes after a minimum number of sessions, we excluded five of the 10 previously included studies (Groene 1993; Brotons 2000; Gerdner 2000; Sung 2006; Raglio 2008; Characteristics of excluded studies). However, we included 12 new studies after evaluating 121 references including 25 full-text evaluations, which resulted in the total of 17 included studies. A new search on 12 April 2016 identified eight potentially eligible additional studies which still warrant review against inclusion criteria for the next update of this review (Hsu 2015; Raglio 2015; Curto Prieto 2015; Hsiung 2015; Rouch 2017; Thornley 2016; 신보영, 황은영. 2015; 최경숙 2015), in addition to a study for which we are waiting for clarification from the authors about the results (Hong 2011). These are listed under Characteristics of studies awaiting classification and Characteristics of ongoing studies.

Figure 1. Study flow diagram.



Included studies

Details of the included studies are presented in the [Characteristics of included studies](#) table. One article (Narme and colleagues 2012: [Narme 2012-study 1](#) and [Narme 2012-study 1a](#)) reported on two studies with rather similar designs indicated with study 1 and study 2 in the article (note that study 2 is indicated with 1a in our analyses). More articles with additional results or background of the study were available for five studies ([Cooke 2010](#); [Raglio 2010b](#); [Lin 2011](#); [Vink 2013](#); [Narme 2014](#)).

Fourteen studies had a parallel groups design ([Lord 1993](#); [Svansdottir 2006](#); [Guétin 2009](#); [Raglio 2010a](#); [Raglio 2010b](#); [Lin 2011](#); [Ceccato 2012](#); [Narme 2012-study 1](#) and [Narme 2012-study 1a](#) (also referred to as study 2); [Sung 2012](#); [Sakamoto 2013](#); [Vink 2013](#); [Narme 2014](#); [Liesk 2015](#)); and three used a crossover design with first-period data available for all ([Clark 1998](#); [Cooke 2010](#); [Ridder 2013](#)).

The seventeen studies were performed in 11 countries. Whereas the two oldest studies were from the USA ([Lord 1993](#); [Clark 1998](#)), the studies published after 1998 were from a variety of other regions and countries: 11 studies conducted in seven countries in Europe (Italy, France, Germany, the Netherlands, and Iceland, including also one study performed in two countries, Denmark and Norway; [Ridder 2013](#)), three studies from two countries in Asia (Taiwan and Japan), and one study from Australia. The studies were all performed in institutional settings of nursing homes, residential homes and geriatric hospital wards. Dementia severity varied.

The interventions were active ([Cooke 2010](#); [Raglio 2010a](#); [Raglio 2010b](#); [Sung 2012](#); [Liesk 2015](#)); receptive ([Clark 1998](#); [Guétin 2009](#)); or a mixture of the two forms (the other 10 studies). Appendix 2 describes the music-based therapeutic intervention and other activities of all studies. Music included live or recorded music that met preferences of the group or individual. The active forms often combined playing of instruments and singing activities, and some also combined with movement such as clapping hands and dance. Sessions varied in duration between half an hour and two hours. The total number of sessions ranged from six ([Narme 2012-study 1](#)) to 156 ([Lord 1993](#)), with a median total number of 12 sessions until the end of treatment assessment. The frequency ranged between one session per week ([Guétin 2009](#); [Sakamoto 2013](#)) and six sessions per week ([Lord 1993](#)), with a median and more typical number (mode) of two sessions per week (two per week was employed in 10 studies). These figures probably reflect number of sessions offered, as the number of attended session may be lower. There are few reports about implementation fidelity including adherence and dose received, but [Ridder 2013](#) reports that a minimum of 12 sessions were offered, but the participants received 10 sessions on average.

In seven of the studies, we could be sure from the report that the interventions had been delivered by an accredited music therapist ([Svansdottir 2006](#); [Raglio 2010a](#); [Raglio 2010b](#); [Lin 2011](#); [Ceccato 2012](#); [Ridder 2013](#); [Vink 2013](#)). In four studies, it was unclear whether a music therapist was involved (no profession reported in the older studies, [Lord 1993](#) and [Clark 1998](#); probably delivered by trained music therapists but it was not stated explicitly in [Guétin 2009](#); and delivered by musicians trained in the delivery of sessions and in working with older people with dementia but unclear if these were formally trained music therapists in [Cooke 2010](#)). In the other six studies, the intervention was not delivered by a music therapist (psychologist and other supervisor(s) with no training in music therapy, [Narme 2012-study 1](#); [Narme 2012-study 1a](#); [Narme 2014](#); trained research assistants, [Sung 2012](#); music facilitator, [Sakamoto 2013](#); music teacher specialised in teaching older people, [Liesk 2015](#)).

Seven of the 17 studies compared the music intervention with an active control intervention, all with the same number of sessions and frequency as the music group. Two-armed studies compared with the following interventions: reading ([Cooke 2010](#); [Guétin 2009](#)), a cognitive stimulation intervention ([Liesk 2015](#)), painting ([Narme 2012-study 1](#)), cooking ([Narme 2012-study 1](#) and [Narme 2012-study 1a](#) - also referred to as study 2; [Narme 2014](#)), or variable recreational activities which included handwork, playing shuffleboard, and also cooking and puzzle games ([Vink 2013](#)). Two studies had three arms with the active control group working on jigsaw puzzles ([Lord 1993](#)); or receiving a passive group music intervention which did not meet our inclusion criteria for a therapeutic music-based intervention ([Sakamoto 2013](#)).

The outcomes 'emotional well-being' including quality of life, mood disturbance or negative affect (also as part of behavioural scales), and 'behavioural problems' (agitation or aggression, and behaviour overall) and 'cognition' were often assessed. Social behaviour was less commonly assessed ([Lord 1993](#); [Narme 2012-study 1](#); [Narme 2012-study 1a](#); [Narme 2014](#)); and the meta-analyses of end-of-treatment scores included only the three studies from Narme and colleagues. The Cohen-Mansfield Agitation Inventory (CMAI, for agitation; [Cohen-Mansfield 1986](#)), Mini-Mental State Examination (MMSE, for cognition; [Folstein 1975](#)), and the Neuropsychiatric Inventory (NPI, for behaviour; [Cummings 1994](#)) in particular were frequently used. Item-level NPI outcome data were reported in the article or the author additionally provided data about depression, anxiety, and agitation outcomes.

Excluded studies

We screened a total of 737 records and we excluded 652 ([Figure 1](#)). We excluded 69 of 85 records examined in full text (see [Characteristics of excluded studies](#) for a selection of excluded stud-

ies which were close but did not qualify upon careful consideration). They were often excluded because the participants did not have dementia, or because of a design other than an RCT. Further, and often less obvious, we critically reviewed whether the intervention met the inclusion criteria for a music-based therapeutic intervention, and whether the reported outcomes included any assessments after fewer than five sessions. There are a number of studies on group music interventions such as group music in addition to movement interventions (e.g. [Sung 2006](#)): these were excluded because music was not the main or only therapeutic element, or was not provided with individual therapeutic intent. Further, some studies assessed outcomes during the treat-

ment sessions only, combining immediate effects, for example on behaviour during the first session, with effects after multiple sessions (e.g. [Gerdner 2000](#)). Studies awaiting classification included conference abstracts, articles about studies in Asia which we could not retrieve or evaluate in time, and new studies published after the search ([Characteristics of studies awaiting classification](#)).

Risk of bias in included studies

The results of the assessment of risk of bias are presented in the [Risk of bias in included studies](#) tables, in [Figure 2](#) and [Figure 3](#), and in funnel plots ([Figure 4](#) and [Figure 5](#)).

Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Ceccato 2012	?	?	+	+	+	+	?
Clark 1998	?	?	+	?	?	?	+
Cooke 2010	+	+	+	+	+	+	+
Guétin 2009	?	?	+	+	?	?	+
Liesk 2015	+	?	+	?	+	?	+
Lin 2011	+	+	+	?	+	?	+
Lord 1993	+	+	+	?	?	?	+
Narme 2012-study 1	?	?	+	+	+	?	+
Narme 2012-study 1a	?	?	+	+	+	?	+
Narme 2014	?	?	+	+	+	?	+
Raglio 2010a	+	?	+	?	+	?	+
Raglio 2010b	?	?	+	+	+	?	+
Ridder 2013	?	+	+	+	+	?	?
Sakamoto 2013	?	?	+	+	+	+	+
Sung 2012	+	?	+	?	?	?	+
Svansdottir 2006	?	?	+	?	?	?	?
Vink 2013	+	?	+	?	?	?	+

Figure 3. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.

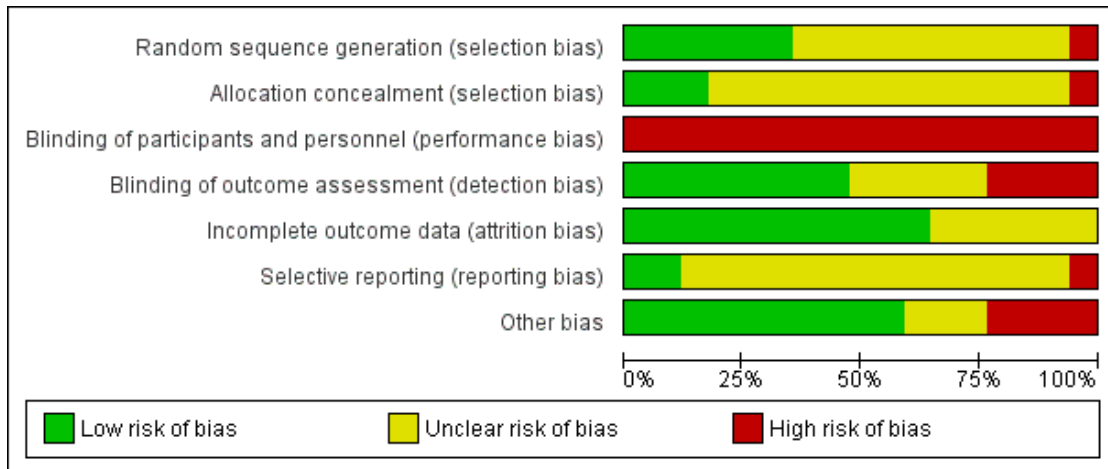


Figure 4. Funnel plot of comparison: I Music therapy versus usual care or versus other activities: end of treatment, outcome: I.3 Negative affect or mood disturbances: anxiety (11 studies, 12 dots because 1 study used 2 control groups, one with usual care and one with other activities)

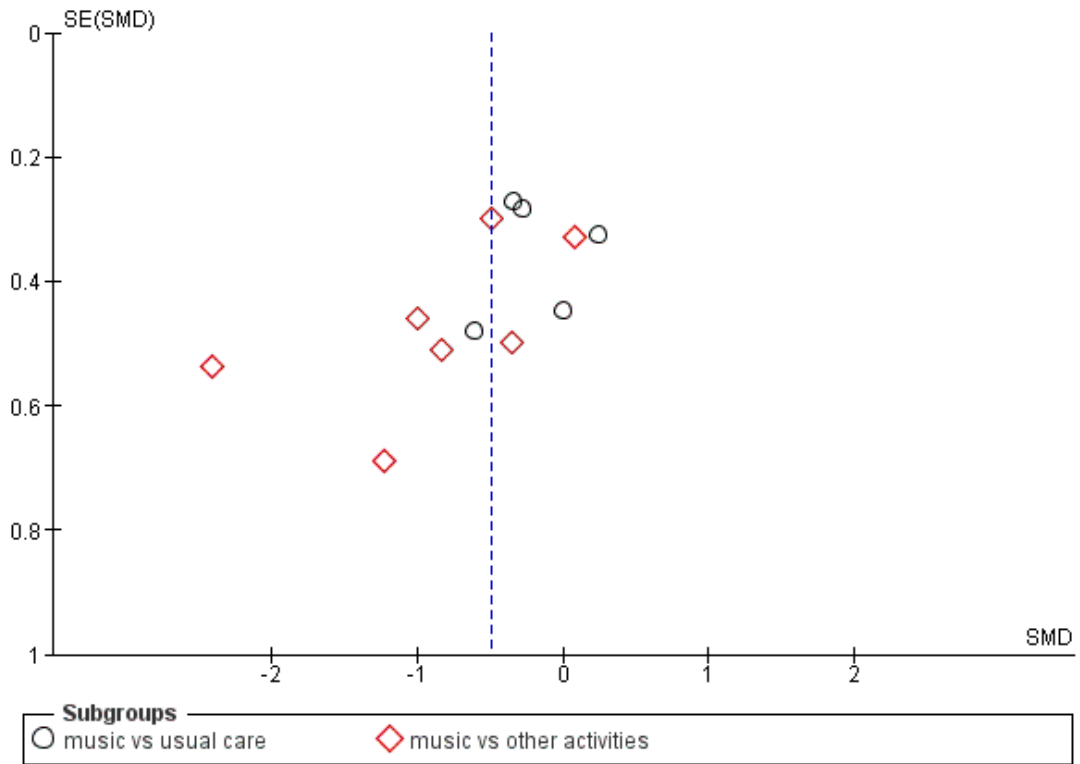
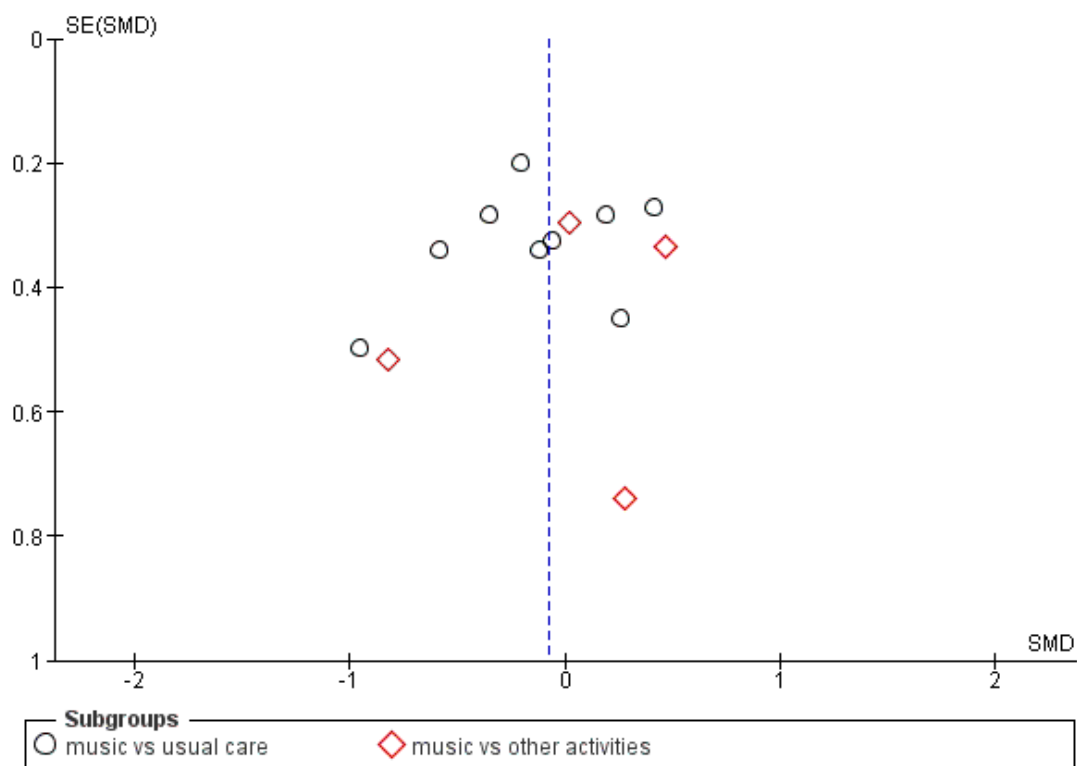


Figure 5. Funnel plot of comparison: 1 Music therapy versus usual care or versus other activities: end of treatment, outcome: 1.4 Problematic behaviour: agitation or aggression (12 studies, 13 dots because 1 study used 2 control groups, one with usual care and one with other activities)



There were a number of possible biases and often we could not assess the risk of bias due to poor reporting. Only risk of attrition bias was either low or unclear, as often no or only few participants were lost to follow-up and there were few missing outcome assessments. Risk of performance bias was high for all studies because participants and staff could not be blinded to the intervention. Regarding the other items, in more recent studies risk of bias was lower and the reporting in terms of interventions, rationale, chosen procedures, design and results was generally better. Still, we are unsure about the methodological quality of a number of studies because several items were rated as unclear.

