

Individual music therapy for agitation in dementia: an exploratory randomized controlled trial

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Objectives: Agitation in nursing home residents with dementia leads to increase in psychotropic medication, decrease in quality of life, and to patient distress and caregiver burden. Music therapy has previously been found effective in treatment of agitation in dementia care but studies have been methodologically insufficient. The aim of this study was to examine the effect of individual music therapy on agitation in persons with moderate/severe dementia living in nursing homes, and to explore its effect on psychotropic medication and quality of life.

Method: In a crossover trial, 42 participants with dementia were randomized to a sequence of six weeks of individual music therapy and six weeks of standard care. Outcome measures included agitation, quality of life and medication.

Results: Agitation disruptiveness increased during standard care and decreased during music therapy. The difference at -6.77 (95% CI (confidence interval): $-12.71, -0.83$) was significant ($p = 0.027$), with a medium effect size (0.50). The prescription of psychotropic medication increased significantly more often during standard care than during music therapy ($p = 0.02$).

Conclusion: This study shows that six weeks of music therapy reduces agitation disruptiveness and prevents medication increases in people with dementia. The positive trends in relation to agitation frequency and quality of life call for further research with a larger sample.

Keywords: agitation disruptiveness; psychotropic medication; quality of life; person-centered care; caregiver burnout

Introduction

Worldwide 36 million people are estimated to live with dementia, and this number is rapidly increasing (Alzheimer's Disease International, 2012). The majority of residents in nursing homes have dementia, with percentages ranging from 61.5% (Huber et al., 2012) to 80% (Alzheimer's Society, 2013). Of those with dementia who live in nursing homes and care facilities, 48%–82% show symptoms of agitation (Zuidema, Koopmans, & Verhey, 2007). Agitation in later stages of dementia is described as the most significant symptom causing patient distress and caregiver burden (Brown, Howard, Candy, & Sampson, 2012; Cohen-Mansfield & Libin, 2004). In a cognitive-behavioral tradition, agitation is defined as 'inappropriate verbal, vocal or motor activity that is not judged by an outside observer to result directly from the need or confusion of the individual' (Cohen-Mansfield, 1991, p. 2). The term is used to describe a cluster of symptoms and is not a diagnostic term. Symptoms of agitation include abuse or aggressive behavior toward self or other, appropriate behavior performed with inappropriate frequency, or behaviors that are inappropriate according to social standards (Cohen-Mansfield, Marx, & Rosenthal, 1989).

A rather contrasting definition of agitation is presented in the person-centered approach where agitation is seen as closely related to needs. In this understanding, agitation is not described as an aspect of a disease process, but is understood as reactions to unmet psychosocial needs, and

therefore, as attempts to communicate these needs (Kitwood, 1997) and as ways to cope (Woods, 2001). The prevalence of agitation is predicted by the psychosocial environment in the nursing home (Zuidema et al., 2007) or in the entire workplace culture (Stein-Parbury et al., 2012), and in order to provide a culture of care where the focus is not on the symptoms of agitation but on the cause, 'the interpersonal interactions of care staff must be such that persons with dementia are understood, especially in relation to their feelings' (Stein-Parbury et al., 2012, p. 408).

Often agitation is treated with psychotropic (psychoactive) medication, specifically antipsychotic drugs (Ballard, Waite, & Birks, 2012; Rolland et al., 2012). Antipsychotics are prescribed twice as often to nursing home residents with dementia than to those without dementia (Rolland et al., 2012) and show beneficial effects on aggression after short-term treatment, "but limited benefits in longer term therapy" (Ballard, Corbett, Chitramohan, & Aarsland, 2009, p. 532). There are increasing concerns in relation to serious adverse effects such as decreased quality of life, accelerated cognitive decline, and even stroke and death by the use of antipsychotics (Ballard et al., 2009; Brown et al., 2012). In several countries, constrained use of antipsychotics is recommended, and 'an urgent need to explore the potential benefits and risks offered by alternative classes of drugs, including opioids' are sought (Brown et al., 2012, p. 3). Critical voices claim that antipsychotics, and psychotropic medication in

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general, are sometimes prescribed to persons with dementia with 'the only aim to dampen the activity without considering the cause' (Melin & Olsen, 2006, p. 115). High levels of agitation are described to be significantly associated with low levels of quality of life (Samus et al., 2005; Wetzels, Zuidema, de Jonghe, Verhey, & Koopmans, 2010), and the use of psychotropic medication is associated with reduced quality of life (Ballard et al., 2001). With regard to the severe side effects of psychotropic drugs, specifically antipsychotics, psychological interventions and staff-training programs should be applied in the first place (Ballard et al., 2009; Guthrie, Clark, & McCowan, 2010; Seitz et al., 2012).

People with dementia have impairments that influence perception, attention, memory and social engagement, and interactions that involve music could be ways of compensating for, or bypassing, those impairments and thus lead to decreases in agitation. Music increases engagement and engagement duration, specifically in 'one-on-one socializing' (Cohen-Mansfield et al., 2011, p. 863). The 'Sound Training for Attention and Memory', a manualized music-based protocol, shows no significant change in agitation (Ceccato et al., 2012), but music played in daily care situations reduces agitation (Casby & Holm, 1994; Gerdner & Swanson, 1993; Remington, 2002; Sung & Chang, 2005; Tabloski, McKinnon-Howe, & Remington, 1995; Thomas, Heitman, & Alexander, 1997; Zare, Ebrahimi, & Birashk, 2010). In addition to reduced agitation, music played in care situations leads to a higher degree of compliance in a person with dementia (Clark, Lipe, & Bilbrey, 1998; Thomas et al., 1997). This effect is increased if caregivers, instead of playing pre-recorded music, actively sing in the care situations (Brown, Götell, & Ekman, 2001; Hammar, Emami, Götell, & Engström, 2011). This approach seems to lead to reduced aggression, less resistance and a higher degree of reciprocity between the caregiver and a person with dementia. It is documented that the person with dementia even joins in singing in these situations (Brown et al., 2001). Four review articles on non-pharmacological interventions have highlighted the positive effect of music and music therapy on agitation, but also identified methodological limitations and insufficient rigorous evidence (Hulme, Wright, Crocker, Oluboyede, & House, 2010; Kverno, Black, Nolan, & Rabins, 2009; Spiro, 2010; Wall & Duffy, 2010).

