Journal of Alzheimer's Disease. 2016. 52(1):303–315

Comparing the effects of multisensory stimulation and individualized music sessions on elderly people with severe dementia: a randomized controlled trial

Alba Sánchez, Ana Maseda, M. Pilar Marante-Moar, Carmen de Labra, Laura Lorenzo-López and José Carlos Millán-Calenti

Abstract. The objective of this study was to compare the effects of a multisensory stimulation environment (MSSE) and individualized music sessions on agitation, emotional and cognitive status, and dementia severity in a sample of institutionalized patients with severe dementia. Twenty-two participants with a diagnosis of severe or very severe dementia were randomly assigned to two groups: MSSE and individualized music sessions. Both groups participated in two 30-min weekly sessions over 16 weeks. Outcomes were agitation (Cohen-Mansfield Agitation Inventory, CMAI), mood (Cornell Scale for Depression in Dementia, CSDD), anxiety (Rating Anxiety in Dementia, RAID), cognitive function (Severe Mini-Mental State Examination, SMMSE), and the overall severity of dementia (Bedford Alzheimer Nursing Severity Scale, BANS-S). They were assessed at baseline (pre-trial), in the middle (mid-trial), at the end of the intervention (post-trial), and 8 weeks after the intervention (follow-up). Patients in the MSSE group showed significant improvement in their RAID and BANS-S scores compared with the individualized music group post- versus pre-trial. With regard to agitation, there was improvement during the intervention in both the MSSE and individualized music groups in the CMAI total score after 16 weeks of intervention, with no significant differences between the groups. The results suggest that MSSE could have better effects on anxiety symptoms and dementia severity in comparison with individualized music sessions in elderly patients with severe dementia.

Keywords: Dementia, elderly, individualized music, multisensory environments, multisensory stimulation, randomized controlled trial, Snoezelen

INTRODUCTION

Severe dementia presents a substantial societal burden because of its prevalence and costs and the suffering incurred by patients and their caregivers [1]. Patients with severe dementia present a wide range of symptoms that include marked cognitive, language, and functional impairment, and they show specific behavioral problems [2, 3]. Over the past few decades, the interest in this field has increased considerably, and care for people at this stage of the disease has become a priority for the near future [4, 5].

To date, dementia pharmacological treatment trials have shown no consistent, robust benefits [6] or adverse side effects [7], which has led to an increased interest in the use of non-pharmacological approaches. Given that verbal communication with patients with severe dementia is markedly impaired, they have difficulties in benefiting from classical non-pharmacological cognitive interventions [8]. In these stages of dementia, the Guideline on Sup- porting People with Dementia and Their Carers in Health and Social Care developed by the National Institute for Health and Clinical Excellence and the Social Care Institute for Excellence (NICE-SCIE) [9] recommends sensory stimulation as the primary form of psychological intervention to reduce neuropsychiatric symptoms. Patients with severe dementia experience the world at a sensory level, with reduced ability to integrate sensory experiences and understand contexts. Therefore, they need appropriate environmental structure and stimulation, which can be achieved by sensory interventions [10, 11].

One of the more popular sensory interventions suitable for people with severe dementia is the multisensory stimulation environment (MSSE) [12]. The MSSE typically occurs in a pleasant and relaxing room known as a "Snoezelen" room. The concept originated in the Netherlands in the 1970s and was initially introduced for leisure activities involving adults with learning difficulties. Since the beginning of the 1990s, Snoezelen has been used as a non-pharmacological therapy in people with dementia [13]. Snoezelen rooms stimulate the primary senses, allowing the person to freely explore a variety of objects and materials, such as fiber- optic cables, water columns, aroma therapy, different music/sounds, tactile objects, and screen projectors, among others [14, 15].

To date, the underlying mechanism of action of MSSEs can be explained by two theoretical constructs, one neurobiological and another behavioral. From the neurobiological perspective, institutionalized patients in the final stages of dementia may receive too little stimulation or, on the contrary, excessive or inappropriate stimulation, such as doors slamming or patients screaming [16]. The Kovach Model of Imbalance in Sensoristasis (MIS) suggests that these imbalances in the pacing of sensory- stimulation and sensory-calming activities affect behavior and instrumental and social functioning [17]. In this context, MSSE constitutes an adequate intervention because it offers a range of activities that can be either sensory stimulating or calming regarding their effects, matching the therapeutic needs of the patient [18, 19].

On the other hand, the behavioral position, proposed by the Functional Analytic Multisensory Environmental Therapy (FAMSET) [20, 21], suggest that the MSSE provides the elder with noncontingent sensory reinforcement which evokes states of reward and the relaxation response.

Previous studies [16, 22–24] that included people with mild to severe cognitive impairment (Global Deterioration Scale, GDS 4–7) [25] found that MSSE in a Snoezelen room was as effective as individualized activity sessions in improving neuropsychiatric symptoms. However, very recently, it has been found that in patients with severe or very severe cognitive decline (GDS 6–7) [8], Snoezelen has better effects than cognitively demanding one-to-one activities on neuropsychiatric symptoms and dementia severity, supporting the idea that it is a particularly appropriate intervention for patients in the late stages of the disease.

Because the use of MSSE in a Snoezelen room requires a significant investment of economic resources [26], controlled studies are needed to demonstrate whether its benefits are better than those provided by other sensory interventions, such as individualized music for example. This has been defined as music that was integrated into the individual's life and is based on personal preferences prior to the onset of cognitive impairment [27, 28]. According to the mid-range theory of individualized music intervention for agitation (IMIA) [29], presenting music that was carefully selected to be meaningful to the person during his or her younger years stimulates memory of remote events. Eliciting memories associated with positive feelings may have a soothing effect and alleviate or decrease agitated behaviors. In previous studies [29, 30], the use of individualized music has shown positive effects on anxiety and agitation in people at different stages of dementia, indicating that it could be a viable alternative for treating neuropsychiatric symptoms.

Therefore, the main objective of the current study was to compare the effects of MSSE in a Snoezelen room and individualized music sessions on agitation, emotional and cognitive status, and dementia severity in a sample of institutionalized elderly individuals with severe dementia.

MATERIALS AND METHODS

Design

We conducted a randomized controlled trial in which participants were stratified according to their cognitive status and subsequently randomly assigned to 1 of 2 groups (MSSE or individualized music).