Allocation

All included studies were RCTs. However, the randomization procedure was not always described in detail (Figure 2). Moreover, allocation concealment was described and adequate in detail in only three studies, all of which were published in 2010 or later (Cooke 2010; Lin 2011; Ridder 2013). One older study stated that participants were “non-systematically separated” into groups without further detail, which we considered posed a high risk of

selection bias (Lord 1993).

Blinding

Blinding of therapists and participants to the intervention is not possible. Therefore, the studies are at high risk of performance bias even though therapists do not generally assess outcomes and participants may not be aware or have no specific expectations or are unable to self-report. The outcomes were assessed unblinded, by the research team or unblinded nurses, in at least four studies (Figure 2). For example, Narme and colleagues describe two studies differing in detection bias (Narme 2012-study 1; Narme 2012-study 1a). The first study involved a high risk of detection bias because the outcomes ‘anxiety’ (measured with the State-Trait Anxiety Inventory for adults, STAI-A) and, as assessed from the first two minutes of filmed interviews, ‘emotions’ (from facial expressions) and ‘social behaviour’ (discourse content), were assessed by nurses who were not blinded for the interventions (music intervention or painting) (Narme 2012-study 1). By contrast, in the sec-

ond study (Narme 2012-study 1a), risk of detection bias was low because the outcomes were assessed by five independent observers who were blinded for the type of intervention (music intervention or cooking). Risk of detection bias resulted in downgrading of the quality of the evidence for all end-of-treatment outcomes (to 'serious'; [Summary of findings for the main comparison](#)); and for all long-term outcomes (to 'very serious' - all outcome assessment was unblinded; [Summary of findings 2](#)).

Incomplete outcome data

Self-reported outcomes were rarely employed. Incomplete outcome data were not identified as problematic in any of the studies. Occasionally death, hospitalisation, acute illness, or no interest in the therapy occurred across the different study arms; and cases with no outcome data were not included in the analyses. Therefore, attrition bias was probably not highly prevalent, and probably did not affect the pooled estimates. Newer studies often visualized cases lost to follow-up and missing outcome assessment in detail using flow diagrams. Nevertheless, in addition to the two oldest studies, some newer studies also only reported the number of cases randomized and analysed and did not explicitly report reasons for missing outcome data by study arm, or how these were handled.

Selective reporting

Most studies did not refer to initial plans, a study protocol or trial registration. Therefore, it is unclear to what extent bias due to selective outcome reporting is pertinent. We found some indication of inconsistent reporting of primary and secondary outcomes which, however, did not seem to affect the pooled estimate (Cooke 2010). Only one study clearly referred to a change in initial plans (Ceccato 2012); and one study referred to a trial registration, and outcome reporting was consistent with the registration (Sakamoto 2013). We did not downgrade the quality of the evidence because of unclear risk of selective reporting.

Regarding publication bias: funnel plots for outcomes with sufficient studies (anxiety, 11 studies of which one with both a 'usual care' and 'other activity' control group, [Figure 4](#); and agitation or aggression, 12 studies, also one with two types of control groups, [Figure 5](#)) indicate possible publication bias for the anxiety outcome. For anxiety, the largest effects were found in studies with the largest standard error, and publications about studies with small effects and large standard error might be missing.

Other potential sources of bias

We found some potential other sources of bias. Outcome assessment may be either imprecise or biased by the use of non-validated outcome measures with suboptimal distributions (such as skewed distributions, e.g. number of times yelling was observed;

Clark 1998) and different procedures for the baseline and outcome assessment (Sakamoto 2013). Further, we found problems with the reporting of outcomes or we suspected errors (Lord 1993; and for this reason, Hong 2011 was moved to [Studies awaiting classification](#)). Implementation fidelity, including non-adherence, was infrequently described, but Liesk 2015, the only study with null findings, reported on this in detail. Finally, there may be bias through a financial or intellectual conflict of interest when funding was provided by a source with a potential interest in the effectiveness of music therapy. This may apply to two studies (Ceccato 2012; Ridder 2013), but it should be noted that no source of funding was reported for more studies (Lord 1993; Clark 1998; Raglio 2010a; Raglio 2010b; Lin 2011; Liesk 2015). Only two studies were both definitely delivered by a music therapist and funded by a source unrelated to music or music therapy (no potential financial conflict of interest, but the music therapists (co)authored the article; Svansdottir 2006; Vink 2013). More studies did not report any funding source.

Effects of interventions

See: [Summary of findings for the main comparison Music-based therapeutic interventions compared to usual care or other activities for people with dementia: end of treatment effects](#); [Summary of findings 2 Music-based therapeutic interventions compared to usual care or other activities for people with dementia: long-term effects \(scores 4 weeks or more after treatment ended\)](#)

Results at the end of treatment are summarised in [Summary of findings for the main comparison](#) and longer term effects in [Summary of findings 2](#).

Of the 17 included studies, 16 studies with a total of 620 participants contributed to meta-analyses of effects. One study reported data on emotional well-being, social behaviour and cognition, but not in enough detail for us to include it in meta-analyses (Lord 1993). Several authors provided additional data such as SDs or item-level outcome data of scales for general behavioural assessments. We pooled data for all end-of-treatment outcomes, and for all but one long-term outcome - cognition - because there was only one study. Of note: of the 17 studies, all but one study - Liesk 2015 - reported some significant improvement in outcomes of the music intervention versus control (all outcomes, including also, e.g. physiological outcomes that we did not evaluate). The methodological quality in terms of risk of bias, but also other quality considerations, varied substantially across the studies and the particular outcomes.

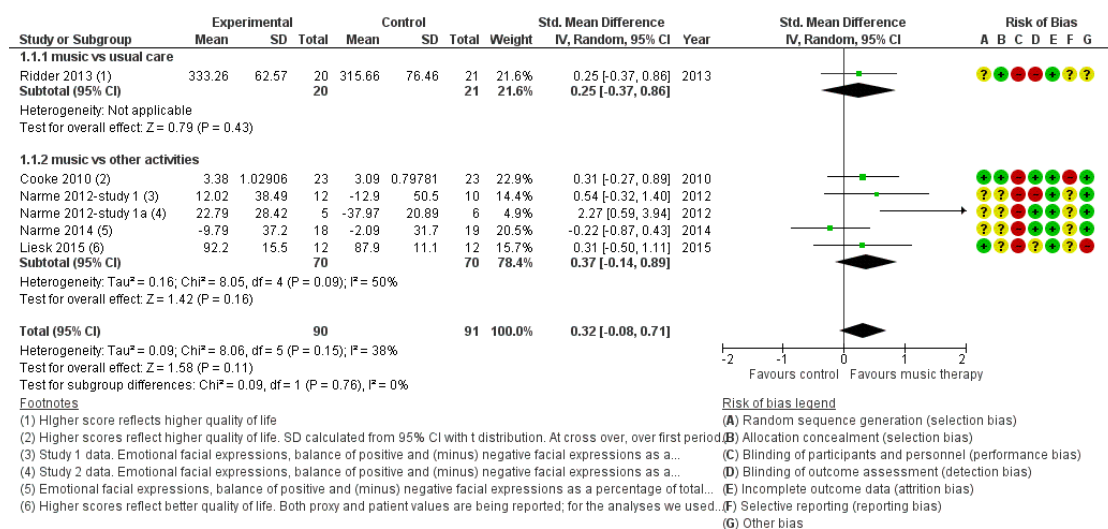
Emotional well-being including quality of life

We included six studies with 181 participants in the analysis of end-of-treatment scores for the critically important outcome of emotional well-being and quality of life. In half of the studies, a validated quality-of-life measure was used (the Dementia Quality of Life, DQOL (Cooke 2010), a German translation of the De-

mentia Quality of Life Instrument, DEMQOL (Liesk 2015), and a Danish translation of the Alzheimer's Disease-Related Quality of Life, ADRQL (Ridder 2013). In the three studies conducted by Narme and colleagues (Narme 2012-study 1; Narme 2012-study 1a; Narme 2014) emotional well-being referred to counts of positive and negative facial expressions as assessed from the first two minutes of filmed interviews. There was no clear evidence of an effect at the end of treatment (Summary of findings for the main comparison; standardized mean difference, SMD 0.32, 95% CI -0.08 to 0.71; Analysis 1.1 and Figure 6). Heterogeneity was only low to moderate ($I^2 = 38\%$; $\text{Chi}^2 P = 0.15$). There was no blinding

of outcome assessment in two of the six studies. The overall quality for effects of music-based interventions on emotional well-being and quality of life at end of treatment was low, downgraded for serious risk of bias and imprecision (wide confidence interval). The quality was very low for long-term outcomes for which there were only two very small studies and very serious imprecision (Narme 2012-study 1a; Narme 2014). There was no clear evidence of an effect (SMD 0.47, 95% CI -0.10 to 1.05; Analysis 2.1; Summary of findings 2), but because of the very low quality, this is a very uncertain result.

Figure 6. Forest plot of comparison: 1 Music therapy versus usual care or versus other activities: end of treatment, outcome: 1.1 Emotional well-being and quality of life .

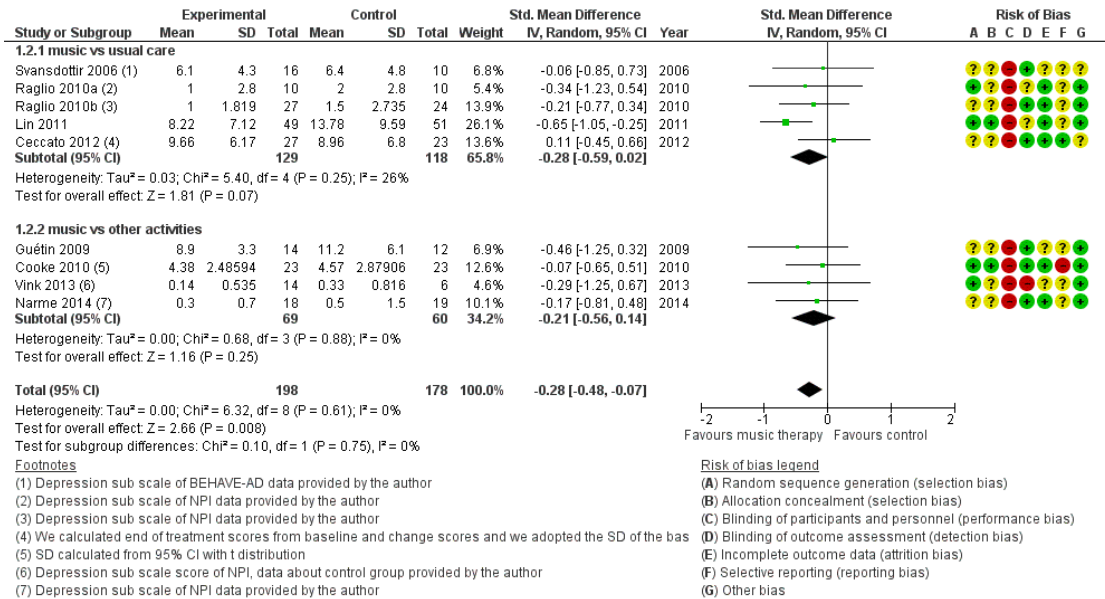


Mood disturbance or negative affect: depression

Nine studies contributed 376 participants to the analysis on end-of-treatment effect (Figure 7) and five studies contributed 234 participants to the analysis on long-term effects. Depression or depressive symptoms were measured with (translated versions of) the Geriatric Depression Scale (GDS) or with a subscale of the Behavioural Pathology in Alzheimer's Disease (BEHAVE-AD) or the Neuropsychiatric Inventory (NPI). Heterogeneity was not important ($I^2 = 0\%$) for either end-of-treatment or long-term outcomes. We downgraded both outcomes for risk of bias, due to lack of blinding in many studies. Imprecision was more of an issue

for long-term outcomes. The overall quality of the evidence was moderate for end-of-treatment effects and very low for long-term outcomes. We found that music-based therapeutic interventions probably reduced depressive symptoms at the end of treatment (SMD -0.28, 95% CI -0.48 to -0.07; Summary of findings for the main comparison; Analysis 1.2 and Figure 7). There was no evidence of a reduction in the longer term, with a smaller estimate and a confidence interval including no effect (SMD -0.01, 95% CI -0.27 to 0.24; Summary of findings 2; Analysis 2.2) although again the very low quality of the evidence made this result very uncertain.

Figure 7. Forest plot of comparison: I Music therapy versus usual care or versus other activities: end of treatment, outcome: I.2 Negative affect or mood disturbances: depression.

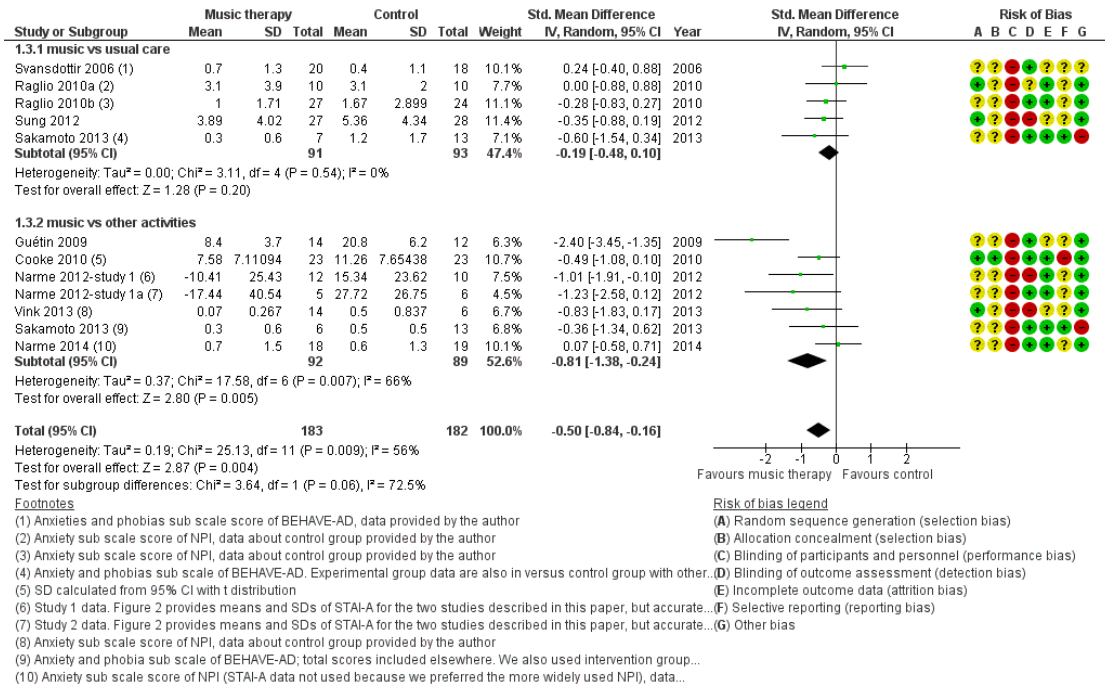


Mood disturbance or negative affect: anxiety

The other mood item we considered was anxiety. For this outcome, at the end of treatment, we included 11 studies with 365 participants. A variety of (translated) outcome measures were used; Rating Anxiety in Dementia Scale (RAID), State-Trait Anxiety Inventory for Adults (STAI-A), Hamilton Anxiety Scale, and sub-scale scores of the BEHAVE-AD and NPI. Heterogeneity was substantial for end-of-treatment effects (I² = 56%; Chi² P = 0.009) and longer-term effects (I² = 72%; Chi² P = 0.006). In addition

to serious inconsistency, there was serious risk of bias, imprecision and - for the end of treatment outcome - possible publication bias (Figure 4). Hence we judged the quality of the evidence at both time points to be very low. We can therefore have very little confidence in the results. Anxiety was lower in the music intervention group at the end of treatment (SMD -0.50, 95% CI -0.84 to -0.16; 11 studies with 365 participants; Summary of findings for the main comparison; Analysis 1.3 and Figure 8), but not in the longer term (SMD -0.23, 95% CI -0.86 to 0.41; 5 studies with 160 participants; Summary of findings 2; Analysis 2.3).

Figure 8. Forest plot of comparison: I Music therapy versus usual care or versus other activities: end of treatment, outcome: 1.3 Negative affect or mood disturbances: anxiety.