Music therapy treatment demands a qualified music therapist and can be defined as the professional use of music experiences and the relationships that develop through them with the aim to promote health (Bruscia, 1998). A recent literature review carried out as a narrative synthesis analysis (McDermott, Crellin, Ridder, & Orrell, in press) in a number of quantitative and mixed-method studies shows that music therapy on persons with dementia reduces short-term agitation (Brotons & Marti, 2003; Brotons & Pickett-Cooper, 1996; Ledger & Baker, 2007; Ridder, 2003; Ridder, Wigram, & Ottesen, 2009; Svansdottir & Snaedal, 2006). Even though there are positive results from several studies, there is a lack of knowledge about the long-term effects (Särkämö et al., 2012), and the methodological quality of 10 studies included in a

Cochrane review was too poor to draw conclusions (Vink, Bruinsma, & Scholten, 2011).

The literature shows promising results in the use of music therapy for reducing agitation; however, with methodological challenges in relation to sample size, outcome measures, population characteristics and standardization of the music therapy treatment, further research is called for. Randomization procedures and blinding of treatment are requested in high-quality studies, but these are complicated in relation to psychosocial interventions carried out in cultures of care with close interaction between participant, caregiver and therapist. In this study we suggest a pragmatic randomized controlled trial (RCT) that is primarily designed to determine the effects of the music therapy intervention under the usual conditions in which it is applied in the clinical reality (Rolvsjord, Gold, & Stige, 2005; Thorpe et al., 2009). The study examines individual music therapy on agitation frequency and agitation disruptiveness in persons with moderate to severe dementia, living in nursing homes, and additionally explores its effects on psychotropic medication and quality of life.

Methods

Trial design

The study was designed as a pragmatic, two-armed, crossover, exploratory, randomized controlled study. Participants were randomly allocated to either music therapy or standard care, with the conditions switched at the mid-point data collection. Randomization took place after data collection at baseline in Week 0. The primary outcomes, agitation (Cohen-Mansfield Agitation Inventory (CMAI)) and quality of life (Alzheimer's Disease-Related Quality of Life (ADRQL)), were scored at baseline, in Week 7 and Week 14. Weeks 1–6 and 8–13 contained of either music therapy or standard care with no individual music therapy. The use of psychotropic medication was registered together with baseline data and demographic data in Week 0, and registered again in Week 14. Several documented research case studies served as preparation for the study protocol (Ridder, 2003; Ridder & Aldridge, 2005; Ridder et al., 2009). The researchers designed the study protocol in collaboration with a group of clinicians from Denmark and Norway. In this way data collection was adjusted to daily clinical practice and it was possible to collect data from several different nursing homes as part of the daily routines. The project was approved by The Human Research Ethics Board at Faculty of Humanities, Aalborg University; the Danish Research data register; and the Regional Committee for Medical and Health Research Ethics, Western Norway (REK Vest).

Participants

Participant recruitment commenced in July/August 2010, and data were collected in three 15-week periods during fall 2010, spring 2011 and fall 2011 at 14 different nursing homes; 4 in Denmark and 10 in Norway. Eligibility

criteria for participants were: (1) nursing home resident with moderate to severe dementia, (2) diagnosis of dementia stated in medical journal, (3) referral to music therapy in accordance with the established referral procedures, (4) symptoms of agitation and (5) completion of consent procedures. Demographic data were obtained from contact staff with information on health and symptoms, and included diagnosis, somatic symptoms, health status, aids, activities of daily living, language function, participation in activities and social networks, length of stay at nursing home, reason for referral to music therapy, and finally, scores on cognitive functioning, mini-mental state examination (MMSE) (Folstein, Folstein, & McHugh, 1975) and global deterioration staging (GDS) (Reisberg, Ferris, de Leon, & Crook, 1982). In order to inform the music therapist about the participant, information on life-story was obtained from journal or from relatives. For participants with an expected low MMSE score due to severe dementia, the assessment was done by contact staff and as such carried out as a proxy rating. Each nursing home registered pairs of participants who fulfilled eligibility criteria, and who were ready to start with music therapy in Week 1, or in Week 8 if randomized to standard care first. The music therapy treatment for this study was offered as a part of daily clinical practice and consequently it had to be possible for the music therapists to schedule the biweekly individual sessions within their daily working routines. For all music therapists this required some change, for example, if they normally only worked with groups, if individual music therapy was usually offered weekly, and/or for longer periods. Even though 14 nursing homes agreed to participate in the study, and no participants declined, only a relatively small number of participants were enrolled, because data collection was time consuming and demanded careful planning.