Participants

The sample was selected from among the residents of a specialized dementia elderly center in A Coruña (Spain). The inclusion criteria were having a diagnosis of dementia and the presence of severe or very severe cognitive decline (GDS 6–7). Dementia diagnosis was noted on the medical history, provided by a neurologist before placement in the gerontological complex, and corroborated by the elder care

center's medical doctor. The GDS was administered by a clinical psychologist with experience in assessing people to determine their levels of severity: severe (GDS 6) or very severe (GDS 7) cognitive decline. The exclusion criteria were the presence of a hearing impairment or other sensory disorder that would adversely affect interactions with the multisensory stimulation objects (e.g., severe vision impairment) and being bedridden.

After this evaluation, the clinical psychologist checked the participants' eligibility based on the inclusion and exclusion criteria, using an initial sample of 22 participants. A computer-based random number generator was used to randomly divide the sample into 2 groups of 11 subjects according to GDS score. The initial sample size decreased to 18 during the follow-up period due to participants' deaths (n = 3) or dropouts (n = 1). The patients' progress through the trial is shown in a Consolidated Standards of Reporting Trial (CONSORT) diagram (Fig. 1). The final sample consisted of 18 participants, with 9 participants in each group.

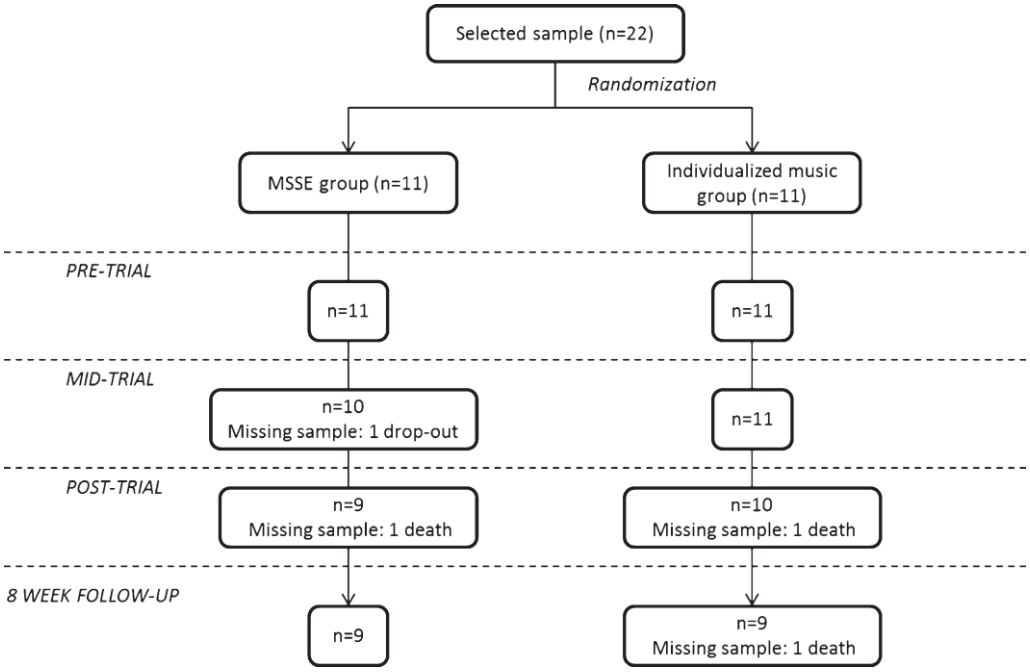

Fig. 1. Consolidated Standards of Reporting Trial (CONSORT) diagram. MSSE-multisensory stimulation environment.

The study protocol was approved by the ethics committee at the University of A Coruña, and it conformed to the principles embodied in the Declaration of Helsinki. Before data collection began, all participants' proxies were informed about the study, and the proxies were used as legally authorized representatives to provide informed consent for the elderly patients with dementia to participate in the research.

Procedure

The MSSE group participated in multisensory sessions in a Snoezelen room, which included elements such as alternating-color fiber-optic cables, two water bubble columns within two mirrors, a water bed, a rotating mirror ball with a color light projector, a video, an interactive projecting system, musical selections, aroma therapy equipment with fragrant oils, and a tactile board with various textures, among others. In this group, the intervention followed the characteristics that define the MSSE [22]: the patients were offered visual, auditory, tac- tile, and olfactory stimulation, and the therapists adopted a non-directive, enabling approach, encouraging patients to engage with sensory stimuli of their choice. The

stimuli used were non-sequential and un- patterned, experienced moment by moment without relying on short-term memory to link them to previous events.

The individualized music group participated in music sessions according to their musical preferences. The intervention occurred in a quiet room away from others. Each music intervention session was presented in a "free field" on a computer, and the volume of the music was set at an appropriate level for each participant. In this group, the therapist followed a directive approach, selecting the music for each session and taking into account the preferences and interests of the participants.

Participants from both groups took part in two weekly sessions for a period of 16 weeks, until they completed 32 sessions. Sessions lasted 30 min unless the participant expressed a desire to leave. In both groups, the sessions followed an internal structure that involved an introduction to the session, holding the session, and winding the session down. However, there was some flexibility within the standardization in the MSSE group, in keeping with the traditional philosophy of multisensory stimulation.

The sessions were conducted by professionals in the field of psychology or occupational therapy, with equivalent education and training in the method- ology used. To avoid creating positive or negative expectations, the MSSE and the individualized music sessions were presented to the staff and caregivers as two equally valid therapies.

As a result of this design, the differences found between the two conditions could be specifically attributed to the multisensory stimulation rather than to more general therapeutic effects such as the one-to-one attention to the patients.

Data on the participants' sensorial preferences and interests were previously collected to design the con- tent of the sessions and to minimize the behavioral problems that some participants could present within the MSSE and the music contexts. In the MSSE group, sensorial preferences in the Snoezelen room were assessed based on the procedure suggested by Pace et al. [31].

In the individualized music group, the significance of music prior to the patient's onset of cognitive impairment was determined. Family members were asked about their relatives' music preferences using the Assessment of Personal Music Preference (APMPQ) (family version)" [32]. This instrument was developed and tested [33] to obtain detailed information about personal music preferences and to identify the importance of music in the person's life during her or his independent living. It comprises a series of questions about the individuals' favorite types of music, forms of music, artists or performers, and specific song titles prior to the onset of the cognitive impairment. The family version of the APMPQ is used when the participants are unable to answer the questions due to cognitive impairment. This version has been successfully used by family members of res- idents who live in long-term care facilities [33]. In our study, some items were revised to include different types of Spanish music to make this assessment tool adequate for collecting information about the music preferences of older adults in Spain.