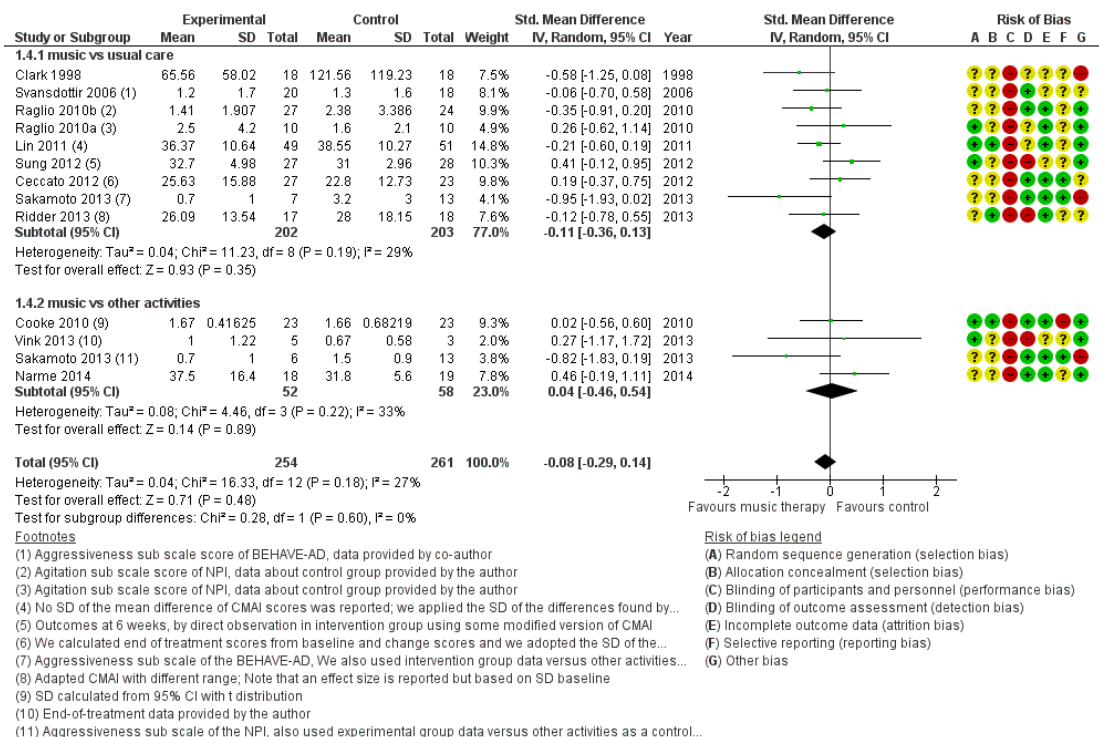


Behavioural problems: agitation or aggression

Twelve studies with 515 participants contributed to the end-of-treatment effect analysis, and four studies with 225 participants contributed to the long-term effect analysis. Outcome measures used for agitation were (translated versions of) the Cohen-Mansfield Agitation Inventory (CMAI) and the agitation subscale of the NPI; and for aggression, the aggressiveness subscale of the BEHAVE-AD and counts of observed aggressive behaviour. Heterogeneity was low to moderate at end of treatment and longer term (I² = 27%, Chi² P = 0.18, and I² = 37%, Chi² P = 0.19, respectively). Inconsistency and imprecision were not serious for

the end-of-treatment outcome, but inconsistency was serious for the long-term outcome, as was imprecision. Both outcomes were downgraded for risk of bias. There was no evidence of publication bias (regarding end-of-treatment effect; Figure 5). We rated the quality of the evidence as moderate for the end-of-treatment outcome but very low for the long-term outcome. We found no evidence of an effect on agitation or aggression at the end of treatment (SMD -0.08, 95% CI -0.29 to 0.14; Summary of findings for the main comparison; Analysis 1.4 and Figure 9) nor in the long term (SMD -0.02, 95% CI -0.36 to 0.33; Summary of findings 2; Analysis 2.4).

Figure 9. Forest plot of comparison: I Music therapy versus usual care or versus other activities: end of treatment, outcome: I.4 Problematic behaviour: agitation or aggression.

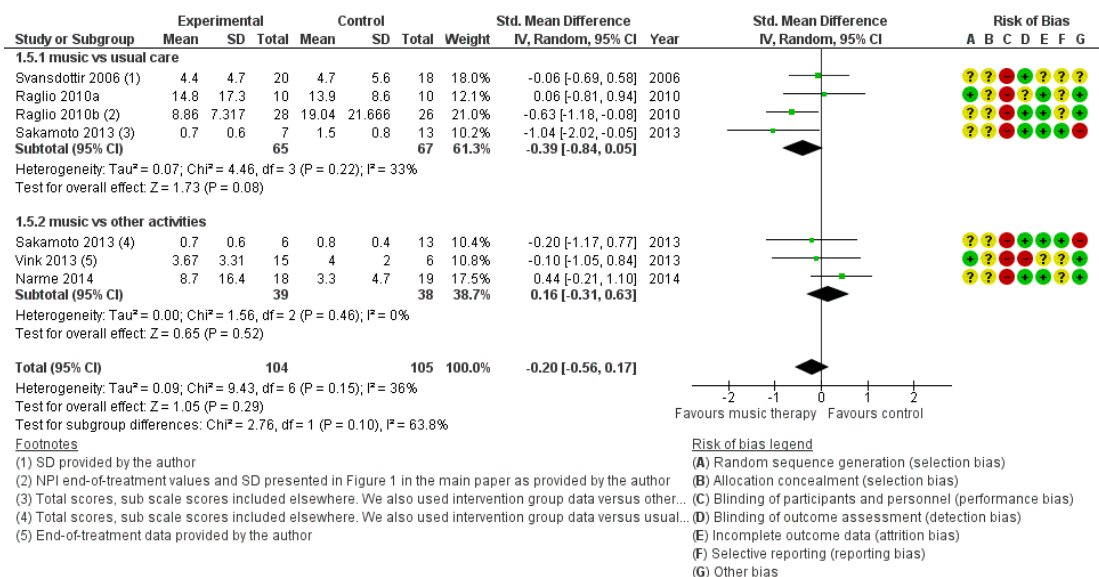


Behavioural problems overall

Six studies with 209 participants contributed to the end-of-treatment effect analysis, and three studies with 125 participants contributed to the analysis of longer term effects. Outcome measures were (translated versions of) the BEHAVE-AD and NPI. Heterogeneity was low to moderate for the end of treatment effect ($I^2 = 36\%$, $\text{Chi}^2 P = 0.15$). The quality of the evidence was low due to serious risk of bias and imprecision. We found no evidence of

an effect of music-based therapeutic interventions on problematic behaviour overall at the end of treatment (SMD -0.20 , 95% CI -0.56 to 0.17 ; [Summary of findings for the main comparison; Analysis 1.5 and Figure 10](#)). There was no evidence of a long-term effect either (SMD 0.05 , 95% CI -0.30 to 0.41 ; $I^2 = 0\%$, $\text{Chi}^2 P = 0.38$, heterogeneity was not important; [Summary of findings 2; Analysis 2.5](#)) although we considered this very low quality evidence.

Figure 10. Forest plot of comparison: I Music therapy versus usual care or versus other activities: end of treatment, outcome: I.5 Problematic behaviour overall.

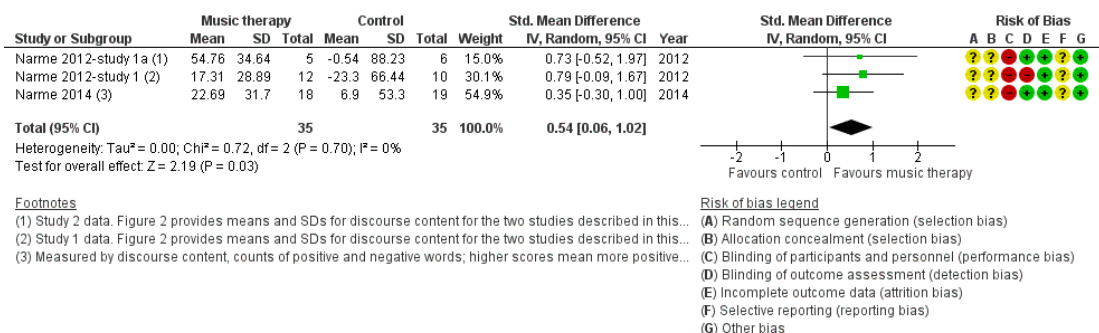


Social behaviour

The three studies of Narme and colleagues (Narme 2012-study 1; Narme 2012-study 1a; Narme 2014) contributed 70 participants to the end-of-treatment effect analysis and two of them contributed 48 participants to the analyses of longer term effects. For all, the outcome was the contents of conversation (positive versus negative expressions when interviewed about current feelings and personal history). Lord 1993 reported on effects on their self-made questionnaire on social interaction, mood and recall (combined outcome) but there were no separate figures for social interaction and therefore we could not use the data for the meta-analysis. We

downgraded the evidence at both time points due to serious or very serious risk of bias and very serious imprecision. There was also moderate to substantial heterogeneity (I² = 54%, Chi² P = 0.14) in the long-term analysis. We considered the quality of the evidence to be very low for both outcomes and were therefore very uncertain about the result of more positive expressions in the music-based interventions group at the end of treatment (SMD 0.54, 95% CI 0.06 to 1.02; 3 studies; I² = 0%, Chi² P = 0.70; Summary of findings for the main comparison, Analysis 1.6 and Figure 11). There was a similar SMD but an even wider confidence interval in the analysis of long-term effects (SMD 0.53, 95% CI -0.53 to 1.60; Analysis 2.6; Summary of findings 2).

Figure 11. Forest plot of comparison: I Music therapy versus usual care or versus other activities: end of treatment, outcome: I.6 Social behaviour: music vs other activities.

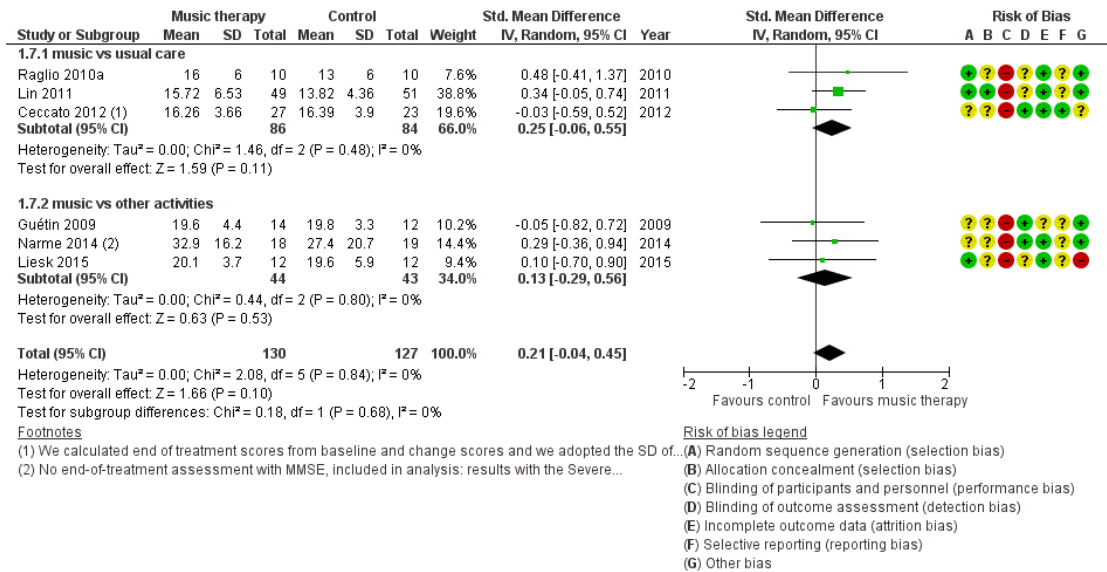


Cognition

Six studies contributed 257 participants to the end-of-treatment effect analysis and there was only one study, with 100 participants, that assessed long-term effects. Outcome measures used in the analyses were (translated versions of) the Mini-Mental State Examination (MMSE) and the Severe Impairment Battery (SIB). We used the MMSE data if these were available in addition to other cognition measures such as Prose Memory tests, the FAS-Test (Controlled-Oral-Word-Association Test), or the Alzheimer's Dis-

ease Assessment Scale cognitive subscale (ADAS-cog). The end-of-treatment results were imprecise but not inconsistent. There was no important heterogeneity ($I^2 = 0\%$; $\text{Chi}^2 P = 0.84$). There was serious risk of bias. The overall quality of the evidence was low and suggested that music-based interventions may not affect cognition at the end of treatment (SMD 0.21, 95% CI -0.04 to 0.45 ; [Summary of findings for the main comparison](#); Analysis 1.7 and [Figure 12](#)). The only study that assessed long-term effects found a SMD of 0.13 (95% CI -0.26 to 0.52); we considered this very low quality evidence.

Figure 12. Forest plot of comparison: 1 Music therapy versus usual care or versus other activities: end of treatment, outcome: 1.7 Cognition.



Any other adverse effects

These were not reported.

Effects of interventions delivered by a music therapist and in studies with a potential financial conflict of interest

The sensitivity analyses with analyses restricted to studies where the intervention was definitely or possibly delivered by a qualified music therapist resulted in similar end-of-treatment effect es-

timates (there was no sensitivity analysis for the social behaviour outcome because no study remained). When restricting to studies that were definitely delivered by a music therapist, most effects were similar, but there was a smaller effect on anxiety. In the four of 11 studies in which the intervention was definitely delivered by a music therapist, the estimate for anxiety was -0.15 (SMD -0.15 , 95% CI -0.54 to 0.24 ; with less heterogeneity; $I^2 = 16\%$, $\text{Chi}^2 P = 0.31$; 129 participants).

When we restricted analyses further to studies definitely delivered by a music therapist and having no potential financial conflict

of interest, or no funding source reported, we found somewhat different estimates, but there were very small numbers of studies and participants in these analyses.

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

Music-based therapeutic interventions compared to usual care or other activities for people with dementia: long-term effects (scores 4 weeks or more after treatment ended)			
Interpretation of SMD: a difference of < 0.40 standard deviations can be regarded as a small effect, 0.40 to 0.70 a moderate effect, and > 0.70 a large effect			
Patient or population: people with dementia (all resided in institutional settings)			
Intervention: music-based therapeutic interventions			
Comparison: usual care or other activities			
Outcomes (long-term) measured with a variety of scales except for social behaviour	Anticipated absolute effects * (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)
	Score with music therapy compared with usual care or other activities		
Emotional well-being including quality of life	The score in the intervention group was 0.47 SDs higher (0.10 lower to 1.05 higher)	48 (2 RCTs)	⊕○○○ VERY LOW ¹²
Mood disturbance or negative affect: depression	The score in the intervention group was 0.01 SDs lower (0.27 lower to 0.24 higher)	234 (5 RCTs)	⊕○○○ VERY LOW ¹³
Mood disturbance or negative affect: anxiety	The score in the intervention group was 0.23 SDs lower (0.86 lower to 0.41 higher)	160 (5 RCTs)	⊕○○○ VERY LOW ¹²⁴
Behavioural problems: agitation or aggression	The score in the intervention group was 0.02 SDs lower (0.36 lower to 0.33 higher)	225 (4 RCTs)	⊕○○○ VERY LOW ¹³⁴
Behavioural problems: overall	The score in the intervention group was 0.05 SDs higher (0.30 lower to 0.41 higher)	125 (3 RCTs)	⊕○○○ VERY LOW ¹³
Social behaviour - music vs other activities	The score in the intervention group was 0.53 SDs higher (0.53 lower to 1.6 higher)	48 (2 RCTs)	⊕○○○ VERY LOW ¹²
Cognition - music vs usual care	The score in the intervention group was 0.13 SDs higher (0.26 lower to 0.52 higher)	100 (1 RCT)	⊕○○○ VERY LOW ¹²

* Interpretation of SMD: a difference of < 0.40 standard deviations can be regarded as a small effect, 0.40 to 0.70 a moderate effect, and > 0.70 a large effect.

CI: Confidence interval; SMD: standardised mean difference; SD: standard deviation

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

¹ Risk of bias: no blinding of therapists and patients (not possible), and no blinding of outcome assessment

² Imprecision: very small number of participants and broad confidence interval includes both benefit and harm

³ Imprecision: small number of participants and rather broad confidence interval

⁴ Inconsistency: multiple non-overlapping confidence intervals

DISCUSSION

Summary of main results

The aim of this review was to evaluate the effect of music-based therapeutic interventions on a range of outcomes relevant for people with dementia. The specific focus was to assess whether they can improve emotional well-being including quality of life, mood disturbance or negative affect, behavioural problems, social behaviour, and cognition.