Randomization was possible through the pairing of participants, where one participant would start while the other received standard care as usual. Each participant was registered with a code, to be used by the researchers for further data administration. The randomization was carried out immediately after baseline data collection, using a concealed sequence procedure. This was done by the researchers (HMOR in Denmark and LGQ in Norway), and witnessed and signed by a third party (a university secretary or a colleague not involved in the study). The researchers gave the result of the random allocation directly to the music therapists without involving staff. With this simple sampling strategy, conditions regarding the nursing home setting and music therapy were matched, whereas conditions regarding, for example, diagnosis, gender and severity of dementia, were not controlled for. During proxy interviews, researchers and staff were instructed to regard only the past week, and not to address any participation in music therapy the weeks previous to this.

The nursing home setting

The nursing homes signed the collaboration agreement and contributed to the study by allowing time (three times,

30 minutes per participant) for proxy interviews. The interviews were carried out via phone, with a researcher, who was blind to the treatment, asking the proxy respondent to rate the outcome measures (CMAI and ADRQL). All nursing homes already offered music therapy as part of their facility treatment; some with the music therapists employed as an external consultant, some with the music therapists as an integrated part of the interdisciplinary team. Many of the music therapists offered milieu therapeutic services as well. The three proxy interviews for data collection took place on the same day for each participant pair. The time points for data collection and the music therapy sessions were scheduled so they did not collide with planned breaks and holidays.

Music therapy interventions and control

Individual music therapy was given biweekly over a period of six weeks, altogether 12 sessions, by clinicians with approved university training in music therapy, dedicated to follow the ethical codes for the music therapy profession in their country, which includes professional supervision of the clinical work. Entry level for the music therapy profession in Denmark and Norway is a five-year university education leading to a Master's degree. The music therapists were members of their national networks of music therapy in dementia care where teaching and discussion of best practice and theoretical foundation were an important part of the meetings. Participants assigned to the control group received standard care in the nursing home. For some participants this meant that they continued in, for example, group sing-along sessions as usual. Treatment fidelity for the individual music therapy was assessed as follows: after each session the music therapist completed a one-page form including a decision tree that, on a four-point scale,¹ mapped the use of the following five types of activity: vocal or instrumental *improvising* (either 'free' improvisation or based on songs/melodies), *singing* (to well-known songs, unknown songs or pre-recorded music), *dancing/moving* (to live or pre-recorded music), *listening* (to live or pre-recorded music), and *other activities* (talking, going for a walk, etc.). The overall aim of the music therapy was to facilitate initiative, engagement, self-expression and mutual understanding (Ridder, 2011), and hereby fulfill psychosocial needs through *positive person work* and by enhancing *personhood* (Kitwood, 1997). This person-centered² and relational approach was familiar to the clinicians through seminars, workshops and supervision, and was integrated with various therapeutic techniques. The clinicians read and discussed texts that offered a theoretical understanding of music therapy in dementia care, and they were familiar with the theoretical concepts and understandings of communicative musicality, acoustic cuing techniques, musical regulatory elements, and social engagement (Ridder, 2003, 2007, 2011). The clinicians were instructed to be aware of a least three different ways of applying music in therapy with people with dementia: (a) catching attention and creating a safe setting, (b) regulating arousal level to a point where self-regulation is possible and (c) engaging in social

communication in order to fulfill psychosocial needs (Ridder, 2011). Even if this study was measuring agitation, music therapy was not focused on decreasing agitation. Music therapy and agitation were assumed to be linked in a way that a decrease in agitation can be explained as a measurable 'side effect' of having psychosocial needs met.

Outcome measures

Agitation was assessed as the primary outcome measure in Weeks 0, 7 and 14 with use of the CMAI nursing home form³ (Cohen-Mansfield et al., 1989). The CMAI assesses 29 agitated behaviors, rated by a proxy caregiver, e.g., pacing, hiding or hoarding things, hitting (including self), repetitive sentences or questions. The 29 items are divided in four subgroups: physical aggressive, physical non-aggressive, verbal aggressive, non-verbal non-aggressive. In addition to the 7-point *frequency* scale, we used a later version of CMAI where a 5-point *disruptiveness* scale is added (Cohen-Mansfield, 1991). The frequency scale, CMAI-fr, ranges 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 1–7 point scale was transformed to scores 0–6, leading to a maximum total score of 66, and the 1–5 point CMAI-di scale was transformed to scores 0–4, leading to a maximum total score of 44.

High inter-rater reliabilities with agreement rates ranging from 85%–90%, and kappa coefficients that averaged 0.78 with significance levels from 0.01 to 0.001, are reported (Cohen-Mansfield & Libin, 2004, p. 882). A decrease in CMAI score is interpreted as a decrease in agitation. CMAI is rated over a period of two weeks, however, 'informant ratings can achieve moderate agreement with direct observation when valid instruments and informants are used' (Cohen-Mansfield & Libin, 2004, p. 881).

The prescription of medication was registered at baseline (Week 0) and reviewed in Week 14, with all changes in medication reported on the corresponding date. This included a list of prescriptions of psychoactive medication: antidepressants, antipsychotics and hypnotics/anxiolytics as well as antidementia drugs. For each participant an increase/decrease during standard care/music therapy or no change was registered.

Quality of life was assessed using the ADRQL (Rabins, Kasper, Kleinman, & Black, 1999). ADRQL is an interviewer-administered instrument consisting of 48 items divided in the five following subcategories: social interaction (SI), awareness of self (AS), feelings and mood (FM), enjoyment of activities (EA) and response to surroundings (RS). The respondent, who is a proxy caregiver to the person with dementia answers with 'agree' or 'disagree' to the items, e.g., 'shows interest in events from past', 'dozes off or does nothing', 'talks about wanting to leave'. For the calculation of ADRQL scores, a weighted-factor analysis was applied. Maximum score for each sub-category was 100, with 500 as maximum for the total ADRQL score. Correlation of each scale to the total ADRQL is described to range from 0.53 (RS) to 0.82 (SI), and good internal consistency with Cronbach's alpha at 0.86 (Black, Rabins,

& Kasper, 2009). The research assistants watched the training DVD on ADRQL, read the accompanying material, the interview guide, and familiarized themselves with each item of the questionnaires as well as the overall procedure. Both versions of CMAI and ADRQL were adapted for this study in that the proxy respondent was asked to consider only the previous week, and not the *two* previous weeks, which is the standard in both tools.