Agitation, mood, anxiety, cognition, and dementia severity were assessed at baseline (pre-trial, week 0), in the middle (mid-trial, week 8), at the end of the intervention (post-trial, week 16), and 8 weeks after the intervention (follow-up), for long-term monitoring. The period of long-term assessments has been established in the MSSE context as one month after sessions [16].

Assessment instruments

The validated Spanish version [34] of the Cohen- Mansfield Agitation Inventory (CMAI) [33] was used to assess the frequency of agitated behaviors in the participants. The CMAI consists of 30 items rated on a 7-point scale of frequency, where 1 means never and 7 means several times per hour. The total score is calculated by adding the scores of each of the individual items. Through a factor analysis, Cohen-Mansfield et al. [35] found the following three factors of agitation in the nursing home: aggressive behavior (hitting, kicking, pushing, scratching, tearing things, cursing or verbal aggression, and grabbing); physically nonaggressive behavior (pacing, inappropriate clothing or disrobing, trying to get to a different place, managing things inappropriately, general restlessness, and repetitious mannerisms); and verbally agitated behavior (complaining, constant requests for attention, negativism, repetitious sentences or questions, and screaming). In this study, the total score for each factor was obtained by adding the scores of the corresponding items. The CMAI inter-reliability [35] ranged from 0.88 to 0.92, and the internal consistency reliabilities (Cronbach's alpha, a) [36] ranged from 0.86 to 0.91.

The Spanish version [37] of the Cornell Scale for Depression in Dementia (CSDD) [38] was used to assess mood. This scale was specifically developed to assess signs and symptoms of major depression in patients with dementia. Information is elicited through two semi-structured interviews, one with an

informant and one with the patient. The CSDD consists of 19 items that are rated for severity on a scale of 0–2 (0 = *absent*, 1 = *mild or intermittent*, 2 = *severe*). The total score is obtained by adding all scores, for a minimum score of 0 and a maximum of 38. Scores above 10 indicate probable major depression, and scores above 18 indicate definite major depression. In the Spanish population, the CSDD has shown good test-retest reliability (0.61 to 0.84) and good internal consistency (a = 0.81) [37].

Anxiety was assessed using the Rating Anxiety in Dementia (RAID) [39] scale, which was specifically developed to measure anxiety in dementia patients. This is a brief screening measure that comprises 20 items divided into four subgroups: worry, apprehension and vigilance, motor tension, and autonomic hypersensitivity. Each item is rated on a four-point scale: absent (0), mild or intermittent (1), moderate (2), and severe (3). Information about the patient's symptoms over the past two weeks is gathered from all available sources of information: the patient's caregiver, the patient, medical notes, and clinical observations; subsequently, the scale is scored based on the clinician's final judgment. The total score is obtained by totaling the scores for the first 18 items, and scores at 11 or above indicate significant anxiety symptoms. The RAID has demonstrated good internal consistency (a = 0.83), inter-rater reliability (0.82 to 1.00), and test-retest reliability (0.84 to 1.00).

Cognitive function was assessed using the Spanish version [40] of the Severe Mini Mental State Examination (SMMSE) [41], which was designed to assess severe dementia, preventing the floor effect found when using the MMSE [42]. This simple instrument does not require specialized training or foreign material, and it is not tiring for patients with dementia (it takes less than 5 min to administer). It consists of 10 items on autobiographical knowledge (complete name and date of birth), constructional praxis tests, phonological loop (spelling), and semantic verbal fluency step (animal category generation). The SMMSE also tests receptive and expressive language skills along with elementary executive functions and visual-spatial abilities, which are likely to be preserved in severely impaired patients. The total score ranges from 0 to 30 points, with lower values indicating lower cognitive function. The SMMSE has shown both construct and criterion validity for assessing severely impaired Alzheimer's disease patients [41]. In the Spanish population, the SMMSE has shown high internal consistency (a = 0.88), inter- rater reliability (0.69 to 1.00), test-retest reliability 0 (.64 to 1.00), and construct validity in correlation with the Spanish version of the MMSE (r = 0.59) [40]. The overall severity of dementia was measured by the Bedford Alzheimer Nursing Severity Scale (BANS-S) [43]. The BANS-S is an observational scale that can also be used by people who are unable to follow simple commands, uncooperative or unable to communicate. This is a seven-item scale that combines ratings for interaction ability (speech, eye contact), functional deficits (dressing, eating, ambulation), and occurrence of pathological symptoms (sleep-wake cycle disturbance, muscle rigidity) [44]. Each item is scored on a 4-point scale where a scoring system is specified for each item. The total score ranges from 7 (no impairment) to 28 (most severe impairment). The BANS-S is more sensitive to detecting disease progression beyond the severe stage than are scales that measure only cognitive or functional deficits [43]. The BANS-S has shown good internal consistence (a = 0.80), convergent validity with other cognitive and functional scales (r = 0.62 to 0.79), and discriminant validity in comparison with the Neuropsychiatric Inventory (r = 0.36) [43, 45].

Statistical analysis

Sample characteristics were summarized as the means and standard deviations (SD) of the continuous variables and as frequencies and percentages of the categorical ones. The Shapiro-Wilk test was used to evaluate the normality of the sample, as it is more appropriate for small sample sizes (<50 samples) [46]. Differences between groups were compared using Chi-square test for proportions and the Stu- dent's t test for continuous variables.

Finally, repeated-measures two-way analysis of variance (two-way mixed ANOVAs) was used to assess performance differences in agitation, mood, anxiety, cognitive status and dementia severity over the pre-, mid-, and post-trial assessment points. The within-subject variables were the measures over time (pre-, mid-, and post-trial assessment) and the between-subject variables included the group (MSSE and individualized music).

In addition, the repeated-measures two-way mixed ANOVAs were used to assess performance differences in agitation, mood, anxiety, cognitive status and dementia severity between the post-trial and 8-week follow-up evaluations. In this case, the within-subject variables were the measures over time (post-trial assessment and follow-up) and the between-subject variables included the group (MSSE and individualized music). Differences between groups were tested by a group-time interaction.

Sphericity assumptions were tested using Mauchly's sphericity test. In case sphericity was violated, the results of Pillai's trace test or the epsilon- adjusted univariate F-test (Greenhouse-Geisser) [47] were reported.