Seventeen studies have been included in this review, and we were able to perform meta-analyses on effects at the end of treatment and longer term (mostly four weeks after treatment ended). We found moderate-quality evidence that at the end of treatment music-based therapeutic interventions improved depressive symptoms and did not improve agitation or aggression, and low-quality evidence that it had no effect on emotional well-being including quality of life, overall behavioural problems and cognition. There was very low quality evidence of benefit on anxiety and social behaviour. Sensitivity analyses suggested that the effects were not larger in studies in which the intervention was delivered by a qualified music therapist. There was no evidence of effects four weeks or more after the end of treatment, but the quality of this evidence for all outcomes was also very low.

Overall completeness and applicability of evidence

Only three studies used social behaviour as an outcome, and these were from a single group of researchers in France (Narme 2012-study 1; Narme 2012-study 1a; Narme 2014). The evidence in this review applies to therapeutic effects of music-based therapeutic interventions after at least five sessions. It excludes some group interventions which involved music, but where music was not the main or only therapeutic element. It excludes direct effects during sessions.

Quality of the evidence

The quality of the evidence was moderate for depression and for agitation or aggression at the end of treatment. For all other outcomes it was low or very low. All end-of-treatment outcomes were downgraded for risk of bias; all except depression and agitation or aggression were downgraded for imprecision; and some outcomes were also downgraded for inconsistency.

Many studies used validated outcome measures for behaviour (e.g. the NPI (Cummings 1994) or BEHAVE-AD (Reisberg 1987)), two widely used measures which are recommended because of favourable psychometric properties (Jeon 2011), and for cognition (e.g. the MMSE (Folstein 1975)). We included subscales of the behavioural scales as outcome measures. However, there is less evidence for validity of subscales compared to total scores (Lai 2014).

We combined agitation and aggression in meta-analyses because this is consistent with the definition given by the International Psychogeriatric Association (Cummings 2015); and these items are also combined in the widely used CMAI (Cohen-Mansfield 1986). Some have raised conceptual issues such as overlap of a broad definition of agitation with resistance to care (Volicer 2007). The quality of the reporting was sometimes poor which resulted in uncertainty about the exact methodological quality of the included studies and the evidence for effects. Overall, the studies had small sample sizes. Few studies reported on fidelity of the implementation of the music intervention and other activities, or on other aspects of a process evaluation. Implementation fidelity is often defined as the degree to which an intervention or programme is delivered as intended (Carroll 2007); and in music therapy trial specifically, treatment fidelity refers to “methodological strategies used to monitor the delivery of the music therapy intervention as described in the treatment manual” (Bradt 2012). Treatment fidelity includes adherence to an intervention, exposure or dose, quality of delivery, participant responsiveness, and programme differentiation to identify essential components of the intervention (Carroll 2007), and therefore includes, but is not limited to, participant (or staff) adherence and responsiveness.

Some of the included studies selected people with agitated behaviour before the intervention, or people who were more likely to be interested in music-based interventions. On the other hand, there were studies in which people with musical knowledge were excluded (Raglio 2010a), or without such selection criteria. Dropout was mostly due to health-related conditions such as hospitalisation, illness or mortality. Dropout due to lack of interest was reported for a control activity (cognitive stimulation programme) and dropout due to “problems in the group” in a music intervention group (Liesk 2015), but none of the other studies reported any unfavourable effects of the music-based interventions. We do not know if there were any unreported adverse effects such as a sore throat after singing. We also do not know if, without selectively including people based on subjective judgement of whether they will probably accept the intervention, some individuals with dementia might experience disadvantages of the intervention. Possibly, effects in these studies depend on participants having problems at baseline (being selected as in need of treatment for specific problems) and hence to there being substantial room for improvement. Specific subgroups might benefit from music-based therapeutic interventions more than others.

There may be publication bias through selective reporting of studies and selective outcome reporting in the relevant literature. Although few protocols were registered, we found inconsistencies in the reporting of outcome measures in one study that reported on the study in multiple papers (Cooke 2010). Moreover, despite most of the meta-analyses we ran not resulting in significant pooled effects, 16 of the 17 studies (all, except for Liesk 2015) reported at least one significant effect. For some studies this included outcomes beyond the scope of this review, such as heart rate, but it

could indicate selective reporting of significant findings or analytic methods that resulted in significant findings. Further, the funnel plot showing end-of-treatment effects on anxiety suggested possible publication bias. There may also be a financial conflict of interest if the study is funded by a source interested in the outcomes, or an intellectual conflict of interest in case the study is performed by the music therapist who authors the article, but there were insufficient data to examine possible effects of conflicts of interest.

Potential biases in the review process

Although we have done an extensive literature search in the most commonly used databases and also thoroughly handsearched music therapy journals, it may however be that not all conducted RCTs were retrieved.

Agreements and disagreements with other studies or reviews

A recent review on effects of music therapy on behavioural and psychological symptoms of dementia found larger SMDs for behavioural problems overall (-0.49 , 95% CI -0.82 to -0.17) and for anxiety (-0.64 , 95% CI -1.05 to -0.24) compared with our findings (Ueda 2013). However, that review included non-randomized trials and cohort studies and studies which we excluded because they did not meet our criteria for therapeutic interventions. They found an even larger effect for studies that lasted three months or longer (-0.93 , 95% CI -1.72 to -0.13), a subgroup we did not analyse separately.

The review by Chang 2015 included 10 studies, including Raglio 2008 which we excluded in the updated version of our review because after re-evaluation, we judged this to be a quasi-randomized study; Sung 2006 which after re-evaluation did not meet our criteria for a music-based therapeutic intervention (it was music with movement); and Janata 2012 which we excluded because streaming music also did not meet our criteria for a therapeutic intervention. Chang 2015 included studies that compared with usual care, excluding other activities except for reading sessions as the comparator (Guétin 2009; Cooke 2010; perhaps also including a study on ICU patients with no dementia). Our review had a longer search period than 2000 to 2014 and we included articles in French and German. Both we and Chang 2015 found substantial heterogeneity in our analyses of anxiety, but we also found that the funnel plot indicated possible publication bias and that the quality of the evidence for an effect on anxiety was very low. Effect sizes for cognition were smaller than for mood in both reviews. However, Chang 2015 found a significant effect on “disruptive behaviours” whereas we did not find evidence of an effect on behavioural problems (agitation/aggression), and we found an effect on depression which they did not, despite a larger effect size than in our review (-0.39 and -0.28 , respectively).

A recent review by [Zhang 2017](#) included non-randomized studies and studies that we excluded because of insufficient therapeutic-based goals and their methods and findings differed in a number of other ways. Their subgroup analyses for effect on “disruptive behaviour” (overall behavioural scales and agitation) suggested a higher SMD for non-randomized studies (-1.02 versus -0.65 (text) or -0.52 (Table) for parallel RCTs). They found a larger SMD for disruptive behaviour (-0.42 , 95% CI -0.74 to -0.11 , compared to -0.20 in our work). Compared to our review, they found a similar SMD for cognition (SMD 0.20 , 95% CI -0.09 to 0.49), and smaller SMDs for anxiety (-0.20 , 95% CI -0.37 to -0.02), depression (SMD -0.16 , 95% CI -0.41 to 0.08) and quality of life (SMD -0.12 , -0.36 to 0.12 ; negative SMDs however favoured music therapy). [Zhang 2017](#) performed different analyses, probably comparing scores before and after the intervention to calculate a SMD with a general check of whether there were baseline differences. This may explain different SMDs also for individual studies, and the quality assessments of the same included studies rarely corresponded with ours. For example, [Svansdottir 2006](#) was an outlier for effect on behaviour in [Zhang 2017](#) (SMD -3.88), compared with an SMD of -0.06 for end-of-treatment scores in our work. Also, in this case, [Zhang 2017](#) assigned points for quality because of blinding of the therapist whereas we rated high risk for performance bias for all studies (in view of standardized methods to allow for comparison of very different interventions and situations) and in this case, [Svansdottir 2006](#) also disclosed that the first author “conducted the music therapy.” [Zhang 2017](#) judged all studies to be of acceptable quality, even those with a total score of 3 (Supplemental table) or higher than 4 (text) on a 0 to 10 scale where one of the items was the random allocation. Finally, their secondary outcomes (depression, anxiety and quality of life) were prioritised in our review because of the evident importance for the person with dementia him/herself. Multiple other recent reviews have summarized effects and concluded, without meta-analyses, that the intervention is beneficial. Some focused on specific outcomes such as behavioural and psychological symptoms of dementia (e.g. [Raglio 2012](#)); or covered different types of outcomes such as physiological outcomes (e.g. [McDermott 2013](#), who also noted a lack of evidence on long-term effects). [Petrovsky 2015](#) focused on effects on anxiety and depression in people with mild dementia, but included studies with participants who had varying severity of dementia as long as it was not limited to severe dementia. They found that the evidence was inconclusive based on 10 studies, including some with a pre-post test design. We were able to include more RCTs because authors provided data about mood items in overall behavioural scales. [Ing-Randolph 2015](#) reviewed effects of group music interventions, including music therapy, on anxiety. They found that music interventions reduced anxiety in seven of eight included studies.

The clinical importance of the effect of music-based interventions on depression is somewhat uncertain because of the vari-

ety of scales used, although there was no heterogeneity in effects across the studies. The SMD for depression (-0.28) and anxiety (-0.50 ; but very uncertain due to serious risk of bias, imprecision, inconsistency and probable publication bias) was within the range of, or larger than, pooled estimates of effects of medication on depression in people with dementia (antidepressants, 6 trials, SMD favouring medication 0.29 , 95% CI 0.02 to 0.60 , [Nelson 2011](#); selective serotonin reuptake inhibitors, 12 trials, effect sizes favouring medication 0.06 to 0.10 , [Sepehry 2012](#)). There may be fewer side effects of music-based therapeutic interventions compared with medication.

AUTHORS' CONCLUSIONS

Implications for practice

Music-based therapeutic interventions may be used for people with dementia residing in institutional settings, to treat depressive symptoms. Depression is very common in people with dementia irrespective of the stage of dementia ([Verkaik 2007](#)); and it is related to low quality of life ([Banerjee 2009](#); [Beerens 2014](#)). It is not clear whether effects will persist beyond the intervention period and music-based interventions may need to be continued for prolonged periods for a sustained effect.

Implications for research

Guidelines for the design and implementation of RCTs of music therapy are available ([Bradt 2012](#)). For dementia, more well-conducted studies are needed to establish more precisely the effects of music therapy and related interventions in the treatment of people with dementia, including effects on positive outcomes such as emotional well-being, quality of life and social behaviour. Outcomes may also cover behaviour that may not be disturbing to others but compromises quality of life, such as apathy, which is highly prevalent and often highly persistent over the course of dementia (dementia or cognitive impairment, [van der Linde 2016](#); Alzheimer's disease, [Zhao 2016](#)). Outcomes such as pain and discomfort have been used for testing effects of music therapy at the end of life, mostly among people with cancer ([McConnell 2016](#)); these are also important outcomes for people with dementia. Overall behavioural scales (which include items on hallucinations, euphoria, etc.) might be rather too broad for use as outcome scales for effects of music therapy. Future studies should follow the CONSORT guidelines for reporting of randomized trials, use adequate methods of randomization with adequate concealment of allocation of the participants to (parallel) treatment groups, blind the outcome assessors to treatment allocation (and report this) and be of sufficient duration to assess persistence of effects after the end of treatment. Blinding of participants is difficult but not impossible, especially with active control groups, when the participants

are unaware of the hypothesis of the study and which intervention is considered the active intervention (Bradt 2012). We discourage the use of cross-over designs because possible long-term effects of music-based interventions risk carry-over effects when crossing over. Study protocols should be registered and primary and secondary outcomes should be reported accordingly. Reporting of effects should preferably include mean differences and standard deviation of differences between baseline and follow-up, or effect sizes, which only a few studies (namely Ceccato 2012 and Ridder 2013) have reported so far. Funding sources should be reported and any potential conflict of interest through possible interest in the outcomes should be considered and disclosed, such as an interest in finding favourable effects of the therapy. This also includes cases where the therapist delivering the intervention (co)authors the article.

More research is needed to differentiate between various therapeutic approaches using music: to examine, for example, whether there is a difference between receptive and active approaches, or how response relates to duration of individual sessions (noting that any dose-response relationships may not be linear, due to participants' difficulties with sustaining concentration or the risk of overstimulation with longer sessions). It is important to establish whether pre-existing problematic or challenging behaviour moderates the effects. Further research is also required to compare music-based therapeutic activities in which music is the main or only therapeutic element, to other group activities involving music. If more data were available, it would be helpful for future analyses to distinguish between usual care and other musical or non-musical activities in the control group. In the existing literature, the professional background of the therapist was sometimes unclear, or there was no information about the training of the music therapists or their experience of delivering music-based therapeutic interventions specifically to people with dementia. It is important

to provide detail on who delivers the intervention in order to facilitate classification of interventions as music therapy delivered by a qualified, trained and experienced music therapist, other music-based therapeutic interventions, or other interventions involving music, and to allow corresponding subgroup analyses. However, targeted studies may be more appropriate to evaluate effects of training because subgroup analyses risk confounding if, for example, qualified therapists see people with more complex problems. Further studies may also focus on effects in special groups such as young-onset dementia, or on different settings, including community settings with more people with early dementia.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Ceccato 2012

Methods	RCT (parallel) No information on data collection period reported
Participants	Country: Italy. 5 support centres. N = 51 people with dementia and 50 of them were included in analyses (1 had only pre-test data); 28 participants in experimental group (27 in analyses) and 23 participants in control group (21 female in experimental group and 19 female in control group) Mean age: 85.5 years (SD 5.9) in experimental group and 87.2 years (SD 7.1) in control group Dementia diagnosis: formally diagnosed with the DSM-IV. Inclusion criterion was Mini-Mental State Examination (MMSE) score from mild (MMSE 18 to 24) to moderate (MMSE 12 to 18) People with acute medical illness were excluded, and a number of additional inclusion criteria applied, including being “sensitive to sound/musical stimuli”; “the desire and capacity to remain in the setting”; “presence of sufficient (also residual) hearing and perceptive-communicative and relational skills”
Interventions	1) Sound Training for Attention and Memory in Dementia (STAM-Dem). Mixed active-receptive group intervention with 24 sessions of 45 minutes in 12 weeks. STAM-Dem includes 4 phases: 1) stimulus-movement association, 2) reaction to acoustic stimuli, 3) shifting attention, and 4) orderly and inverted repetition. The intervention combines listening to music, clapping hands, tapping the table, and repeating sounds. The professional music therapists were trained to administer the STAM-Dem protocol. Supervision was provided throughout the course of the intervention by the protocol’s author 2). Those in the control group continued with the normal “standard care” provided
Outcomes	Primary outcome <ul style="list-style-type: none"> Cognitive functioning was measured with the Mini-Mental State Examination (MMSE), attentional matrices, forward and reverse digit-span exercise, Immediate Prose Memory test (MPI) and Deferred Prose Memory test (MPD). Secondary outcomes <ul style="list-style-type: none"> Behaviour was measured with the Cohen-Mansfield Agitation Inventory (CMAI). The timeframe of the CMAI was last 2 weeks. Mood was measured with the Geriatric Depression Scale (GDS). ADL was measured with the Index of Independence in Activities of Daily Living (ADL) by nurses, adequacy 6 functions. Some other outcomes may have been measured only in the STAM-DEM group. Follow-up was planned but not carried out. No follow-up was conducted after the intervention because of a lack of funding.
Notes	Randomization was done separately for each centre (6 randomizations in total). This is also the reason why there were more people in the experimental group (28 versus 23) Funding: F.S. Zerbaro Centre at Tregnago (president, director and manager)

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "They were divided up using an on-line randomization program by personnel not involved in the study, thereby ensuring totally "blind" conditions." However, there were 6 randomizations with small numbers
Allocation concealment (selection bias)	Unclear risk	Unclear how blinded.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Pre- and postintervention testing was also administered by professionals who had no other role in the project; blind conditions were thus obtained for assignment treatment."
Incomplete outcome data (attrition bias) All outcomes	Low risk	1 participant dropped out and 1 participant had no post-test data. Unclear if this was the same participant as the number allocated to the intervention group was incorrect in the Figure
Selective reporting (reporting bias)	Low risk	They admit that they did not follow the plans here: no follow-up was conducted after the intervention because of a lack of funding
Other bias	Unclear risk	Funding sources might have an interest in the study outcomes

Clark 1998

Methods	RCT (crossover 2 weeks + 2 weeks). No information on data collection period reported.
Participants	Country: USA. N = 18 (14 female, 4 male). Mean age: 82 (range 55 to 95), residents in a nursing home with Alzheimer-type dementia. Inclusion criteria presence of dementia and a history of aggressive behaviour exhibited during care giving routines

Clark 1998 (Continued)

	<p>Presence of dementia was assessed with the MMSE (Mean = 10, range 0 to 22); most residents had severe dementia.</p> <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Uncorrected hearing impairment. • Absence of family member who could provide knowledge of a potential participant's music preferences.
Interventions	<p>(1) Favourite music during bathing (receptive intervention).</p> <p>(2) No music during bathing.</p> <p>Following a 2-week (10-sessions) observation period, conditions were reversed. A total of 20 sessions (bathing episodes; 10 control, 10 experimental) were observed over a period of approximately 4 weeks. Probably the intervention was provided for all bathing episodes and all were observed</p>
Outcomes	<p>Behaviour: frequency of aggressive behaviours (no specific measure was used, but counts and mean counts across specific behaviours)</p>
Notes	<p>No information about funding available.</p> <p>Note that the study also included younger people with dementia</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "After being enrolled in the study, participants were randomly scheduled for observation during bath time under either a control (no music) condition or an experimental condition." No further information is provided on randomization.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information provided.
Selective reporting (reporting bias)	Unclear risk	The study protocol is not available.