Statistical analysis

All continuous variables were screened graphically to confirm normality of distributions. We compared baseline characteristics (continuous variables) between the groups to examine the success of randomization, using *t*-tests for independent samples. To analyze effects of music therapy compared to standard care in this crossover design, we used two approaches: first, we conducted an overall descriptive analysis where we analyzed means and standard deviations at each time point and showed the development in each group graphically. Second, we analyzed change in each condition (music therapy or standard care), i.e., the change from the beginning to the end of the respective condition, regardless of the order in which they were received. This enabled us to compare the conditions directly (within participants) in an inferential statistical analysis using paired *t*-tests. The difference in change scores between conditions was transformed into effect sizes (i.e., divided by the baseline SD) with 95% confidence intervals (CIs) to facilitate clinical interpretation. Both approaches have their unique advantages and drawbacks. The advantage of the first strategy is that it shows changes over time and allows for (descriptive) examination of sequence/order effects and carry-over effects. (Testing for carryover is not recommended for statistical and interpretational reasons, see Senn, 2002, p. 12.) It does, however, not make use of the unique advantages of crossover designs, which is to compare the effects of alternative conditions within participants and thus to eliminate random variation. The second strategy does that and is, therefore, more powerful than the first. For that reason, we used only the second strategy for inferential purposes.

We analyzed all available participants on an intention-to-treat (ITT) basis (i.e., all participants randomized were analyzed, regardless of whether they received the whole intended therapy) because this is a conservative strategy that allows inferences to a population *referred to* music therapy, rather than a population that has *received* it. Missing data points were excluded in the main analysis. In addition we conducted a sensitivity analysis using 'last observation carried forward' (LOCF), where missing data points are replaced by the last available value. A LOCF analysis is overly conservative but allows examination of the potential influence of missing values. We also added a per-protocol analysis where participants who received less than eight sessions were excluded. However, the ITT analysis was regarded as the main analysis, as is recommended in current guidelines for clinical trials (Moher et al., 2010).

Effects of music therapy on medication were analyzed as dichotomous variables (increase versus no increase). We used McNemar's χ^2 test to determine whether increases in medication occurred more often during music therapy or during standard care. Like for the continuous variables, sensitivity analyses were performed as LOCF (i.e., assuming no change in medication where information was missing). An additional sensitivity analysis was performed assuming the negative outcome (i.e., an increase in medication) where the information was missing.

Results

Participant flow

During the data collection period 45 participants were assessed for eligibility and signed consent (in most cases

consent was signed by relatives). Before baseline data collection three participants withdrew: one participant was hospitalized and dropped out before randomization, making it possible to recruit a new participant for the paired randomization procedure. After the baseline data collection 42 participants were randomized to either standard care first ($n = 21$) or music therapy first ($n = 21$). See flow diagram, Figure 1, for details.

Baseline characteristics

The majority of the participants were female (69%) and from Norway (76%). Age range was 66–96 years with 81 years as the mean age. Age data were incomplete with only information on age from 26% of the participants as this was not clearly asked for in the health status data. An independent sample *t*-test was applied to test