Eta-squared values ($\eta 2$) were reported as indicators of effect size. We interpreted the importance of the effect size using the benchmarks for "small" ($\eta 2$ of 0.02), "medium" ($\eta 2$ of 0.13), and "large" ($\eta 2$ of 0.26) offered by Cohen (1988) [48]. Statistical significance was set at a p value of less than 0.05. Statistical analysis was performed using IBM SPSS Statistics v.21.0 (Armonk, NY: IBM Corp., USA).

RESULTS

Table 1 shows the sociodemographic characteristics of the sample at baseline. The mean age of the sample (n = 22) was 88.9 years (SD ± 6.80), and of the participants, 68.2% were women. With respect to marital status, 68.2% of the patients were widowed. Regarding the education level, 36.4% had secondary education.

At baseline, the groups were homogeneous. There were no significant differences between the MSSE and the individualized music group in age, gender, marital status, or educational level.

Table 1. Sociodemographic characteristics of the residents with dementia at week 0 (Baseline, Pretrial)[a]

	MSSE (n = 11)	Music (n = 11)	Total (n = 22)	P–value
Age (years)				
Mean (SD)	88.09 (6.80)	88.73 (7.36)	88.41 (6.93)	0.835
Age range	78–102	77–97	77–102	
Gender, n (%)				
Female	6 (54.5)	9 (81.2)	15 (68.2)	0.170
Male	5 (45.5)	2 (18.2)	7 (31.8)	
Marital status, n (%)				
Single	2 (18.2)	2 (18.2)	4 (18.2)	0.308
Married/partner	2 (18.2)	0 (0)	2 (9.1)	
Widowed	6 (54.5)	9 (81.8)	15 (68.2)	
Separated/divorced	1 (9.1)	0 (0)	1 (4.5)	
Educational level, n (%)				
No formal education	2 (18.2)	3 (27.3)	5 (22.7)	0.912
Primary	3 (27.3)	3 (27.3)	6 (27.3)	
Secondary	4 (36.4)	4 (36.4)	8 (36.4)	
College or higher degree	2 (18.1)	1 (9.0)	3 (13.6)	

MSSE, multisensory stimulation environment group; SD, standard deviation. a Significance: p–value < 0.05.

Effect on Agitation

With regard to agitation, improvement was found in both groups in the CMAI total score ($F(2,34)$ = 3.837, p = 0.031, $\eta 2$ = 0.166) between pre-, mid-, and post-intervention (Fig. 2). However, no significant differences were found between groups.

For both groups, the scores improved in the follow-up period compared with the post-trial assessment in the physically nonaggressive behavior factor ($F(1,16)$ = 5.518, p = 0.032, $\eta 2$ = 0.159), with no significant differences between the groups. With regard to aggressive behavior and verbally agitated behavior, no significant time effects or intergroup differences were observed.

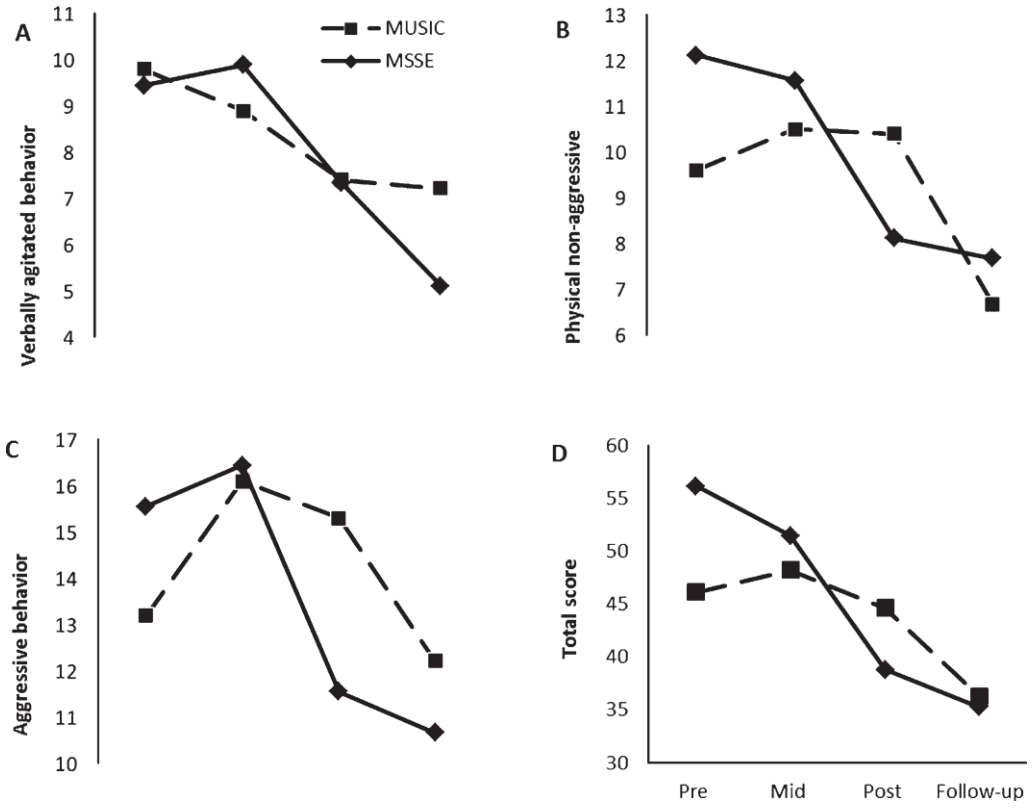

Fig. 2. Cohen-Mansfield Agitation Inventory (CMAI) during the trial and follow-up: verbally agitated behavior (A), physical non-aggressive (B), aggressive behavior (C), and total score (D). Higher scores = worse agitated behavior.

Effect on mood

The CSDD scores remained stable during the intervention in the MSSE group, whereas in the individualized music group, they worsened from pre- trial to post-trial (Fig. 3); however, the results were not significant. During the follow-up period, both groups reflected significant improvement in their scores ($F(1,16) = 9.822$, $p = 0.006$, $\eta 2 = 0.374$).