Clark 1998 (Continued)

Other bias	High risk	Questionable outcome measure and distribution. The authors report in the article on the effects of the extreme intra-subject and inter-subject variability characteristic of this population in this study Quote: "For example, one subject was responsible for 408 and 84 occurrences of yelling behaviour in the no music and music conditions, respectively". Therefore, highly skewed distributions (the observation hardly occurred) causing imprecision
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Cooke 2010

Methods	RCT (crossover). Data collection from October 2008 to March 2009.	
Participants	Country: Australia. 2 mixed-gender long-term care facilities, which provided low (assisted living) and high (nursing home) care N = 47 (33 female and 14 male). Age: 3 people between 65 and 74, 13 between 75 and 84, 28 between 85 and 94 and 3 people aged 95+ Dementia diagnosis: a confirmed diagnosis of early- to mid-stage dementia, OR probable dementia (i.e. a cognitive impairment level of 12 to 24 on MMSE) OR Alzheimer's dementia according to DSM-IV criteria. At baseline, the mean MMSE score was 16.51, representing middle-stage dementia (SD = 6.737) Participants had "a documented behavioural history of agitation/aggression on nursing/medical records within the last month."	
Interventions	1) Active live group music programme (30 minutes per session) and listening to pre-recorded instrumental music (10 minutes per session) led by 2 musicians 2) Reading group chosen as the control group activity so as to provide a comparable activity. The facilitator of the 40-minute sessions was trained research assistant Both the active group music programme and the control activities ran 3 mornings a week (Monday, Wednesday and Friday) for 8 weeks, and the facilitators were trained in the delivery of the sessions and in working with older people with dementia	
Outcomes	Primary outcome <ul style="list-style-type: none"> Agitation was measured with the Cohen-Mansfield Agitation Inventory - Short Form (CMAI-SF) and overall and sub scale scores are reported for a modified 14-item short form. Timeframe: previous 2 weeks. Secondary outcome <ul style="list-style-type: none"> Anxiety was measured with the Rating Anxiety in Dementia Scale (RAID). Timeframe: previous 2 weeks. Quality of life was measured with Dementia Quality of Life (DQOL) using overall and sub scale scores. Depression was measured with Geriatric Depression Scale (GDS). 	

	<ul style="list-style-type: none"> Outcomes were measured at baseline, mid-point (after the first 8-week intervention arm) and post-intervention (after the second 8-week intervention arm). 	
Notes	Funding: funded by the National Health & Medical Research Council, Australia	
Risk of bias		
	Risk of bias	
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomisation process was conducted by the study's biostatistician, who was blinded to the identity of potential participants, using a computer-generated programme"
Allocation concealment (selection bias)	Low risk	Quote: "The randomisation process was conducted by the study's biostatistician, who was blinded to the identity of potential participants, using a computer-generated programme"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote about CMAI-SF: "Aged care staff who provided most care to the participant, but blinded to treatment groups, were asked to rate the ..." Quote about RAID: "Research assistants (RAs) blinded to the treatment groups asked participants to rate, on a scale from '1 = absent' to '3 = severe', how often he/she had experienced each symptom in the previous two weeks" Research assistant completed DQOL and GDS (Figure 1). Quote: "Both measures were conducted by trained RAs blinded to the treatment groups at a time most convenient for the participant (i.e. any day of the week from 9am-5pm). The RAs took the role as interviewer, taking the participants through the measures by asking them questions to elicit their response"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Prior to all sessions, participants were asked if they wished to attend. This resulted in some refusals and differences in attendance levels amongst participants

Cooke 2010 (Continued)

		Following a missing values analysis, which indicated data to be missing at random, an ITT analysis, in which all randomized participants were included (n = 47), was undertaken. Missing values in the outcome measures were imputed with multiple imputation methods
Selective reporting (reporting bias)	High risk	Inconsistencies compared with the trial registration which was retrospectively registered in 2012. Number of registration therefore not in article. Registration points to anxiety as a secondary outcome, not a primary outcome. Moreover, quality of life and depression were not reported as secondary outcomes
Other bias	Low risk	

Guétin 2009

Methods	RCT parallel group trial; total duration 18 months, with a follow-up period of 6 months Participants resided in the nursing home between September 2007 and April 2008
Participants	Country: France. N = 30 (22 female, 8 male), 1 centre. Mean age: experimental group 85.2 (range 75 to 93 years); control group 86.9 (range 74 to 95 years) Diagnosis of dementia: mild to moderate stages of AD; Inclusion criteria <ul style="list-style-type: none"> • Mini Mental State score between 12 and 25 and Hamilton Anxiety Scale score of at least 12. • At baseline, MSSE mean score 19.8 (4.4) for the music therapy group and 20.7 (3.4) for control group. Exclusion criteria <ul style="list-style-type: none"> • People with a major depressive disorder or other major psychiatric disorders • "...patients considered highly likely not to comply with the protocol or to drop out of the study as well as those suffering from a life-threatening illness during the envisaged study period".
Interventions	1) Individual receptive music therapy method, the 'U-sequence method', which involved listening to music sequences, selected from preferred musical styles delivered through headphones, in the participant's room. 2) Reading sessions Weekly sessions during 16 weeks (total of 16 sessions).
Outcomes	1) Level of anxiety (Hamilton Scale; total score ranging from 0 to 56) 2) Level of depression (Geriatric Depression Scale; maximum score is 30) 3) Mini-Mental State Examination Score (MMSE). Outcomes assessed at day 0, week 4, week 8, week 16 and week 24 by an independent

	neuropsychologist assessor
Notes	Funding: this research could be carried out thanks to support from Centres Mémoire de Ressources et de Recherches, Les Violettes nursing home, Université René Descartes - Paris V, Institut Alzheimer, the Rotary Club and La Fondation Médéric Alzheimer

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Probably yes, but no details provided. "The study design corresponded to a randomised, controlled, comparative, single-centre study, with the results evaluated under blind conditions." "The patients were allocated to the different groups by randomisation at the end of the inclusion visit."
Allocation concealment (selection bias)	Unclear risk	No details provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Participants and caregivers not blinded, outcome assessor blinded: "The results obtained at D0, W4, W8, W16 and W24 were collected by an independent neuropsychologist assessor (D.L.), not belonging to the care team and unaware of the type of intervention."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear whether dropouts caused bias. "Two patients were prematurely withdrawn from the study in the intervention group: 1 between W8 and W16 owing to an intercurrent event not related to the study (life-threatening situation, hospitalisation), and the second died between W16 and W24. Four patients were withdrawn from the study in the control group: 1 between W4 and W8 due to dropping out, 1 between W4 and W8 owing to an intercurrent event not related to the study (hospitalisation), 1 patient died between W4 and W8, and the last patient dropped out between W16 and W24"

Guétin 2009 (Continued)

Selective reporting (reporting bias)	Unclear risk	No study protocol available.
Other bias	Low risk	Baseline imbalances do not appear to have caused bias.

Liesk 2015

Methods	RCT (parallel). No information on data collection period reported.
Participants	Country: Germany. 5 nursing homes. 26 participants with dementia were randomized. 2 had no complete baseline data, and 24 (12 in each group) were included in analyses Mean age: 83.6 years in music group (SD 5.1; range 72 to 89); and 84.3 in cognitive stimulation group (SD 5.4, range 70 to 90) Diagnosis of dementia: partly formally diagnosed with ICD 10 and partly not formally diagnosed. People with mild to moderate dementia were included People with vision or hearing impairment or life-threatening illness were excluded
Interventions	1) Active group music intervention 'Musikgeragogik' which included singing folk songs and canons and instrumental performance, 12 sessions of 90 minutes in 6 weeks 2) Cognitive stimulation intervention: adapted Cognitive training program from NEUROvitalis, 12 sessions of 90 minutes in 6 weeks
Outcomes	Cognition was measured with the Mini-Mental-Status-Test (MMST), DEmTect (and subscales), MTF/ROF (Modified Taylor Figure/Rey-Osseterrieth Figure), Mac-Q (Selbteinschätzung-Gedachtnis), Trail Making Test A, FAS-Test (Controlled-Oral-Word-Association Test), BTA (brief test of attention) Quality of life was measured with a quality of life instrument (DEMQOL) and DEMQOL-Proxy (no full name, developed by Smith and colleagues; Smith 2005). ADL was measured with the Barthel-index, IADL and ADL (Aktivitäten des taglichen Lebens) Also the NOSGER (nurses' observation scale for geriatric patients) was measured, but it is unclear for which outcome Outcomes were measured at baseline (before randomization) and 1 or 2 days after the last session
Notes	No explanation about the instruments that were used. The instruments are only mentioned in the Table with results. Unknown for which outcome the NOSGER-entschätzung is used Low fidelity in music intervention group (see 'Other bias' quote below) Bottom effect cognitive measure and more problems described (also in Discussion section of the article) which was part of the goal of the article No information about funding reported.

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Die randomisierte Zuteilung der Programme auf die Einrichtungen fand computergestützt statt". (Randomized computer-assisted allocation of the programs [at the level of individuals with dementia] was performed at the facilities)
Allocation concealment (selection bias)	Unclear risk	No description about allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear who administered the instruments and whether these persons were blinded for the intervention type
Incomplete outcome data (attrition bias) All outcomes	Low risk	Few participants missed outcome data and this was clearly reported
Selective reporting (reporting bias)	Unclear risk	No research protocol available.
Other bias	High risk	Participants in the control group frequently developed an acute illness resulting in missing sessions. Quote: "Während keiner der 12 Teilnehmer des MP akut erkrankte, fielen 5 der 12 Teilnehmer des KS zwischen zwei und vier Sitzungen aus." (While none of the 12 participants in the music intervention group became acutely ill, 5 of the 12 participants in the cognitive stimulation group missed between two and four sessions). People who attended fewer than 8 of 12 sessions were excluded from the analyses, so these people still contributed to outcome data. Therefore, adherence or fidelity may be a problem even though they already preselected people who were probably interested in music therapy

Methods	RCT (parallel). Data collection between August 2008 and January 2009.
Participants	Country: Taiwan. 3 nursing home facilities. Of 104 included people with dementia (52 per group), 100 participants (49 participants in experimental group and 51 in control group) were included in analyses (53% female in total group; 53.06% female in experimental group and 52.94% female in control group) Mean age: 82 in total group (range 65 to 97, SD 6.80), 81.46 years in experimental group and 82.15 years in control group Diagnosis of dementia: participants had been diagnosed by a physician as having dementia, using the Diagnostic and Statistical Manual of Mental Disorders, 4th edition Text Revision (DSM-IV-TR)
Interventions	1) Experimental group: mixed active-receptive music group intervention modified of the protocol developed by Clair and Berstein, 12 sessions of 30 minutes in 6 weeks; provided by a music therapist 2) Control group: continued to engage in their normal daily activities
Outcomes	Physically non-aggressive behaviours, physically aggressive behaviours, verbally non-aggressive behaviours, and verbally aggressive behaviours were measured with Chinese Version of the Cohen-Mansfield Agitation Inventory (C-CMAI). The instrument rates a subject's agitated behaviour and its frequency over the previous 2 weeks. The C-CMAI includes 29 items, each rated on a 7-point scale (1 to 7) ranging from never (1 point) to several times an hour (7 points), with a total score of 29 (minimum) to 203 (maximum) . CMAI frequency referred to the previous 2 weeks Depression was measured with the Chinese Version of the Cornell Scale for Depression in Dementia (C-CSDD) Cognition was measured with the Chinese Version of the Mini-Mental State Examination (C-MMSE) These outcomes were measured by another member of the research team in experimental and control group at baseline (1 week before start intervention), immediately after 6th and 12th sessions, and at 1 month after cessation of the intervention Cortisol levels were used as a biomarker for depression and was measured at baseline, immediately after 6th and 12th sessions
Notes	Funding: no information provided.

Risk of bias**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "subjects consisted of a total of 104 elderly persons who were randomly assigned to the experimental (n = 52) and control group (n = 52) by permuted block randomization." (p 671, Lin 2011) and "permuted block randomisation computer-

		based program” (p 672, Lin 2011) Quote: “Using permuted-block randomisation, a separate researcher randomized participants into the experimental or usual-care control group within each nursing home. We determined blocked randomization with a block size of 26 using the Research Randomizer computer program, which generates a list of random numbers to be used for allocating participants to the two groups. We generated the allocation sequence with the Research Randomizer program prior to the recruitment of participants and ...” (Chu 2014)
Allocation concealment (selection bias)	Low risk	Quote: “participants and(continued) concealed the results in sequentially numbered and sealed opaque envelopes, which we opened when participant were ready for allocation. After four randomization series, we assigned the 104 participants to the experimental or control condition in a blinded manner” (Chu 2014)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear who reported the C-CMAI However, Chu 2014 described that the C-CSDD and MSSE were reported by an other member of the research team Quote: “Another member of the research team administered the study instruments 1 week before the start of the intervention (Time 1), immediately following the 6th (Time 2) and 12th (Time 3) sessions of the intervention, and 1 month after the final intervention session (Time 4) and collected salivary cortisol samples at Times 1-3. The same person administered the instruments each time” (Chu 2014)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Few cases lost to follow up, and only 1 in experimental group was not interested
Selective reporting (reporting bias)	Unclear risk	No protocol available.
Other bias	Low risk	

Lord 1993

Methods	RCT (parallel), total duration of 6 months. No information provided about begin and end dates of the study
Participants	Country: USA. N = 60 (42 female, 18 male) residents in a privately funded home for older people. Age range : 72 to 103 years. Diagnosis of dementia: all clinically diagnosed with dementia of the Alzheimer's type (method not specified) The 60 participants were "randomly selected from approximately 200 patients clinically diagnosed as having Alzheimer disease"
Interventions	(1) Mixed active-receptive group intervention with music listening and playing along (30-minute sessions delivered 6 times per week for a period of 6 months). (2) Jigsaw puzzle activities (30-minute sessions 6 times per week for a period of 6 months) . (3) No special treatment, but involved in usual recreational activities of drawing, painting, and watching television
Outcomes	Cognition, social skills (interaction) and emotional well-being as assessed with a self-made questionnaire: general impressions (assessed before and after intervention period) + participants' disposition and social coercion (assessed with a focused 30-sec, observation on 1 subject for 3 periods during each activity session for the first 2 weeks and final 2 weeks of the study (resulting in 36 observations for each participant in the first 2 weeks and 36 observations in the last 2 weeks)
Notes	No information reported about funding. Randomization was stratified by gender.

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "The patients were non-systematically separated into three groups of equal size"
Allocation concealment (selection bias)	High risk	Quote: "To assure equal representation by gender, the random division was implemented first with the female and then with the male patients" No further information provided on the method to conceal the allocation sequence
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.