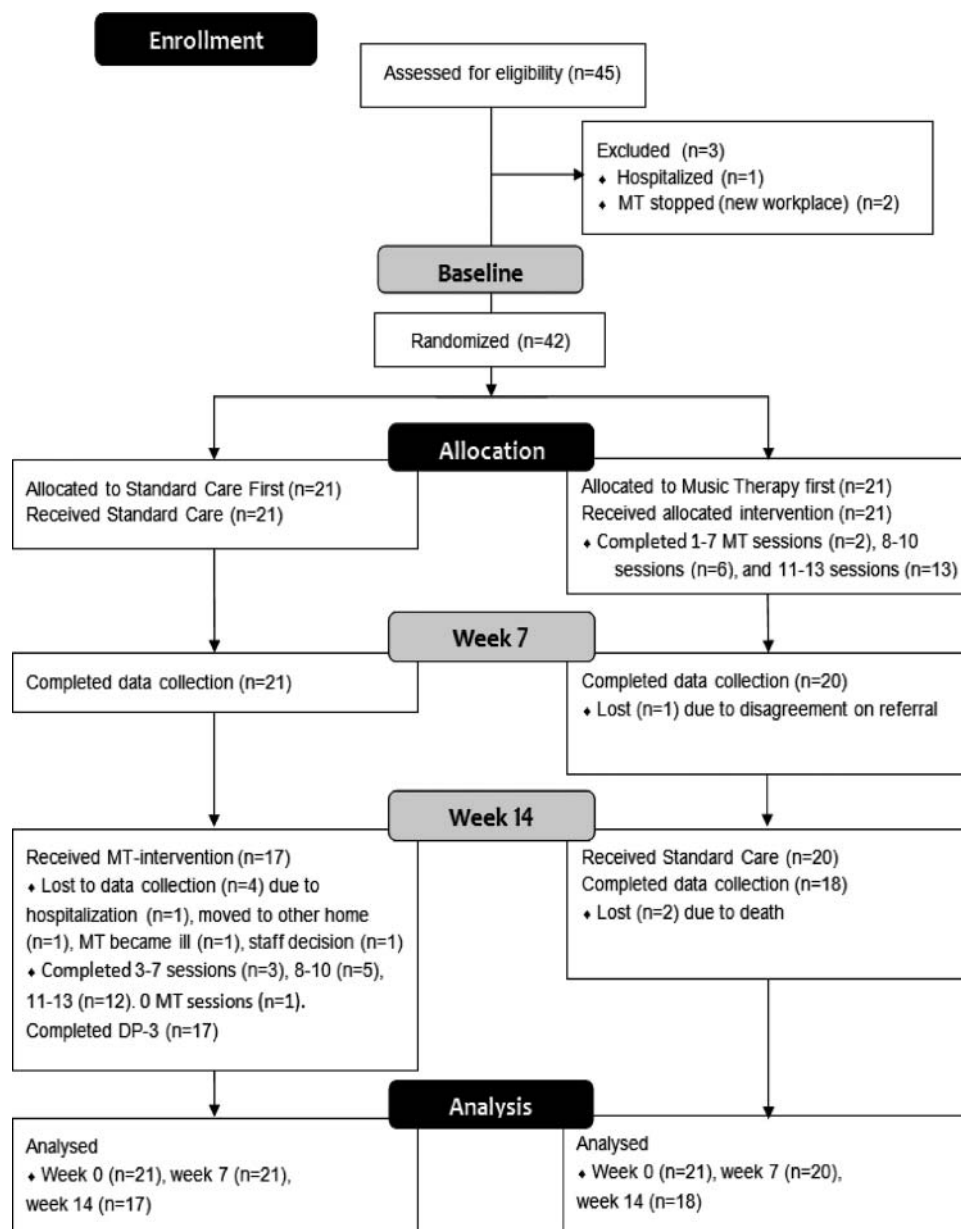


Figure 1. Participant flow (CONSORT).

Table 1. Baseline characteristics ($N = 42$) and comparison between groups.

Features at baseline Characteristic, mean (s.d.)	Standard care first ($n = 21$)		Music therapy first ($n = 21$)		p^a
	n		n		
Mini-mental state examination	20	5.25 (4.83)	19	9.84 (5.97)	.012*
Global deterioration scale	20	5.80 (.62)	19	5.54 (.69)	.079
Staff proxy level	21	2.52 (1.12)	21	2.71 (1.19)	.597
Agitation, frequency (CMAI-fr)	21	30.98 (16.64)	21	30.21 (12.72)	.868
Agitation disruptiveness (CMAI-di)	21	16.95 (13.62)	21	15.71 (8.15)	.723
Quality of life (ADRQL)	21	314.09 (85.46)	21	334.14 (57.36)	.377
Age	5	80.20 (8.672)	6	82.17 (8.841)	.720
Medication, %	n		n		
Any psychotropic medication	15	71%	15	71%	
Antipsychotics	7	33%	8	38%	
Antidementia medication	9	43%	8	38%	

Note: ^a p : Mean difference t -test * $p < 0.05$.

for equality of means between the two groups (see Table 1). There were no significant differences between groups in relation to age or outcome measures (CMAI and ADRQL); however, there was a significant difference in relation to MMSE, the group allocated to standard care first showing a significant lower mean score in cognitive functioning. It is relevant to notice that this difference is not reflected in the score on the global deterioration scale or in relation to agitation and quality of life, and we therefore conclude that the groups at baseline were equal at a fairly acceptable level and could be used for further analysis.

Further details on the demographic data showed that the majority of the participants had lived in their respective nursing homes for several years, with 2 years and 4 months as the mean time. Only 10% of the participants had lived at the nursing home for less than 6 months. Considering the proxy staff members who scored the primary outcome measures, 24% of these had only known the participant for less than half a year, whereas only 29% had known the participant for more than two years. The data collection was done by one proxy rater in 81% of the cases, but in eight of the cases (19%) a different staff member served as proxy rater at the second or third data-collection point. The majority of the participants were diagnosed with dementia of Alzheimer's type (40%) or dementia without any further specification (38%). The rest (22%) were diagnosed with more atypical types of dementia (vascular or mixed dementia, alcohol-induced dementia, Lewy body dementia or frontotemporal dementia) and were all but one randomly allocated to music therapy first.

Characteristics of music therapy

All participants were offered a minimum of 12 music-therapy sessions, and 40 participants received on average 10 sessions ($SD = 2.82$, range 0–13) (see flow chart, Figure 1). In total, 414 music therapy sessions were conducted. The sessions lasted on average 33.80 minutes ($SD = 9.91$) with 77% of the sessions taking place in the

participants' own living room. In the sessions, the participant and/or music therapist were 'singing' (26% of the time) and doing 'other activities', e.g., going for a walk or talking (26% of the time). The participants would listen to the therapist making music or listen to music, together with the therapist (24% of the time), and they would, on average, be dancing/moving to music improvising for the remainder of time (16% and 7%, respectively). None of the music therapists were registered as having little experience in working as music therapists or as newly educated. However, 11 (29%) had only little experience working in dementia care, but were experienced from working with other client groups. The majority (45%) were experienced music therapists in dementia care, having worked 1–5 years in the field, and 26% were highly experienced music therapists having worked for more than 5 years in the field.

Case example

Each music therapist completed a report of the music-therapy course where they gave information about their own qualifications, the participant's needs and problems, the therapy process, their reflections on clinical method, evaluation, and further comments. In order to provide some qualitative description of the characteristics of the music therapy offered, we will add a case description of Mrs M. who is 85 years old and diagnosed with vascular dementia (GDS: 6; MMSE: 10). The description is based on a short excerpt of the clinical notes from the Danish music therapist Lise Høy Laursen. The notes are shortened, slightly revised and anonymized.