Effect on anxiety

With regard to anxiety, a significant group-time interaction was found in the RAID scores from pre-trial to post-trial (Fig. 4). There was improvement in the MSSE scores during the intervention but not in the individualized music group (Pillai's Trace, $F(2,16) = 2.141$, $p = 0.013$). The scores improved in both groups during the follow-up period compared with the post-trial assessment ($F(1,16) = 6.500$, $p = 0.021$, $\eta 2 = 0.267$), with no significant differences between the groups.

Effect on cognitive status

For the SMMSE (Fig. 5), both groups displayed a similar decline in their scores during the trial. No significant time effects or intergroup differences were found.

Effect on dementia severity

A significant group-time interaction was also observed for the BANS-S (Fig. 6). There was improvement in the scores between pre-, mid-, and post-intervention assessments in the MSSE group but not in the individualized music group (Greenhouse- Geisser, $F(1.46,24.89) = 7.193$, $p = 0.007$, $\eta 2 = 0.233$). During the follow-up period, the BANS-S scores in both groups worsened compared with the post-trial assessment. However, the results were not significant.

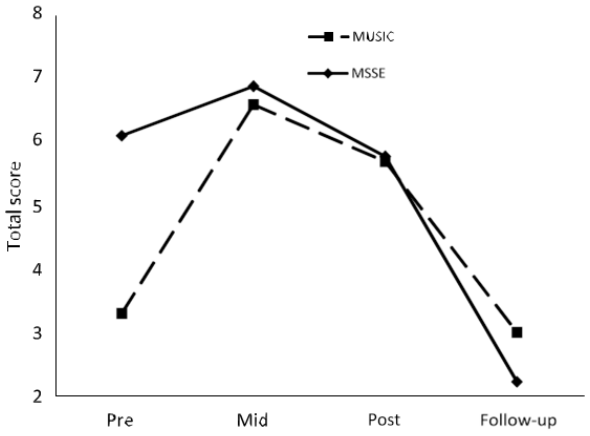

Fig. 3. The Cornell Scale for Depression in Dementia (CSDD) total scores during the trial and follow-up (higher score = worse mood)

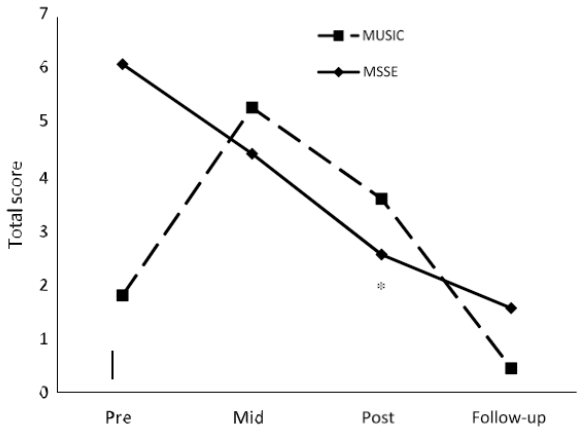

Fig. 4. Rating Anxiety in Dementia (RAID) total scores during the trial and follow-up (higher score = more anxiety symptoms).
*group-time interaction effect from pre- to post-trial ($p < 0.05$).

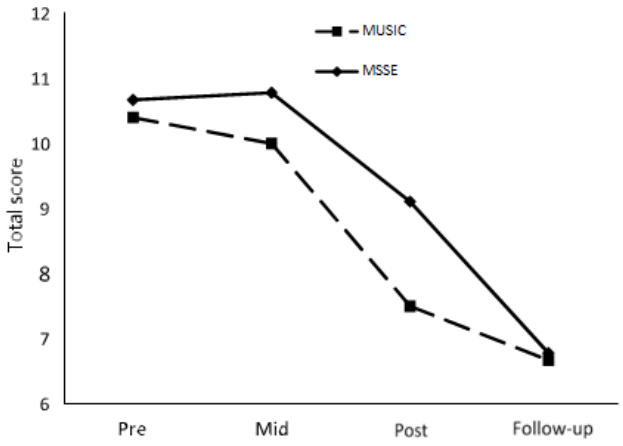

Fig. 5. Severe Mini-Mental State Examination (SMMSE) total scores during the trial and follow-up (lower score = worse cognitive state)

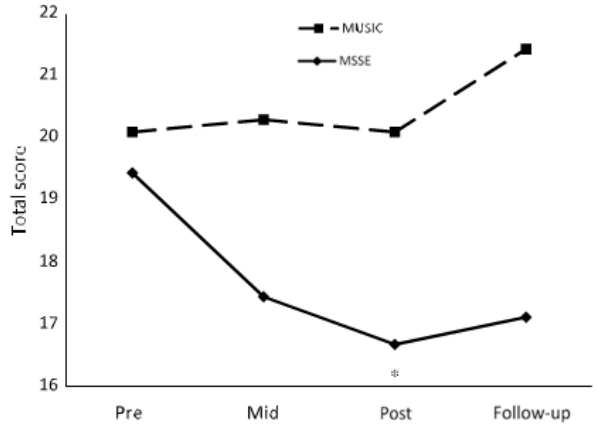

Fig. 6. Bedford Alzheimer Nursing Severity Scale (BANS-S) total scores during the trial and follow-up (higher score = more severe impairment). *group-time interaction effect from pre- to post-trial ($p < 0.05$).

DISCUSSION

Effect on agitation

There was improvement in both the MSSE and individualized music groups in the CMAI total score after the 16 weeks of intervention. According to the benchmarks of Cohen (1988) [48], the effect size was medium. This result indicates that both MSSE and individualized music may be appropriate interventions to reduce agitation symptoms in people with advanced dementia.

Agitation in dementia is common and distressing. Although it has been associated with brain changes, recent findings suggest it is often a symptom of lack of understanding or unmet needs that the person with dementia is unable to explain [49]. Due to adverse effects of medication, most of the best practice guidelines suggest non-pharmacological treatments as the first-line therapy in the treatment of agitation [50]. However, staffs in nursing homes encounter difficulties in selecting and employing effective non-

pharmacological interventions for agitation. As a result, patients with agitation are too often inappropriately restrained physically or chemically [51].

Two systematic reviews [49, 51] have found that sensory interventions may be particularly appropriate in reducing agitation in people with dementia. Multisensory [24, 52, 53] and individualized music [54] interventions have shown long-term benefits in decreasing agitation in people with moderate to severe dementia. However, there is still little evidence about the efficacy of sensory interventions in samples of people with severe dementia. Sánchez et al. [8] found that MSSE in a Snoezelen room might be an appropriate intervention for reducing agitation in severe dementia, although their effectiveness was equivalent to the individualized one-to-one activities. With regard to individualized music, Gerdner et al. [29] showed a significant reduction in agitation, as measured with the modified CMAI, in comparison with classical music in a sample of institutionalized elderly patients with severe cognitive impairment. Furthermore, Park et al. observed [55] that individualized music reduced agitation in the modified CMAI in people with dementia (MMSE mean score of 8.08) who lived at home.