Lord 1993 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information was provided on blinding of the outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information provided.
Selective reporting (reporting bias)	Unclear risk	Not enough detail was reported about the outcome measures. No study protocol available
Other bias	High risk	We were unable to reproduce the results. No statistical tests were reported for the between-group comparisons, only for the within-group The article reports that the number of correct answers for each of the 3 groups was summed for baseline and post treatment, and then a 1-way analysis of variance conducted. No information on how the data were analysed, whether the baseline was used as a covariate. Table 1 analysis of variance, although showing significant differences between the 3 therapies, does not seem valid. For example, the degrees of freedom within groups are not correct. To interpret this table far more information is required. Even if the results in table 2 are accepted, all that can be deduced is that the treatments were different. They may be different in the level of participation in the therapies, but that does not explain whether the therapy itself brought any benefit

Narme 2012-study 1

Methods	RCT (parallel). Study 1 lasted 6 weeks. Start and end dates are not reported
Participants	Country: France. The first study enrolled 22 participants who resided on a geriatric unit, which is part of Valenciennes hospital. In study 1, 10 of 22 were female (6 of 11 in the music intervention group, and 4 of 11 in a painting group). MMSE 3 to 18 for study 1, age is not described. No diagnostic criteria for dementia are mentioned
Interventions	Study 1 1) Mixed active-receptive group music therapy, 6 × 2-hour sessions, 2 per week (over 3

Narme 2012-study 1 (Continued)

	weeks) 2) Art therapy involving painting sessions with a variety of materials, 6 × 2-hour sessions, 2 per week Both interventions were delivered by 2 psychologists.
Outcomes	Outcomes were hypothesized to be more favourable for music therapy compared with the other activity <ul style="list-style-type: none"> • Emotional state (and social behaviour) from discourse content and emotional facial expressions as assessed from first 2 minutes of filmed interviews. • Further, emotional status was assessed as mood, with the State-Trait Anxiety Inventory for Adults (STAI-A; timeframe not specified).
Notes	Funding: l'Agence nationale pour la recherche du ministère français de l'enseignement supérieur et de la recherche (ANR-09-BLAN-0310-02) et de l'Institut Universitaire de France à Séverine Samson

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No explanation how random sequence was generated.
Allocation concealment (selection bias)	Unclear risk	No information about allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Study 1: high risk of bias because outcomes were assessed by nurses who were not blinded for the interventions
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only few were lost to follow-up.
Selective reporting (reporting bias)	Unclear risk	No study protocol was available.
Other bias	Low risk	

Narme 2012-study 1a

Methods	Study 1a is indicated as "Study 2" in the article. RCT (parallel). Study 2 lasted 9 weeks. Start and end dates are not reported
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Narme 2012-study 1a (Continued)

Participants	Country: France. Study 2 enrolled 14 participants, of whom 11 were included in the analyses. Participants resided on a geriatric unit, which is part of Valenciennes hospital. Gender and age are not described. Participants had moderate to severe Alzheimer's dementia (MMSE < 12 for study 2, no diagnostic criteria mentioned)
Interventions	Study 2 1) Mixed active-receptive group music therapy, 8 × 2-hour sessions, 2 per week (over 4 weeks) 2) Cooking sessions, 8 × 2-hour sessions, 2 per week that included preparing a different recipe collectively, with roles distributed according to the participants' abilities. Participants were encouraged to taste ingredients, and verbalize remembrances Both interventions were delivered by 2 psychologists.
Outcomes	Outcomes for which stronger and more sustainable effects were hypothesized for music therapy compared with the other activity (measured 2 and 4 weeks after the last intervention) <ul style="list-style-type: none"> • Emotional state (and social behaviour) from discourse content and emotional facial expressions as assessed from first 2 minutes of filmed interviews. • Further, emotional status was assessed as mood, with the State-Trait Anxiety Inventory for Adults (STAI-A; timeframe not specified).
Notes	Funding: l'Agence nationale pour la recherche du ministère français de l'enseignement supérieur et de la recherche (ANR-09-BLAN-0310-02) et de l'Institut Universitaire de France à Séverine Samson

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No explanation how random sequence was generated.
Allocation concealment (selection bias)	Unclear risk	No information about allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcomes of study 2 were assessed by 5 independent and blinded observers
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only a few were lost to follow up.
Selective reporting (reporting bias)	Unclear risk	No study protocol was available.

Narme 2012-study 1a (Continued)

Other bias	Low risk
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Narme 2014

Methods	RCT (parallel). The study lasted 10 weeks. Start and end dates are not reported
Participants	Country: France. 48 participants living in a residential care home which is part of Reims University Hospital. At baseline, 37 were included in the analyses of which 32 were female participants (15 in the music therapy group, and 17 in a cooking group) Mean age in the music intervention group was 86.7 years (SD 6.4); in the cooking group, it was 87.5 years (SD 6, no decimal provided) Participants had Alzheimer's or mixed dementia according to DSM-IV criteria. Inclusion criterion: Mini-Mental State Examination (MMSE) 20 or lower. Mean MMSE in the music therapy group was 9.6 (SD 5.3), and in the cooking group, it was 10.8 (SD 8.4) "Only native French speakers were recruited in order to ensure familiarity with the songs selected for music sessions." Medication use was stable
Interventions	1) Mixed active-receptive group music therapy, alternating listening and playing and singing along; 8 × 1-hour sessions, twice a week (during 4 weeks) 2) Cooking sessions as another pleasant activity in a group setting, which included preparing a different recipe during 8 sessions, twice a week, collectively, with roles distributed according to the participants' abilities
Outcomes	1) Main outcomes (outcomes for which improvement was hypothesized) were as follows <ul style="list-style-type: none"> • Behaviour as assessed with the Cohen-Mansfield Agitation Inventory (CMAI; total score up to 203; timeframe not reported but reference provided) and the Neuropsychiatric Inventory (NPI; total score up to 144; timeframe not reported but reference provided). • Emotional state (and social behaviour) from discourse content and emotional facial expressions ("EFE") as assessed from first 3 minutes of filmed interviews about current feelings and personal history. Emotional state was quantified through counting of numbers of negative and positive words, and positive and negative EFE. • Further, emotional status was assessed as mood, with the State-Trait Anxiety Inventory for Adults (STAI-A; timeframe not reported, but reference provided). 2) Another outcome (for which an effect "to a lesser extent" was hypothesized) was improved cognition measured with the Severe Impairment Battery (SIB)
Notes	Also, an effect "to a lesser extent" was hypothesized as improved professional caregiver's distress measured with an adapted version of the NPI, a distress scale Funding: "Agence Nationale pour la Recherche" of the French Ministry of Research (contract n° ANR-09-BLAN-0310-02)

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement

Narme 2014 (Continued)

Random sequence generation (selection bias)	Unclear risk	There was no explanation as to how the participants were randomly assigned to each of the groups
Allocation concealment (selection bias)	Unclear risk	There was also no information about allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All observers were blind to the group to which the participant was allocated, although only one was blind to the pre- or post-test treatment phase. Further, only the first 3 minutes of interviews were analysed, which we feel decreases chances that raters can infer the group from the interviews. Regarding other outcomes, these were assessed by blinded caregivers and psychologist
Incomplete outcome data (attrition bias) All outcomes	Low risk	Probably about the same number was missing in each of the groups and health problems (n = 6) and death (n = 2) is not likely related to the intervention. Refusal (n = 3) may be more of a problem, but this was the case in only 3 of 48 randomized (although unknown in which group)
Selective reporting (reporting bias)	Unclear risk	No protocol available.
Other bias	Low risk	

Raglio 2010a

Methods	RCT (parallel). Study duration or start and end dates not reported.
Participants	Country: Italy. N = 20 residents of a nursing home, of whom 15 were female (8/10 in the experimental group and 7/10 in the control group) Mean age was 84 (SD 6) for the experimental group, and 87 (SD 6) in the control group The participants had Alzheimer's disease according to NINCDS-ADRDA criteria or vascular dementia according to NINDS-AIREN criteria. Clinical Dementia Rating (CDR) scale means were 1.9 (SD 0.9) in the music therapy group, and 2.2 (SD 0.7) in control group. Mean Mini-Mental State Examination (MMSE) scores at baseline were 17 ± 6, and 13 ± 4, respectively

	“Patients with musical competence or knowledge about music therapy were excluded”
Interventions	1) Active, individual music therapy intervention in which free musical improvisation is used to build a relationship between participant and music therapist; 30 sessions of 30 minutes, twice a week (during 15 weeks) 2) Control group with no music exposure but educational and occupational activities such as personal care, lunch, bath, cognitive stimulation reading a newspaper etc. Frequency or duration is not reported, and these activities are referred to as “standard care”
Outcomes	1) Main outcome (in line with study aims): behavioural and psychological symptoms of dementia measured with the Neuropsychiatric Inventory (NPI; no timeframe reported but reference provided), including depression subscore 2) Other outcomes were cognition, measured with the MMSE and the Alzheimer’s Disease Assessment Scale cognitive sub scale (ADAS-cog), and depression measured with the NPI Heart rate (variability) and (I)ADL were outcomes as well.
Notes	Funding source not reported.

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Software mentioned: “patients were randomised to music therapy treatment or standard care by using the randomisation program QuickCalcs”
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear who assessed the outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropout.
Selective reporting (reporting bias)	Unclear risk	No protocol of the (pilot) study available.
Other bias	Low risk	

Raglio 2010b

Methods	RCT (parallel). This study took place from March to November 2007 in 3 cycles of 12 sessions
Participants	Country: Italy. N = 60 (55 female, 5 male); residents from 5 nursing homes. Mean age (age range) experimental group: 85.4 (74 to 99). Mean age (age range) control group: 84.6 (69 to 96). Inclusion criteria <ul style="list-style-type: none"> • Diagnosis of dementia of the Alzheimer type, vascular dementia or mixed dementia (DSM-IV; Mini- Mental State Examination (MMSE; 0-30) \leq 18/30; Clinical Dementia Rating (CDR; 1-5) \geq 2/5). Mean MMSE in the experimental group was 8.0 (4.8) and 8.6 (2.5) in the control group. Mean CDR was 2.8 (0.4) in the experimental group and 2.9 (0.6) in the control group. • Presence of behavioural disturbances.
Interventions	All participants in the experimental and control groups received standard care (i.e. educational and entertainment activities such as reading a newspaper, performing physical activities, etc.) In addition, the experimental group received 3 cycles of 12 active music therapy sessions (total of 36 sessions) each, 3 times a week. Each session included a group of 3 people and lasted 30 minutes Each cycle of treatment was followed by 1 month of washout period (in the context of a parallel design) while the standard care activities continued over time. The total duration was 6 months
Outcomes	Neuropsychiatric Inventory (NPI).
Notes	No information about funding reported.

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Probably yes, but no details provided "Sixty patients from 5 nursing homes [...] were eligible and were randomly assigned to experimental or control group"
Allocation concealment (selection bias)	Unclear risk	No details provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcome assessor was blinded: "The assessments were made by NH healthcare assistants who were blinded to the aim of the study"

Raglio 2010b (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Dropouts did not appear to cause bias. “During the study 7 patients dropped out, 3 in the experimental and 4 in the control group. The drops-out were due to death (n = 5), transfer to acute hospital because of hip fracture (n = 1) and transfer to another NH (n = 1)”
Selective reporting (reporting bias)	Unclear risk	Changes in Barthel Index scores and MMSE were not presented. In addition, “The patients’ communicative and relational skills did not improve from baseline to the end of the treatment in the experimental group (data not shown).” No study protocol available
Other bias	Low risk	Baseline imbalances do not appear to have caused bias.

Ridder 2013

Methods	RCT, crossover with 2 periods of 6 weeks for the different conditions “Data were collected in three 15-week periods during fall 2010, spring 2011 and fall 2011”
Participants	Countries: Denmark and Norway. 42 people participated from 14 nursing homes (4 in Denmark and 10 in Norway); most were from Norway (76% of the participants) Most (69%) were female and mean age was 81 years (ranging from 66 to 96 years) for the 26% of participants for whom this information was available The participants had a diagnosis of dementia (“stated in medical journal,” no criteria mentioned); 40% had Alzheimer’s dementia, for 38% the type was not specified, 22% had other types of dementia such as vascular, Lewy body, frontotemporal or mixed dementia. Eligible people had moderate to severe dementia. Participants who received music therapy first had a baseline mean Mini-Mental State Examination (MMSE) score of 9.84 (SD 5.97). For the control condition first, mean MMSE was 5.25 (SD 4.83), Global Deterioration Scale (GDS) means were 5.54 (SD 0.69), and 5.80 (SD 0.62), respectively Included participants had symptoms of agitation.
Interventions	1) Individual mixed active-receptive music therapy, a minimum of 12 sessions were offered, but the participants received an average of 10 sessions (SD 2.82, range 0 to 13). Frequency: twice a week (over 6 weeks). Average duration: 33.80 minutes (SD 9.91) 2) The control group (period) received usual care which for some participants meant participating in group sing-along sessions

Outcomes	<p>Primary outcome: agitation as measured with the Cohen-Mansfield Agitation Inventory (CMAI). Timeframe adapted from 2, to 1 week (previous week)</p> <p>In addition to the 7-point frequency scale, a later version of CMAI was used with a 5-point disruptiveness scale. The frequency scale, CMAI-fr, ranged from 1 (never) to 7 (several times per hour), and the disruptiveness scale, CMAI-di, from 1 (not at all) to 5 (extremely). The CMAI-fr 1 to 7 point scale was transformed to scores 0 to 6, leading to a maximum total score of 66 and the 1 to 5 point CMAI-di scale was transformed to scores 0 to 4, leading to a maximum total score of 44.</p> <p>Secondary outcome: quality of life measured with the Alzheimer's Disease-Related Quality of Life (ADRQL). Timeframe adapted from 2, to 1 week (previous week)</p>
Notes	<p>Psychotropic medication use was measured and considered as an outcome as well</p> <p>Funding: GC Rieber Foundation in Bergen and Aalborg University</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants were randomly allocated to 1 of 2 groups (music therapy or standard care first) but it is not described how
Allocation concealment (selection bias)	Low risk	"[A] concealed sequence procedure" was used, witnessed and signed by someone who was not involved in the study
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Interviewers and proxy respondents were not blinded to the treatment allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only a few values were missing; and sensitivity analyses were performed with last observation carried forward
Selective reporting (reporting bias)	Unclear risk	"The researchers designed the study protocol in collaboration with a group of clinicians from Denmark and Norway" but there is no reference to compare with
Other bias	Unclear risk	Funding source might have an interest in the study outcomes.

Methods	RCT (parallel). Study duration, start and end dates not reported.
Participants	Country: Japan. N = 39 people residing in 4 group homes or a special dementia hospital, 32 of whom were female; mean age of the females was 81 years; of the males, slightly lower Participants had Alzheimer's dementia according to DSM-IV criteria. Inclusion criterion: Clinical Dementia Rating scale 3 (severe dementia). The mean Mini-Mental State Examination (MMSE) score at baseline was 4.6 ± 3.5 for the music therapy group, 4.7 ± 4.8 for the passive music intervention group, and 4.7 ± 3.9 for the control group that received usual care Participants had no relevant hearing disorders and no experience of playing musical instruments
Interventions	1) Interactive mixed active-receptive music therapy intervention with 10 × 30-minute sessions once a week (over 10 weeks) 2) Passive individual music intervention (not therapy) with 10 × 30-minute sessions once a week 3) Control group: "Each control group participant spent time with one caregiver in their own room as usual, without any music intervention (silent environment)"
Outcomes	Behavioural and psychological symptoms of dementia as measured with the Behavioural Pathology in Alzheimer's Disease (BEHAVE-AD) rating scale Timeframe: last 2 weeks, but any changes were by direct observation Another outcome was stress levels which were also measured with the Faces Scale but only on the short term
Notes	Funding: MEXT KAKENHI grant numbers 19592567, 22592586 (2007-2009, 2010-2013)

Risk of bias**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Stratified randomisation" at the level of gender and MMSE, but it was not described how exactly this was performed
Allocation concealment (selection bias)	Unclear risk	"Participants were randomly and blindly assigned to either control, passive, or interactive group" but there is no description of the blinding process
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias)	Low risk	"The primary experimenters were not involved in the intervention or evaluation,

Sakamoto 2013 (Continued)

All outcomes		and the evaluators did not act as music facilitators.” Further, occupational therapists and nurses who did not work in the study institution completed the BEHAVE-AD “The short- and long-term effects of intervention were evaluated by two trained occupational therapists and four trained nurses in a blinded fashion”
Incomplete outcome data (attrition bias) All outcomes	Low risk	There was no drop out.
Selective reporting (reporting bias)	Low risk	The study protocol is available and all pre-specified outcomes are reported in the article
Other bias	High risk	Outcomes (changes in behaviour) were observed by blinded professional caregivers, probably over the last 2 weeks, while baseline assessments seemed to refer to direct observation before the therapy by the therapist

Sung 2012

Methods	RCT (parallel). Total study duration or begin and end dates are not reported
Participants	Country: Taiwan. N = 60 recruited from a residential care facility, of which 55 participated Most (65.8%) were female. Mean age (SD) experimental group, 81.37 (9.14); for the control group, 79.5 (8.76) Diagnosis of dementia is not described. Inclusion criterion was “ability to engage in a simple activity and follow simple directions.” The participants had mild to moderate cognitive impairment according to the Short Portable Mental Status Questionnaire (mean 6.56, SD 2.86 for the music therapy group, and 4.43, SD 3.17 for the control group.) The participants had the “ability to engage in a simple activity and follow simple directions, ability to understand Taiwanese or Chinese, no severe hearing impairment, presence of behavioural and psychological symptoms reported by nursing staff and no obvious symptoms of acute pain or infection”
Interventions	1) Active group music intervention using percussion instruments, familiar music, and also movement. A nursing researcher and 2 trained research assistants delivered 12 sessions of 30 minutes, twice a week (over 6 weeks) 2) No intervention; usual care.