Mrs M. moves about using her walker. Once she played the piano, but is no longer able to do this. Carers have remarked that she shows symptoms of paranoia and aggression, and that she has psychotic episodes. Sometimes she hits carers or peer residents, and she is gradually becoming more depressed and isolated. As a result she is referred to music therapy.

In the first session we go to her room and I play some of the songs her daughter has suggested, one among these

being *Amazing Grace*. She is reluctant, seems not to know what to do, though she soon realizes that I do not demand anything of her. She starts listening to the music, and now and then she joins in singing. In the next sessions she starts telling about her day and about those things she does not understand. The narratives are difficult to follow, but there is no doubt that they are negative and about not trusting others. I listen, and respond by showing my understanding; I do this with my music instead of using words.

In the following sessions she clearly becomes more confident, and she smiles and waves at me when she sees me. She often comments the songs in a positive manner and now, also shows initiative to play on the instruments that I bring (guitar and drum). We play children's songs and improvise. After she has played music she laughs and seems proud.

When the 6 weeks of music therapy are close to ending, her carers tell me that she is less aggressive, she seems happier and smiles more often. They notice that the music calms her down and ask for a CD with our music, so that they can use it when I stop with the sessions. They continue to use the CD and tell me that when Mrs M. is agitated, she calms down when she listens to our recorded songs.

Effects of music therapy on agitation and quality of life

The primary outcomes in relation to agitation and quality of life are reported in Table 2 and illustrated graphically in Figure 2. Table 3 reports the analysis of change during music therapy and standard care. During standard care the frequency of agitation (CMAI-fr) slightly increased (0.46) whereas it decreased during music therapy (−2.96), so that the difference between change in music therapy and standard care was −3.41. This corresponded to a small effect size (−0.21). The difference was not statistically significant. The analysis on agitation disruptiveness, CMAI-di, showed an increase in agitation disruptiveness during standard care (3.26) and a decrease during music therapy (−3.51). This difference reached significance ($p = 0.027$). The difference of −6.77 between conditions corresponded to a medium effect size (0.50). The analysis of quality of life (ADRQL) showed a decrease during standard care (−5.88), but an increase during music therapy (10.42). This difference was not significant ($p = 0.439$). Sensitivity analyses using LOCF confirmed the results of the main analysis: the difference in perceived agitation disruptiveness remained significant ($p = 0.033$). The same was true for the per-protocol analysis excluding those who received less than eight music therapy sessions: effect sizes remained similar and agitation disruptiveness remained significant ($p = 0.020$).

These descriptive analyses (Table 2, Figure 2) also provide two interesting insights into patterns of change. First, improvements during music therapy may have been greater in those who received music therapy later (e.g., agitation disruptiveness was reduced by about 8 points from 20.81 to 12.59; Table 2) than in those who received it first (a much smaller reduction from 15.71 to 15.65; Table 2; see also Figure 2). This might be explained by

Table 2. Group means at baseline, 7 and 14 weeks.

Outcome	Baseline				7 weeks				14 weeks			
	SC first		MT first		SC first		MT first		SC first		MT first	
	n	M (SD)	n	M (SD)	n	M (SD)	n	M (SD)	n	M (SD)	n	M (SD)
Agitation frequency (CMAI-fr)	21	30.98 (16.64)	21	30.21 (12.66)	21	32.12 (13.98)	20	29.05 (15.98)	17	26.09 (13.54)	18	28 (18.15)
Agitation disruptiveness (CMAI-di)	21	16.95 (13.62)	21	15.71 (8.15)	21	20.81 (14.32)	20	15.65 (11.8)	17	12.59 (8.17)	18	17.22 (10.7)
Quality of life (ADRQL)	21	314.09 (85.46)	21	334.14 (57.36)	21	315.66 (76.46)	20	333.26 (62.57)	17	330.09 (71.42)	18	328.96 (80.57)

Note: SC – standard care; MT – music therapy.