Effect on mood

The current results found neither a benefit after 16 weeks of intervention in the CSDD scores nor significant differences between the MSSE group and the individualized music group. Although MSSE has demonstrated immediate positive effects on the moods of people with dementia in the short term, long-term benefits were not as evident [12]. In previous studies [8, 16, 24], MSSE in Snoezelen rooms was not found to be more effective than one-to-one activities in changing moods in the long term in people with either moderate or severe dementia.

Both groups showed significant improvement in their CSDD scores during the follow-up period compared with the post-trial assessment. Based on the benchmarks of Cohen (1988) [48], the effect size was large. These improvements were observed 8 weeks after the end of the intervention, and therefore they were presumably not direct interventional effects but rather accessory effects that were likely due to the progression of the disease over time; it has been found that depressive symptoms peak after the moderate stages of the illness and decrease in the late stages [56]. This improvement could also be explained by the seasonal differences between the intervention and follow-up periods. Whereas the intervention was carried out in winter/spring, the follow-up took place in summer, resulting in an increase in the levels of light exposure. It has been observed that persons with Alzheimer's disease and other dementias (ADRD) have greater circadian rhythm abnormalities than do healthy older adults and that this circadian disruption is more pronounced during winter months when there is less available daylight [57]. Indeed, light therapy has been shown to reduce CSSD scores in per- sons with ADRD who live in long-term care facilities [58]. Thus, light interventions, particularly during the winter, could be an adequate alternative for reducing symptoms in the institutionalized elderly with dementia.

Effects on anxiety

With regard to RAID scores, in our study, patients in the MSSE group showed a significant improvement during the intervention that was not observed in the individualized music group. Although it is a common symptom in dementia patients, little attention has been paid to anxiety in dementia until recently, which may be because anxiety could overlap with other constructs in this population, such as depression or agitation. Given that at this point it is unclear whether anxiety is part of a broader syndrome in this population, it is recommended that it be assessed independently [59].

Thus far, few studies in the field have included specific measures of anxiety. Ozdemir et al. [60], in a multisensory stimulation program based on the combination of music therapy, painting, and sensory stimulation carried out in groups of 4 or 5 people, observed significant improvement in anxiety levels assessed with the Beck Anxiety Scale in mildly affected Alzheimer's disease patients. With respect to music interventions, Sung et al. [30] reported that institutionalized older adults with dementia who received preferred music sessions had significantly fewer anxiety symptoms on the RAID tool after six weeks compared with those who received the usual standard care.

In individuals with severe Alzheimer's disease, Sakamoto et al. [61] studied the effects of two individualized music interventions (interactive and passive) and found that both reduced the "anxieties and phobias" item of the Behavioral Pathology in Alzheimer's disease (BEHAVE-AD) Rating Scale.

Randomized controlled trials in patients with severe dementia, using specific anxiety tools, are needed to provide stronger evidence about the effects of MSSE and individualized music on anxiety.

In the current study, significant improvement in the RAID scores was found in both groups during the follow-up period compared with the post-trial assessment. Based on the benchmarks of Cohen (1988) [48], the effect size was large. As in the case of depressive symptoms, the improvement in the follow-up may have been due to the progression of the disease itself. Indeed, findings suggest that anxiety symptoms are relatively stable across the range of dementia severity until the profound/terminal stage, when they decrease [59].

Assessing distress symptoms in people with severe dementia is particularly difficult because of their loss of language skills. Therefore, objective measures of distress could be adequate alternatives for this group of patients. In this direction, Suzuki et al. [62] found that music therapy decreased the levels of salivary chromogranin A (CgA), a physiological measure of distress, in institutionalized elderly people with dementia. Recently, a study with brain- injured patients [63] found that MSSE in a Snoezelen room elicited significant changes in spontaneous electroencephalogram (EEG), which involves slowing EEG oscillatory activity, which could reflect the state of relaxation induced by the multisensory stimulation. Thus, for further development in this field, it is desirable that future research with people with severe dementia include these objective measures of distress.

Effect on cognitive status

In the present study, no improvements were found in cognitive status during the intervention, and there were no differences between the MSSE and individualized music groups. This result is consistent with previous studies that did not find significant effects of the MSSE on the cognitive levels in patients with moderate or severe dementia [8, 16, 24]. It is possible that MSSE could have positive effects on cognitive status in healthy elderly people [64] or in mildly affected dementia patients [60], but it may be not effective in more advanced stages of dementia. Regarding music interventions, previous studies have reported positive effects on cognition in people with dementia [65]. Nevertheless, most of these studies include patients in the mild stage of dementia; it is, however, more difficult to obtain benefits in people with severe dementia who have marked cognitive impairment.

Effect on dementia severity

In our study, patients in the MSSE group showed significant improvement in BANS-S scores during the intervention, which was not found in the individualized music group. Following Cohen's (1988) [48], the effect size was large. In a previous study of people with severe dementia [8], we found that patients in the MSSE group also demonstrated significant improvement in the BANS-S scores compared with one-to-one activity sessions. In both studies, the improvements observed during the intervention disappeared during the follow-up period, and these results highlight that in the late stages of dementia, MSSE has positive effects on dementia severity, and it is necessary to continue with the intervention to maintain those effects.

In the advanced stages of the illness, patients achieve only baseline scores on most cognitive status assessment tools [3]. Therefore, in this stage, it is recommended that instruments be used that are specifically oriented to assessing patients with severe deterioration, such as the SMMSE. However, even the advanced dementia-specific tests require language skills for completion, so that patients with very severe impairment often have difficulties in understanding the task requirements. In this regard, it has been pro- posed that when the SMMSE reaches the bottom level, it should be replaced by observer-based scales such as the BANS-S [66]. This tool does not require language skills for completion and can be applied to all subjects because it was more sensitive to detecting

Uni-sensory intervention vs. multisensory stimulation

A positive effect on anxiety symptoms and dementia severity in the MSSE group was observed compared with the individualized music group. A number of possibilities can explain these results. First, individualized music may not be suitable for everyone; for example, it would not be appropriate for a person who did not have an appreciation for music prior to the onset of cognitive impairment [28].