Outcomes	<p>1) Agitation assessed with a modified Cohen-Mansfield Agitation Inventory (CMAI). Timeframe unclear with observations during music therapy session (“The behaviours of the participants during each music session were assessed by the observer assistants using modified CMAI”), and also “frequency of occurrence over 2 weeks.” Unclear how the CMAI was modified</p> <p>2) Anxiety assessed with the Rating of Anxiety in Dementia scale (RAID) assessed over previous 2 weeks</p>
Notes	<p>Most people (76.2%) had not received any formal education.</p> <p>Included residents had behavioural and psychological symptoms as reported by nursing staff</p> <p>Funding: Taiwan National Science Council [NSC 96-2314-B-277-003-MY2]</p> <p>Unclear if agitation effects includes an immediate effect through observations during the music therapy sessions</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	“Participants were randomly assigned to either the experimental or the control group using simple random sampling method with a computer-generated list”
Allocation concealment (selection bias)	Unclear risk	Unclear who handled the allocation schedule.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Detection bias (blinding of outcome assessment): observer assistants completed the CMAI and RAID over the last 2 weeks. Unclear if these were other people than the trained research assistants who gave the music therapy (probably, these were people who knew the person but they were also aware of the intervention because the assessment was during the intervention)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Handling of missing data is not reported; 60 were randomized and 55 were analysed
Selective reporting (reporting bias)	Unclear risk	No published study protocol available.
Other bias	Low risk	

Svansdottir 2006

Methods	RCT (parallel). 6-weeks intervention and 4-weeks follow-up. No information reported about start and end dates of data collection
Participants	Country: Iceland. N = 38 (? female, ? male); residents in 2 nursing homes and 2 psychogeriatric wards Age range: 71 to 87 (recruited sample, N = 48). Diagnosis of dementia: all diagnosed with Alzheimers disease (ICD-10); Global Deterioration Scale (GDS) score of 5 to 7 (moderate to severe dementia)
Interventions	1) Group music therapy (three or four participants per session), mixed active (playing instruments) and receptive (listening), 3 times a week for 6 weeks (total of 18 sessions), 30 minutes per session 2) Standard care as usual.
Outcomes	Behavioural and psychological symptoms of dementia (BPSD) assessed with the Behaviour Pathology in Alzheimer's disease Rating Scale (BEHAVE-AD)
Notes	No clear baseline characteristics presented. Funded by the Research Fund for Alzheimer's Disease and Related Disorders, Landspítali University Hospital

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided.
Allocation concealment (selection bias)	Unclear risk	Quote: "...The 46 remaining patients were then randomised to a music therapy group or a control group, with 23 individuals in each group"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcome assessors were blinded. Quote: "Two nurses were trained in using the BEHAVE-AD scale and they were blinded to the therapy used. The nurses were not part of the staff of the wards".
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information provided.
Selective reporting (reporting bias)	Unclear risk	No data.

Svansdottir 2006 (Continued)

Other bias	Unclear risk	No clear baseline characteristics presented. First author (HBS) provided the music therapy. Quote: “Throughout the study the same qualified music therapist (H.B.S.) conducted the music therapy”
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Vink 2013

Methods	RCT (parallel). Exact duration of total study or start and end dates are not reported, but therapy was provided over a period of 4 months
Participants	Country: the Netherlands. N = 94 residents of 6 nursing homes of which 77 were included in the analyses 70% (n = 54) were female; mean age was 82.16 (SD 6.87) Participants had any type of dementia according to DSM-IV criteria, Cohen-Mansfield Agitation Inventory (CMAI) score of > 44
Interventions	1) Mixed active-receptive group music therapy, which involved listening to live music, interacting with the therapist and playing simple instruments. A maximum of 34 sessions of 40 minutes each were held, twice weekly, over a period of 4 months 2) General recreational activities such as handwork, playing shuffleboard, cooking, and puzzle games. Sessions lasted 40 minutes, similarly twice weekly over 4 months
Outcomes	1) Agitation assessed with the CMAI modified through dichotomising of items resulting in a total score range of 0 to 29. Presence and absence of behaviour was presumably measured by direct observation or with very short time frames (because it was assessed 1 hour before the session, 1 hour after the session, 2 hours after the session and 4 hours after the session) 2) Neuropsychiatric symptoms (behaviour overall, NPI).
Notes	Funding: ZonMW (the Netherlands Organisation for Health Research and Development), the Dutch Alzheimer Foundation (Alzheimer Nederland) and the Triodos Foundation

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	“To ensure randomised allocation, sealed envelopes were used, with at least two persons present to ensure appropriate randomisation“
Allocation concealment (selection bias)	Unclear risk	Only sealing is described; it remains unclear whether envelopes were sequentially numbered and opaque

Vink 2013 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the convener and participants.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "Some of the nurse caregivers who rated the modified CMAI scores were at occasion responsible for taking the residents to either the activity or music therapy room. Complete blinding for some of the nurse caregivers could therefore not be guaranteed."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The explanation of missing data was not clear. There were 7 missing cases in the baseline data in the general activities group, and 4 of the participants died out of 47 allocated. It is not clear if baseline data were missing because participants died before the baseline assessment
Selective reporting (reporting bias)	Unclear risk	The study protocol is not available.
Other bias	Low risk	

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Arroyo-Anlló 2013	Not clear whether it is a RCT and the outcome is self-consciousness
Ballard 2009	RCT, no music-based therapeutic intervention. A small proportion of the study sample followed individualised music as an intervention (n = 35). A non-significant improvement was found on the total CMAI score
Brotons 2000	Only 4 therapy sessions.
Bruer 2007	RCT, crossover, 8 weeks, comparison of group music therapy to video presentation on cognition (MMSE score). Participants were involved in fewer than 5 sessions
Bugos 2005	RCT, people with dementia were excluded in this study, focus on healthy older adults (effects of individualized piano instruction on executive functioning and working memory)
Clair 1996	Not clear if participants were randomized; and they participated in fewer than 5 sessions
Cohen-Mansfield 2010	Not an RCT, no control group included.

(Continued)

Davidson 2011	Not an RCT, no control group included.
Garland 2007	RCT, crossover, comparing audiotapes with simulated family presence to audiotapes with preferred music and a neutral placebo tape to reduce agitation. Fewer than 5 sessions in each group, in which participants listened to preferred music
Gerdner 2000	The analyses covered directly observed agitation, probably over the combined sessions (so inclusive of the first 4 sessions)
Groene 1993	The control group received music therapy as well.
Hanser 1994	RCT, participants did not have dementia but depression.
Hicks-Moore 2008	RCT, comparison of favourite music and hand massage, fewer than 5 sessions
Hokkanen 2008	RCT, no music therapy, the study involved dance and movement therapeutic methods
Holmes 2006	RCT, comparison of live interactive music, passive pre-recorded music or silence for 30 minutes in a single session. Fewer than 5 sessions
Janata 2012	The intervention did not meet our criteria for a therapeutic-based intervention in which contact with a therapist or facilitator is essential. The intervention created “a musical atmosphere” with music programs streamed to the rooms of individuals assigned to a music group for several hours per day
Noice 2009	RCT, no music therapy: a theatrically based intervention was given to 122 older adults who took lessons twice a week for 4 weeks
Otto 1999	RCT, participants did not have dementia.
Pomeroy 1993	RCT, music was part of physiotherapy.
Raglio 2008	Quasi-randomized study.
Riegler 1980	RCT, not clear whether participants were diagnosed with dementia
Satoh 2014	No music-based therapeutic intervention, but physical exercise combined with music
Sung 2006	No music-based therapeutic intervention, but music with movement intervention
Särkämö 2014	No music-based therapeutic intervention, but singing coaching for family caregivers and nurses, and listening to music
Thompson 2005	RCT, single test moment, music as cue to facilitate performance on a category fluency task. No therapeutic intervention
Van de Winckel 2004	RCT, no music-based therapeutic intervention, but music based exercises

(Continued)

Vanderark 1983	RCT, not clear whether participants were diagnosed with dementia
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Characteristics of studies awaiting assessment [ordered by study ID]

Arbus 2013

Methods	RCT (parallel)
Participants	35 persons with Alzheimer's disease living in "an institution for the dependent elderly" in France, with Mini-Mental State Examination (MMSE) score between 5 and 20
Interventions	Intervention group: receptive intervention using "U" sequence; the musical sequence lasts 20 minutes and is made up of several phases that progressively induce a relaxed state in the patient. The phase of maximum relaxation is followed by a stimulating phase." Control group: "Interview with an occupational activity (such as discussion of personal pictures or news) with the caregiver in charge of music therapy sessions with the same period"
Outcomes	Quality of life, agitation, and overall behavioural problems were secondary outcomes (in addition to outcomes other than the seven outcomes of interest for the Cochrane review)
Notes	ClinicalTrials.gov: The study has been completed June 2015; the study has been terminated. No study results are posted (accessed 16 April 2017). If a report on possible results should become available, eligibility should be reviewed, in particular if the intervention meets our criteria for music-based therapeutic interventions

Asmussen 1997

Methods	
Participants	
Interventions	
Outcomes	
Notes	No publication was found up to 2017

Curto Prieto 2015

Methods	Either RCT or quasi-experimental design
Participants	"Institutionalized" people with dementia (24), "in phases 5 and 6" (moderate to advanced dementia)
Interventions	Intervention group: a form of group music therapy Control group: reminiscence-recreation group

Curto Prieto 2015 (Continued)

Outcomes	Mood and cognition, perhaps also (social) behaviour
Notes	Conference abstract. When a full report becomes available, the design needs careful evaluation (a "quasi-experimental study" with a "pre-post test design with a control group" wherein groups were "randomly assigned to a music therapy group or a reminiscence group")

Guetin 2011

Methods	RCT (parallel)
Participants	Thirty people with mild to moderate Alzheimer's disease
Interventions	Intervention group: "individual, receptive music therapy. The musical style was chosen by the patient. The validated 'U' technique was employed" Control group: reading sessions
Outcomes	Anxiety (primary) and depression (secondary)
Notes	Conference abstract. When methods and results (means and SDs) are being reported in more detail, eligibility should be reviewed, in particular if the intervention meets our criteria for music-based therapeutic interventions

Hong 2011

Methods	RCT (parallel)
Participants	Nursing home residents (30) in the Republic of Korea
Interventions	1) Songwriting; music therapy programme employing song-writing activities. 3 stages: a) preparing songwriting, b) songwriting; c) reinforcing songwriting. A therapist administered the active individual intervention. Session of 60 minutes were given for 16 weeks (once per week). 2) Control group: free time was given to the control group instead
Outcomes	Cognition (assessed with the MMSE-K)
Notes	Presentation of results (Figure 2a,b) is incorrect. The intervention and control group are reversed. There is little variability in MMSE-K scores with either no change or change in one direction only

Hsiung 2013

Methods	Pilot RCT (cross-over)
Participants	Ten persons with Alzheimer's disease, Mini-Mental State Examination (MMSE) score range 6-28
Interventions	Intervention condition: music therapy by a trained music therapist; no detail on type of intervention is reported Control condition: not reported

Hsiung 2013 (Continued)

Outcomes	Overall behavioural problems was a primary outcome; secondary outcomes included quality of life, depression and cognition (additionally there were outcomes other than the seven outcomes of interest for the Cochrane review)
Notes	Conference abstract. If a full report becomes available, the type of intervention should be reviewed against our criteria for music-based therapeutic interventions

Hsiung 2015

Methods	RCT (cross-over)
Participants	Persons (27) with moderate Alzheimer's disease
Interventions	Intervention condition: "music therapy by an accredited music therapist following a standardized structured protocol (Clair & Bernstein 1990)." Control condition: "waiting" (probably usual care)
Outcomes	Overall behavioural problems was a primary outcome; secondary outcomes included quality of life, depression, agitation and cognition (additionally there were outcomes other than the seven outcomes of interest for the Cochrane review)
Notes	Conference abstract. If a full report becomes available, the exact type of intervention should be reviewed against our criteria for music-based therapeutic interventions

Hsu 2015

Methods	Mixed quantitative-qualitative feasibility study which included a cluster-randomized trial (randomized at nursing home unit level)
Participants	Nursing home residents with dementia (17) but also 10 staff from two nursing homes in the UK (see Notes)
Interventions	Intervention group: individual active music therapy by music therapist and training of care staff Control group: "standard care"
Outcomes	Well-being and overall behavioural problems (in addition to outcomes other than the seven outcomes of interest for the Cochrane review)
Notes	Needs a detailed evaluation against the inclusion criteria for possible inclusion in the next update of the review. In particular, we will need to decide on comparability with individually randomized trials and whether the intervention meets our criteria for music-based therapeutic interventions. Further, music therapists delivered the intervention but the intervention also included video clips of the sessions which were used to train care staff to improve caregiving. We therefore need to decide if the training of care staff provided in parallel to music therapy is sufficiently comparable with music therapy provided as a single intervention in other studies

Kwak 2013

Methods	“Case control study” but “The participants (...) were assigned randomly to a music therapy group and a control group.”
Participants	Persons with moderate Alzheimer’s disease residing in one of four participating long-term care centres were randomized (probably 120 were randomized and 82 participated)
Interventions	Intervention group: music therapy with active elements provided by music therapists Control group: “standard care”
Outcomes	Behavioural problems overall measured with the BEHAVE-AD; however, aims and results are about agitation disruptiveness (additionally there were outcomes other than the seven outcomes of interest for the Cochrane review)
Notes	Conference abstract. If a full report becomes available, the design needs careful consideration as to whether it qualifies as an RCT

Lyu 2014

Methods	RCT (parallel)
Participants	Persons with mild dementia (93, Clinical Dementia Rating (CDR) score of 0.5 or 1.0) staying in a geriatric hospital in China
Interventions	Intervention group: group music therapy that included singing lyrics provided by a music therapist Two other groups: “lyrics control group” where the same lyrics were read without music, supervised by the music therapist and “blank control group” which represented usual care
Outcomes	Probably overall behavioural problems, and cognition (memory and language; additionally there were outcomes other than the seven outcomes of interest for the Cochrane review)
Notes	We could not timely evaluate the article in Chinese in detail. The study may meet our inclusion criteria but we do not know yet if the analyses were limited to assessments after at least 5 therapy sessions

Raglio 2015

Methods	RCT (parallel)
Participants	Persons with moderate to severe dementia (120) residing in nine institutions (geriatric department, geriatric center, or nursing home) in Italy
Interventions	Intervention group: active music therapy delivered by a music therapist Two other groups: individualized listening which did “not involve any kind of direct relationship with a therapist,” and usual care
Outcomes	Quality of life, overall behavioural problems, depression (and observed social behaviour in participants of the active music therapy group only)
Notes	This study meets our inclusion criteria and will be included in the future update of the Cochrane review