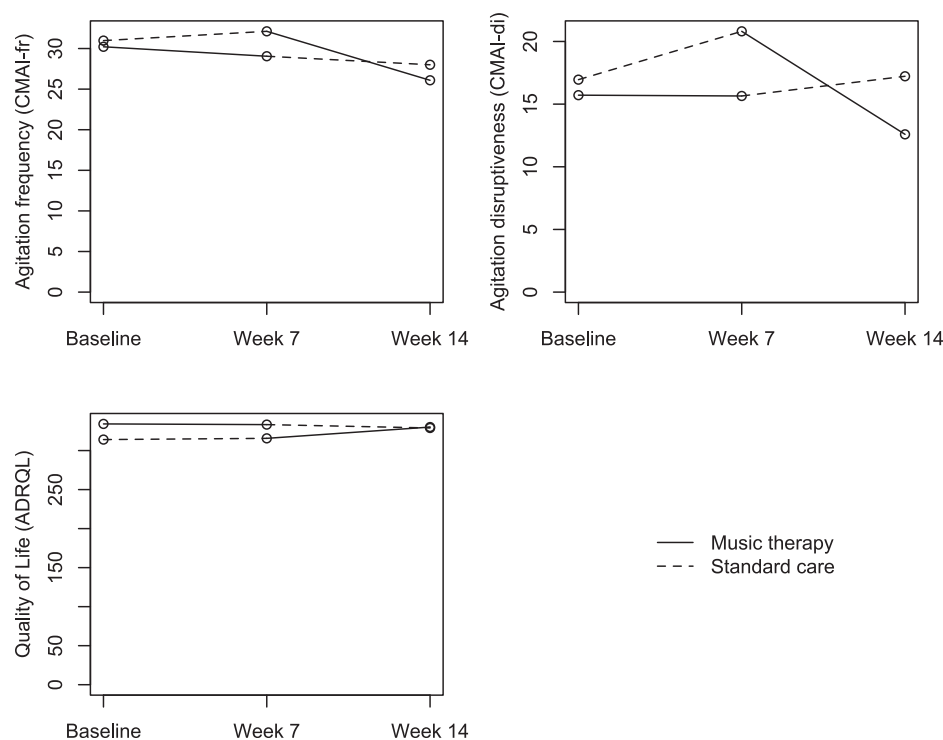


Figure 2. Mean scores for Agitation frequency (CMAI-fr), Agitation Disruptiveness (CMAI-di) and Quality of Life (ADRQL) during music therapy or standard care.

the process of establishing the therapy and the trial. Second, the patterns of change during standard care did not seem to depend strongly on the sequence in which the standard care was received. Little change during standard care was seen in agitation frequency and quality of life, and a tendency of deterioration in agitation disruptiveness, regardless of the period in which standard care was received. This suggested that any carry-over effects were also small.

Effects of music therapy on medication

Participants in this study were referred to music therapy mainly due to agitation and 71% were prescribed psychotropic medication. Of those who were prescribed psychotropic medication 13 were only prescribed one psychotropic drug, and 18 were prescribed a mixture of 2–4 different kinds (e.g., Citalopram, Risperidone, Tolvon, Quetiapine and Oxazepam). Antipsychotics were prescribed to 36% of the participants. Medication was

registered at baseline and again in Week 14. In this period there was no change in psychotropic medication for 48% of participants. For seven participants (17%) an increase in psychotropic drugs was registered during standard care (a period of nine weeks). No increases were registered during music therapy (a period of six weeks). For seven participants (17%) information on medication was incomplete. Out of these a reduction in medication was registered for three participants, but with no information on the dates for reduction wherefore it could not be stated if this occurred during standard care or music therapy. For two participants (5% of the total group) a reduction in psychotropic medication was registered during music therapy. Antidementia drugs (Donepezil, Memantine or Rivastigmine) were prescribed to 17 participants (40%), and were increased during standard care for two participants and decreased during music therapy for one. In two of these incidences it was followed by changes in psychotropic medication as well.

Increases in psychotropic medication occurred significantly more often during standard care than during music

Table 3. Changes in music therapy versus standard care.

Outcome	Change during music therapy	Change during standard care	Difference (95% CI)	Effect size <i>d</i> (95% CI)	<i>p</i> -value
Agitation frequency (CMAI-fr)	-2.96	0.46	-3.41 (-11.18, 4.36)	-0.21 (-0.67, 0.26)	0.378
Agitation disruptiveness (CMAI-di)	-3.51	3.26	-6.77 (-12.71, -0.83)	-0.50 (-0.93, -0.06)	0.027*
Quality of life (ADRQL)	10.42	-5.88	16.3 (-26.02, 58.62)	0.19 (-0.30, 0.69)	0.439

Note: * $p < 0.05$. *p*-values are from paired *t*-tests. Effect sizes were calculated by dividing the difference from this table by the standard deviation at baseline from Table 2.

therapy (McNemar's $\chi^2 = 5.14$, $df = 1$, $p = 0.02$). The same result was obtained in the sensitivity analyses assuming either no change or negative outcome for missing data. It also remained significant in the per-protocol analysis excluding participants who received fewer than eight sessions ($p = 0.02$). Other types of medication were changed too rarely to reach statistical significance. No adverse events were observed during the study.

Discussion

Findings

This study shows that six weeks of music therapy significantly reduced average agitation disruptiveness scores in persons with dementia, compared to standard care. Moreover, during music therapy the prescriptions of psychotropic medication were not increased, whereas they were increased for seven participants during the standard care period. Agitation behaviors are experienced as disruptive and disturbing to caregivers and peer residents and can lead to caregiver burnout and increasing agitation for peer residents. Breaking this circle by reducing agitation disruptiveness is important in the field of dementia care that faces great challenges. With a small effect size a decrease in the *frequency* of agitated behaviors was seen, however, non-significant.

Limitations

It was a limitation of the study that interviewers and proxy respondents were not blinded to the treatment allocation, and in order to achieve confidence in the ratings, respondents and interviewers were instructed to only consider the previous week where treatment was equal for both groups. In a future study the procedures for single blinding are possible to strengthen. Double blinding would demand e.g. a comparison of music therapy treatment versus a placebo condition. Using physiological outcome measures could avoid observer bias, but might lead to interpretational problems (Gold, Fachner, & Erkkilä, 2012).

Collecting data by proxy interviews ensured a high response rate and few missing data. In contrast to this there were data missing in the collection of demographic as well as diagnostic and medical data. A substantial part of the data (17%) in relation to psychotropic medication were either missing at the final data point, or specifications of dates of prescription or seponation were absent. Data on e.g. MMSE may have been imprecise as there was no correlation between MMSE and GDS scores, as normally expected according to Reisberg et al. (2011, p. 163). In a larger sample such internal contradictions and differences would have a chance to be reduced. In order to avoid problems with missing demographic data as well as incongruous information, these data could in a future study be collected by an interviewer who is trained to conduct the MMSE and GDS and who can point out and register the relevant information (type of medication as well as dates for changes) from the medical charts.