Secondly, MSSE in a Snoezelen room could be a more effective intervention than individualized music because it stimulates different senses and allows for greater sensory environment control. In a Snoezelen room, the stimulation may be modified by controlling the number and type of stimuli, and the intensity of the stimulation by matching sensory preferences and individual needs [67]. Individualized music sessions may also be modified to take into account personal interests. However, it is difficult to modify the level of sensory stimulation with individualized music sessions in the same way as in Snoezelen sessions.

Moreover, the differences between groups may be explained in that the music group received a passive (receptive) intervention whereas patients in the MSSE group had more active roles in the therapy. Patients with severe dementia may have difficulty engaging in active (interactive) music-related activities. However, even in this phase of the disease, the use of active individualized music could be a more effective treatment than passive individualized music in managing dementia symptoms [30].

Moreover, to achieve a better understanding of the therapeutic effects of MSSE in people with dementia, it would be valuable to have greater knowledge of the mechanisms that are involved in multisensory integration processing. In healthy aging, despite the ongoing deterioration of the individual sensory systems during aging, there is evidence of an increase in, or maintenance of, multisensory integration processing [68, 69]. However, our understanding about the mechanisms of multisensory integration in people with neurodegenerative disorders is currently still poor.

Limitations and recommendations for future research

One limitation of the present study is the small sample size included in each group, which may account for the non-significant results found in some of the outcome measures. However, the difficulty of obtaining more participants should be considered, especially taking into account their homogeneity and the possibilities for randomization. Future empirical studies with larger samples are necessary to confirm our results.

Furthermore, many patients with severe dementia achieve only baseline scores on the quantitative assessment tools that are used, and thus, some of the treatment benefits perceived by therapists are difficult to capture with these instruments. As such, it would be helpful if future studies in this field included qualitative methods of data collection, which could be more sensitive to the effects of the intervention. Additionally, it would be desirable to add objective measures of distress such as salivary CgA or EEG analysis [62, 63].

Moreover, because setting up a Snoezelen room requires considerable cost and manpower [70], future research is needed to examine whether the Snoezelen benefits are better than those provided by other sensory interventions that require a minor investment of resources such as light therapy or massage [10].

CONCLUSIONS

These findings suggest that MSSE in a Snoezelen room could be more effective than individualized music sessions in reducing symptoms in patients with severe dementia. Patients treated with MSSE have shown positive effects on anxiety symptoms and dementia severity that were not observed in the individualized music group. With regard to agitation, there was similar improvement in both groups, with no significant differences between the two types of interventions.

Future empirical studies with larger samples are necessary to compare the effects of MSSE in a Snoezelen room with other types of sensory intervention in people with severe dementia.

ACKNOWLEDGMENTS

We thank the users and staff of the Gerontology Complex La Milagrosa (managed by the Association of Pensioners and Retired People (UDP) from A Coruña, Spain), without whom the study would not have been possible. We are truly grateful to Prof Roger Baker (Bournemouth University, United Kingdom) for providing us with the information to design

REFERENCES

[1] Herrmann N, Gauthier S (2008) Diagnosis and treatment of dementia: 6. Management of severe Alzheimer disease. *CMAJ* 179, 1279-1287.

[2] Honig LS, Mayeux R (2001) Natural history of Alzheimer's disease. *Aging (Milano)* 13, 171-182.

[3] Koopmans RT, van der Molen M, Raats M, Ettema TP (2009) Neuropsychiatric symptoms and quality of life in patients in the final phase of dementia. *Int J Geriatr Psychiatry* 24, 25-32.

[4] Mitchell SL, Black BS, Ersek M, Hanson LC, Miller SC, Sachs GA, Teno JM, Morrison RS (2012) Advanced dementia: State of the art and priorities for the next decade. *Ann Intern Med* 156, 45-51.

[5] Olazarán J, Agüera-Ortiz L, Osorio RS, Leo´ n-Salas B, Dobato JL, Cruz-Orduña I, González B, Valentí M, Gil-Ruiz N, Frades B, Ramos-García MI, Martínez-Martín P (2012) Promoting research in advanced dementia: Early clinical results of the Alzheimer Center Reina Sofía Foundation. *J Alzheimers Dis* 28, 211-222.

[6] Gandy S, DeKosky ST (2013) Toward the treatment and prevention of Alzheimer's disease: Rational strategies and recent progress. *Annu Rev Med* 64, 367-383.

[7] Devanand DP, Schultz SK (2011) Consequences of antipsychotic medications for the dementia patient. *Am J Psychiatry* 168, 767-769.

[8] Sánchez A, Marante-Moar MP, Sarabia C, de Labra C, Lorenzo T, Maseda A, Millán-Calenti JC (2015) Multisensory stimulation as an intervention strategy for elderly with severe dementia: A pilot randomized controlled trial. *Am J Alzheimers Dis Other Demen*. doi: 10.1177/1533317515618801

[9] National Collaborating Centre for Mental Health (UK) (2007) *Dementia: A NICE-SCIE Guideline on Supporting People with Dementia and Their Carers in Health and Social Care - National Clinical Guidelines N. 42*, British Psychological Society, Leicester, UK.

[10] Behrman S, Chouliaras L, Ebmeier KP (2014) Considering the senses in the diagnosis and management of dementia. *Maturitas* 77, 305-310.

[11] Tariot PN (2003) Medical management of advanced dementia. *J Am Geriatr Soc* 51, S305-S313.

[12] Sánchez A, Millán-Calenti JC, Lorenzo-López L, Maseda A (2013) Multisensory stimulation for people with dementia: A review of the literature. *Am J Alzheimers Dis Other Demen* 28, 7-14.

[13] Moffat N, Barker P, Pinkney L (1993) *Snoezelen: An Expe- rience for People with Dementia*, Rompa, Chesterfield, UK.

[14] Milev RV, Kellar T, McLean M, Mileva V, Luthra V, Thompson S, Peever L (2008) Multisensory stimulation for elderly with dementia: A 24-week single-blind randomized con- trolled pilot study. *Am J Alzheimers Dis Other Demen* 23, 372-376.

[15] Padilla R (2011) Effectiveness of environment-based interventions for people with Alzheimer's disease and related dementias. *Am J Occup Ther* 65, 514-522.