Rouch 2017

Methods	RCT (parallel)
Participants	Persons with mild Alzheimer's disease or mild cognitive impairment (59; but "Patient with a different etiology of cognitive disorder that of Alzheimer's disease" are excluded), in France
Interventions	Intervention group: singing sessions Control group: painting sessions
Outcomes	Primary outcome: "Physical and moral pain" or "pain intensity" rated at "a simplified visual scale;" secondary outcome: other pain intensity scale (Brief Pain Inventory)
Notes	Study completed in June 2016. When study results become available, needs an assessment as to whether people with no dementia have been included, whether we accept pain as an outcome for the review, and whether analyses included outcomes assessed after fewer than 5 sessions

Thornley 2016

Methods	Pilot RCT (parallel)
Participants	Persons with dementia (16) and moderate to severe cognitive impairment admitted to an inpatient psychiatric unit within a large academic hospital in Canada
Interventions	Intervention group: individual, active music therapy provided by an accredited music therapist Control group: active engagement and attention intervention provided by a social worker
Outcomes	Agitation, overall behavioural problems, and some individual item scores of the outcome instruments were reported as well
Notes	"A number of the patients enrolled in this study were hospitalised for two to three weeks" only, and some may therefore not have had the minimum of 5 therapy sessions. Moreover, end-of-treatment scores were reported for only part of the outcomes

Yu-Cheng Pei n.d a

Methods	RCT (parallel)
Participants	Estimated 30 people with "a mild dementia diagnosis" (or "mild to moderate") dementia in Taiwan
Interventions	Intervention group: mixed active-receptive music therapy Control group: "no intervention" (usual care)
Outcomes	Quality of life, depression, and agitation were secondary outcomes; additionally there were outcomes other than the seven outcomes of interest for the Cochrane review
Notes	Estimated trial completion date: September 2014. However, ClinicalTrial.gov reports (status 17 April 2017): "Study has passed its completion date and status has not been verified in more than two years"

Yu-Cheng Pei n.d. b

Methods	RCT (parallel)
Participants	Estimated 30 people with mild to moderate dementia in Taiwan
Interventions	Intervention group: “Musical Dual Task Training protocol is structured with musical content and patients are required to do musical tasks including singing and playing instruments contingent on visual or auditory cues while walking” delivered by a “qualified music therapist” Control group: “walking and talking:” “read a newspaper article prior to a walk and have a conversation with the music therapist based on the content of the news while walking.”
Outcomes	Cognition (primary outcome); agitation (secondary outcome and outcomes other than the seven outcomes of interest for the Cochrane review)
Notes	Estimated primary completion date October 2013. However, ClinicalTrial.gov reports (status 17 April 2017): “Study has passed its completion date and status has not been verified in more than two years”

권서령 2013

Methods	“Pretest-posttest control group design” and “people were randomly assigned to the experimental and control groups”
Participants	Persons with dementia (34) attending a day care center in South Korea
Interventions	Intervention group: music therapy Control group: usual care or other not reported in the abstract
Outcomes	Cognition
Notes	We could not retrieve the full text. First, we would like to evaluate if this was an RCT

김현정 2013

Methods	RCT (parallel)
Participants	Persons with mild dementia (20) “who reside in G Welfare Foundation in D city” (Korea)
Interventions	Intervention group: group music therapy Control group: usual care or other not reported in the abstract
Outcomes	Quality of life and depression
Notes	We could not retrieve the full text. Type of analyses not clear from the abstract. We would need to review if analyses were limited to effects after at least 5 sessions

신보영, 광은영. 2015

Methods	Unclear (“17 of them were assigned to experimental group and the other 17 people were assigned to control group. The musical activities with visual supportive strategies were carried out both experimental group and control group for 10 sessions”)
Participants	Persons with dementia (34) attending a day care center in South Korea
Interventions	Intervention group: musical activities with visual supportive strategies Control group: unclear
Outcomes	Cognition
Notes	Unclear if this was an RCT and how effectiveness could be derived if the control group received the same intervention (“According to this results, it was shown that the musical activities with visual supportive strategies were effective intervention for the cognitive rehabilitation of elderly people with dementia”). It is also unclear if this is music therapy or a combination of more types of therapy. We still need to retrieve the full text to evaluate eligibility

채경숙 2015

Methods	Not reported in the abstract
Participants	Nursing home residents (59) with dementia
Interventions	Intervention group: music therapy Two other groups: “laughing therapy” and “control group”
Outcomes	Depression (in addition to outcomes other than the seven outcomes of interest for the Cochrane review)
Notes	We still need to evaluate the article in Korean, in particular whether this is an RCT, and if so, what the music therapy intervention entails and whether the analyses were limited to results after at least 5 therapy sessions

Characteristics of ongoing studies [ordered by study ID]

Tartaglia 2014

Trial name or title	Personalized Music Therapy and Agitation in Dementia
Methods	Unclear (Intervention Model: Single Group Assignment?).
Participants	Inclusion Criteria: <ul style="list-style-type: none"> ● Diagnosis of dementia with possible or probable cause of Alzheimer’s disease, vascular disease, mixed dementia. ● Moderate stage of dementia, a score of < 20 on MMSE. ● Age 60 to 90 inclusive. ● Preserved hearing (hearing aids are permissible). ● Pittsburgh agitation scale score of ≥ 3 on at least 3 occasions over a period of 5 days. Exclusion Criteria:

Tartaglia 2014 (Continued)

	<ul style="list-style-type: none">• Auditory deficits requiring correction beyond hearing aids.• No substitute decision maker available to indicate music preference and patient unable to answer for themselves.• Recent acute event e.g. MI, fractures, or major infection (not UTI).• Patients receiving standing orders of medication for personal care.
Interventions	Listening to personalized and either non-personalized or no music during daily hygiene care (grooming)
Outcomes	Changes in agitation.
Starting date	May 2014.
Contact information	Dr C Tartaglia, University Health Network, Toronto, Canada.
Notes	Registered trial. Estimated completion in June 2017 (final data collection date for primary outcome measure)

DATA AND ANALYSES

Comparison 1. Music therapy versus usual care or versus other activities: end of treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Emotional well-being and quality of life	6	181	Std. Mean Difference (IV, Random, 95% CI)	0.32 [-0.08, 0.71]
1.1 music vs usual care	1	41	Std. Mean Difference (IV, Random, 95% CI)	0.25 [-0.37, 0.86]
1.2 music vs other activities	5	140	Std. Mean Difference (IV, Random, 95% CI)	0.37 [-0.14, 0.89]
2 Negative affect or mood disturbances: depression	9	376	Std. Mean Difference (IV, Random, 95% CI)	-0.28 [-0.48, -0.07]
2.1 music vs usual care	5	247	Std. Mean Difference (IV, Random, 95% CI)	-0.28 [-0.59, 0.02]
2.2 music vs other activities	4	129	Std. Mean Difference (IV, Random, 95% CI)	-0.21 [-0.56, 0.14]
3 Negative affect or mood disturbances: anxiety	11	365	Std. Mean Difference (IV, Random, 95% CI)	-0.50 [-0.84, -0.16]
3.1 music vs usual care	5	184	Std. Mean Difference (IV, Random, 95% CI)	-0.19 [-0.48, 0.10]
3.2 music vs other activities	7	181	Std. Mean Difference (IV, Random, 95% CI)	-0.81 [-1.38, -0.24]
4 Problematic behaviour: agitation or aggression	12	515	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.29, 0.14]
4.1 music vs usual care	9	405	Std. Mean Difference (IV, Random, 95% CI)	-0.11 [-0.36, 0.13]
4.2 music vs other activities	4	110	Std. Mean Difference (IV, Random, 95% CI)	0.04 [-0.46, 0.54]
5 Problematic behaviour overall	6	209	Std. Mean Difference (IV, Random, 95% CI)	-0.20 [-0.56, 0.17]
5.1 music vs usual care	4	132	Std. Mean Difference (IV, Random, 95% CI)	-0.39 [-0.84, 0.05]
5.2 music vs other activities	3	77	Std. Mean Difference (IV, Random, 95% CI)	0.16 [-0.31, 0.63]
6 Social behaviour: music vs other activities	3	70	Std. Mean Difference (IV, Random, 95% CI)	0.54 [0.06, 1.02]
7 Cognition	6	257	Std. Mean Difference (IV, Random, 95% CI)	0.21 [-0.04, 0.45]
7.1 music vs usual care	3	170	Std. Mean Difference (IV, Random, 95% CI)	0.25 [-0.06, 0.55]
7.2 music vs other activities	3	87	Std. Mean Difference (IV, Random, 95% CI)	0.13 [-0.29, 0.56]

Comparison 2. Music therapy versus usual care or versus other activities: long-term effects

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Emotional well-being and quality of life	2	48	Std. Mean Difference (IV, Random, 95% CI)	0.47 [-0.10, 1.05]
1.1 music vs usual care	0	0	Std. Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
1.2 music vs other activities	2	48	Std. Mean Difference (IV, Random, 95% CI)	0.47 [-0.10, 1.05]
2 Negative affect or mood disturbances: depression	5	234	Std. Mean Difference (IV, Random, 95% CI)	-0.01 [-0.27, 0.24]
2.1 music vs usual care	3	173	Std. Mean Difference (IV, Random, 95% CI)	-0.01 [-0.31, 0.29]
2.2 music vs other activities	2	61	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.52, 0.48]
3 Negative affect or mood disturbances: anxiety	5	160	Std. Mean Difference (IV, Random, 95% CI)	-0.23 [-0.86, 0.41]

3.1 music vs usual care	2	88	Std. Mean Difference (IV, Random, 95% CI)	0.09 [-0.52, 0.70]
3.2 music vs other activities	3	72	Std. Mean Difference (IV, Random, 95% CI)	-0.54 [-1.78, 0.70]
4 Problematic behaviour: agitation or aggression	4	225	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.36, 0.33]
4.1 music vs usual care	3	188	Std. Mean Difference (IV, Random, 95% CI)	-0.16 [-0.45, 0.13]
4.2 music vs other activities	1	37	Std. Mean Difference (IV, Random, 95% CI)	0.50 [-0.15, 1.16]
5 Problematic behaviour overall	3	125	Std. Mean Difference (IV, Random, 95% CI)	0.05 [-0.30, 0.41]
5.1 music vs usual care	2	88	Std. Mean Difference (IV, Random, 95% CI)	0.03 [-0.53, 0.60]
5.2 music vs other activities	1	37	Std. Mean Difference (IV, Random, 95% CI)	0.16 [-0.49, 0.80]
6 Social behaviour	2	48	Std. Mean Difference (IV, Random, 95% CI)	0.53 [-0.53, 1.60]
6.1 music vs usual care	0	0	Std. Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
6.2 music vs other activities	2	48	Std. Mean Difference (IV, Random, 95% CI)	0.53 [-0.53, 1.60]
7 Cognition	1		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
7.1 music vs usual care	1		Std. Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
7.2 music vs other activities	0		Std. Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]

WHAT'S NEW

Last assessed as up-to-date: 12 April 2016.

Date	Event	Description
11 April 2017	New citation required and conclusions have changed	New studies included. Conclusions changed. New author.
12 April 2016	New search has been performed	Updated search and potentially eligible studies included under studies awaiting classification

HISTORY

Protocol first published: Issue 1, 2002

Review first published: Issue 3, 2004

Date	Event	Description
14 April 2010	New search has been performed	An update search was performed for this review on 14 April 2010. New studies were retrieved for possible inclusion or exclusion within the review. Two new studies have been included in this update
26 November 2008	New search has been performed	A new update search was performed on 20 March 2008. New studies were retrieved for possible inclusion or exclusion in the review. Three new studies have been included in this update, and 15 new studies have been excluded. Risk of Bias tables have been completed for all included studies

(Continued)

23 January 2006	New search has been performed	January 2006: The update searches of 5 December 2005 yielded 4 new trials which were not suitable for inclusion. The results and conclusions of this review remain unchanged
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CONTRIBUTIONS OF AUTHORS

- Jenny van der Steen, Mirjam van Soest, Annemiek Vink, Rob Scholten and Hans (Johannes) van der Wouden contributed to all aspects of the review.
- Manon Bruinsma assisted with data-extraction and commenting on drafts.

Consumer editor: Joost de Haas.

Contact editor: Leon Flicker.

The review has been peer reviewed anonymously.

DECLARATIONS OF INTEREST

Annemiek Vink and Manon Bruinsma are involved in music therapy research and dementia. We included a study of Annemiek Vink, which was, however, evaluated by two other authors. The lead author and the co-authors, who are Cochrane experts, made the final decisions about analyses, presentation and interpretation of the data and they do not have a conflict of interest related to finding effects of music therapy.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We adapted terminology for relevant outcomes. The protocol formulated the objective in terms of problems only while emotions and (social) behaviour is broader than that (protocol: “To assess the effects of music therapy in the treatment of behavioural, social, cognitive and emotional problems in older people with dementia.”). In the review, we now consistently refer to: (1) emotional well-being including quality of life; mood disturbance or negative affect, which includes (2) depression and (3) anxiety; behavioural problems which includes (4) agitation or aggression, and (5) behaviour overall; (6) social behaviour; and (7) cognition. We also searched for any (other) possible adverse effects. We adapted the objectives in the abstract to cover both the original aims and how we broadened it to include more positive outcomes as well. Also, the protocol referred to effects in “older people” but there has not been an exclusion criterion based on age. We therefore dropped reference to “older” people.

Publications were assessed by two, and not three reviewers independently. Data were extracted by two reviewers and if needed, in consultation with other reviewers as per protocol. We included RCTs only because unlike at the time the protocol was written, we expected more RCTs to be available. We accepted a physician’s diagnosis of dementia if no data on formal criteria such as DSM-IV, DSM-5 or comparable instruments were available for reason of relevance to clinical practice and known underreporting. We did not analyse by length of treatment (months, length in three groups as in the protocol), but we analysed end-of-treatment data accepting variable durations and number of sessions as long as the outcomes were assessed after a minimum of five sessions. Rather, we aimed at assessing long-term effects, analysing data about assessments at a minimum of four weeks after the end of treatment (with at least five studies available).

We used more stringent criteria with respect to: (1) assessing whether an article reported about a music intervention with an individual therapeutic intent, including - but not limited to - interventions provided by qualified music therapists, (2) analyses referring to outcome assessments after a minimum of five sessions or analyses that include earlier assessments if there is evidence of no different effect over time, (3) control group, and (4) risk of bias.

Regarding (4): if no research protocol was available, risk of reporting bias was set to either unclear or, for specific reasons, as high (also if rated as low in previous versions of the review). With regard to (1), we defined music-based therapeutic interventions or music therapy as: therapy provided by a qualified music therapist, or an intervention meeting at least two of the following criteria: (a) therapeutic objective which may include communication, relationships, learning, mobilisation, expression, mobilisation and other relevant therapeutic objectives; (b) music matches individual preferences; (c) active participation of the people with dementia using music instruments; (d) participants had a clinical indication for the interventions or were referred to the intervention by a clinician. We also required music to be a main element of the intervention (e.g. not moving with use of music). We therefore focused on therapeutic aspects and elements that are more complex and required special skills while also targeted to the individual compared with, for example, playing recorded music for a group activity. We did not require a certified music therapist to provide the intervention, because the profession, exact qualification, training and experience was often unclear, and training programmes may vary between countries. Moreover, the importance of requiring a qualification is unclear in relation to the importance of having experience with the specific needs of people with dementia (for example, a trained music therapist with no experience in comparison with a musician with years of experience in providing therapy to people with dementia). Further (point 3), we required control groups to not receive any music-based therapeutic intervention (even if fewer sessions than the active intervention group). We re-assessed previously included studies by the new criteria and when in doubt, we consulted the lead author of the earlier versions.

Finally, we conducted a series of post hoc sensitivity analyses to explore possible effects of using more stringent criteria with respect to a requirement of a music therapist to deliver the intervention, and funding by parties with a possible interest in effectiveness of music therapy.

NOTES

2016: this new citation version was written with three additional authors. Inclusion of studies until the 2011 update were reconsidered according to the new and more stringent criteria. A further update is planned for the end of 2017 to incorporate studies awaiting classification.

May 2004: this is a completely new review of music-based interventions for people with dementia written by a new and different team of reviewers (Vink and colleagues) from the previous, now permanently withdrawn review of music therapy (Koger and colleagues).

INDEX TERMS

Medical Subject Headings (MeSH)

*Music Therapy; Dementia [rehabilitation; *therapy]; Mental Disorders [therapy]; Randomized Controlled Trials as Topic

MeSH check words

Aged; Humans