The sample size for this study was small with only 42 participants and the study as such had limited test power; nevertheless significant results were found. A larger sample is needed for clarifying the effect of agitation frequency and quality of life, the difference between standard care pre/post music therapy, and also for allowing subgroup analyses to understand more about how music therapy works.

Recommendations for research

An advantage of the crossover trial was that it allowed for a fairly small sample size, and that all participants were offered music therapy. It was possible to carry out the data collection in a reasonably short period and in this way the effect of the expected general neuro-degeneration on the outcome measures was reduced. This study measured changes a whole week after the course of music therapy ended, and did not look at the same-day effects of music therapy, although people with dementia are easily affected by changes in daily life. In future studies same-day measures on the effect of music therapy would be relevant to include, as well as longitudinal perspectives on changes in quality of life and medication.

A significant *increase* in psychotropic medication was registered during standard care, and although the statistical analysis addressed increase versus no change, medication was actually *reduced* for two of the participants during music therapy. The prescription of medication is a 'slow' reacting indicator of change and therefore medication needs to be observed during follow-up periods. For elderly people with dementia there are many adverse effects in the daily use of psychotropic drugs. This study suggests that music therapy might have potentials to reduce the prescription of psychotropic drugs. Future research is needed to estimate mean reductions in medication and investigate whether psychotropic drugs would be more effective or could be given in lower doses when given in combination with music therapy. A large parallel trial should be conducted to confirm the positive results found in this study as well as to examine further the outcomes that were non-significant here. Correlational as well as qualitative studies are called for in order to understand and explain how or under what conditions music therapy works best and to improve the applicability to community settings.

Recommendations for clinical practice

Individual music therapy treatment was not well established in daily clinical practice in the majority of the nursing homes participating in the study. Results suggested that the effect of music therapy may have been greater in Weeks 8–13 than in Weeks 1–6: improvement in disruptiveness scores during music therapy was about 8 points in those who received music therapy later, compared to much smaller improvement in those who received it first (Table 2, Figure 2). This could be

explained by several conditions; e.g., for the music therapist and the staff, the individual treatment became more established, with more effective procedures for collaboration and exchange between staff and music therapist in the second period. The music therapy in the first period could have functioned as a try-out in relation to routines, information sharing with staff, and more experience with methods and techniques (Gold, Erkkilä, & Crawford, 2012).

With the intention to treat analysis we included data even if no or only few music therapy sessions took place. With a larger sample size in future studies it would be relevant to define the characteristics of those participants who benefitted the most from music therapy. This would make it possible to investigate if a certain history with music or acquired skills influences the effect, and if the level of dementia, music preferences, interests across life, or gender and age differences would be predictors of effect. Additionally it is relevant for the clinical field to provide guidelines for best practice, such as dosage issues (number of sessions, session length, intensity of sessions) and recommendation for specific music therapy approaches and techniques. In this study singing played an important role in the therapy but it was not clear whether this was for all participants or for certain subgroups, such as those who suffered from severe dementia.

Although this study investigated individual music therapy, it is most commonly practiced in group, community and care settings. In future studies it would be relevant to also document the effect of music therapy as a systemic and integrated approach that is explicitly based on interdisciplinary collaboration (Stige & Aarø, 2012). Individual music therapy is not successful unless therapist, staff and relatives are aware of their roles in bringing the positive results from the music therapy process outside the individual relation, and bring change in daily life as well. Qualitative and quantitative studies of how music therapists can complement individual therapies with advice-giving and support of staff using music in daily life activities are also warranted.

Conclusion

Agitation in persons with dementia is worldwide considered a serious problem that leads to increased use of psychotropic medication as well as caregiver burnout. In this study we investigated individual music therapy for persons with dementia – an intervention that previous research and clinical experience suggest can be highly relevant for this population. The study protocol allowed for a person-centered approach where the music therapist carried out the intervention adjusted to the needs of the participant. We found that agitation disruptiveness decreased and we therefore recommend music therapy as a valid treatment of agitation and as a possibility to reduce psychotropic medication, as well as to prevent caregiver burnout. The positive trends in relation to agitation frequency and quality of life call for further research with a larger sample.

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Notes

1. Points on the scale: (1) some of the time, (2) half of the time, (3) most of the time, (4) all the time.
2. Person-centered care is well-known in Danish and Norwegian dementia care. A special issue of the *Clinical Gerontologist* (Savundranayagam, 2012) on person-centered care provides an overview of the approach and comprehensive information.
3. CMAI is translated to Norwegian by Harald A. Nygaard and to Danish by Kirsten Abelskov.
4. Norgesminde Plejehjem, Hellerup; Plejecentret Lindegården, Gl. Kolding; Plejecenter Lundehaven, Skovlunde; Plejehjemmet Salem, Gentofte.
5. Aukraheimen, Aukra; Bergen Røde Kors Sykehjem, Bergen; Bjørgene Omsorgs- og Utviklingssenter, Haugesund; Furuset Sykehjem, Oslo; Førde Helsetun, Førde; Lambertseter Alders- og Sykehjem, Oslo; Lilleborg Sykehjem, Oslo; Løvåsen Sykehjem, Bergen; Nygård Sykehjem, Vestfold; Søbstad Sykehjem, Oslo.
6. Anette Moltubakk, Bente Laurbjerg Knudsen, Berit Bøysen, Frode Aass Kristiansen, Kaja Enge, Kathrine Dahle, Kristi Stedje, Lise Høy Laursen, Lærke Formann, Marianne Lie Eide, Olaug Sandve, Silje Dæhli, Simona Fraas Johnsen, Solgunn Knardal, and Susanne Brødsgaard.

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