[16] Baker R, Holloway J, Holtkamp CC, Larsson A, Hartman LC, Pearce R, Scherman B, Johansson S, Thomas PW, Wareing LA, Owens M (2003) Effects of multi-sensory stimulation for people with dementia. *J Adv Nurs* 43, 465-477.

[17] Kovach CR (2000) Sensoristasis and imbalance in persons with dementia. *J Nurs Scholarsh* 32, 379-384.

[18] Jakob A, Collier L (2014) How to make a Sensory Room for people living with dementia - a Guide Book, http://www.kingston.ac.uk/sensoryroom, Accessed on November 20, 2015.

[19] Chitsey AM, Haight BK, Jones MM (2002) Snoezelen: A multisensory environmental intervention. *J Gerontol Nurs* 28, 41-49.

[20] Staal J, Pinkney L, Roane D (2003) Assessment of stim- ulus preferences in Snoezelen therapy for the elderly with dementia. *Br J Occup Ther* 66, 542-551.

[21] Staal J (2012) Functional analytic multisensory environ- mental therapy for people with dementia. *Int J Alzheimers Dis* 2012, 294801.

[22] Baker R, Bell S, Baker E, Gibson S, Holloway J, Pearce R, Dowling Z, Thomas P, Assey J, Wareing LA (2001) A randomized controlled trial of the effects of multisensory stimulation (MSS) for people with dementia. *Br J Clin Psychol* 40, 81-96.

[23] Maseda A, Sánchez A, Marante MP, González-Abraldes I, Labra CD, Millán-Calenti JC (2014) Multisensory stimulation on mood, behavior, and biomedical parameters in people with dementia: Is it more effective than conventional one-to-one stimulation? *Am J Alzheimers Dis Other Demen* 29, 637-647.

[24] Maseda A, Sánchez A, Marante MP, González-Abraldes I, Buján A, Millán-Calenti JC (2014) Effects of multisensory stimulation in a sample of institutionalized elderly people with dementia diagnosis: A controlled longitudinal trial. *Am J Alzheimers Dis Other Demen* 29, 463-473.

[25] Reisberg B, Ferris SH, de Leo´ n MJ, Crook T (1988) Global Deterioration Scale (GDS). *Psychofarmacol Bull* 24, 661-663.

[26] Hensman M, Mudford OC, Dorrestein M, Brand D (2015) Behavioral evaluation of sensory-based activities in dementia care. *Eur J Behav Anal* 16, 295-311.

[27] Gerdner LA (1997) An individualized music intervention for agitation. *J Am Psychiatr Nurses Assoc* 3, 177-184.

[28] Gerdner LA (2012) Individualized music for dementia: Evolution and application of evidence-based protocol. *World J Psychiatry* 2, 26-32.

[29] Gerdner LA (2000) Effects of individualized versus classical "relaxation" music on the frequency of agitation in elderly persons with Alzheimer's disease and related disorders. *Int Psychogeriatr* 12, 49-65.

[30] Sung HC, Chang AM, Lee WL (2010) A preferred music listening intervention to reduce anxiety in older adults with dementia in nursing homes. *J Clin Nurs* 19, 1056-1064.

[31] Pace GM, Ivancic MT, Edwards GL, Iwata BA, Page TJ (1985) Assessment of stimulus preference and reinforcer value with profoundly retarded individuals. *J Appl Behav Anal* 18, 249-255.

[32] Gerdner LA, Hartsock J, Buckwalter KC (2000) *Assessment of Personal Music Preference (family version)*, The University of Iowa Gerontological Nursing Interventions Research Center: Research Development and Dissemination Core, Iowa City, Iowa.

[33] Gerdner LA (2005) Use of individualized music by trained staff and family: Translating research into practice. *J Gerontol Nurs* 31, 22-30.

[34] Cervilla JA, Rodríguez Cano T, Gurpegui M (1995) Prevalencia de Conductas Agitadas en Ancianos. *An Psiquiatr* 11,5-6.

[35] Cohen-Mansfield J, Marx MS, Rosenthal AS (1989) A description of agitation in a nursing home. *J Gerontol A Biol* 44, M77-M84.

[36] Finkel SI, Lyons JS, Anderson RL (1992) Reliability and validity of the Cohen–Mansfield agitation inventory in insti- tutionalized elderly. *Int J Geriatr Psychiatry* 7, 487-490.

[37] Pujol J, De Azpiazu P, Salamero M, Cuevas R (2001) Sintomatología depresiva de la demencia. Escala de Cornell: Validación de la versión en castellano. *Rev Neurol* 33, 397-398.
[38] Alexopoulos GS, Abrams RC, Young RC, Shamoian CA (1988) Cornell Scale for Depression in Dementia. *Biol Psychiatry* 23, 271-284.
[39] Shankar KK, Walker M, Frost D, Orrell MW (1999) The development of a valid and reliable scale for rating anxiety in dementia (RAID). *Aging Ment Health* 3, 39-49.
[40] Buiza C, Navarro A, Díaz-Orueta U, González MF, Alaba J, Arriola E, Hernández C, Zulaica A, Yanguas JJ (2011) Evaluación breve del estado cognitivo de la demencia en estadios avanzados: Resultados preliminares de la validación española del Severe Mini Mental State Examination. *Rev Esp Geriatr Gerontol* 46, 131-138.
[41] Harrell LE, Marson D, Chatterjee A, Parrish JA (2000) The Severe Mini-Mental State Examination: A new neuropsychologic instrument for the bedside assessment of severely impaired patients with Alzheimer disease. *Alzheimer Dis Assoc Disord* 14, 168-175.
[42] Folstein MF, Folstein SE, McHugh PR (1975) Mini-Mental state: A practical method for grading the cognitive state of patients for the clinician. *J Psychiatry Res* 12, 189-198.
[43] Volicer L, Hurley AC, Lathi DC, Kowall NW (1994) Measurement of severity in advanced Alzheimer's disease. *J Gerontol* 49, M223-226.
[44] Volicer L, Hurley AC, Blasi ZV (2001) Scales for evaluation of End-of-Life Care in Dementia. *Alzheimer Dis Assoc Disord* 15, 194-200.
[45] Bellelli G, Frisoni GB, Bianchetti A, Trabucchi M (1997) The Bedford Alzheimer Nursing Severity scale for the severely demented: Validation study. *Alzheimer Dis Assoc Disord* 11, 71-77.
[46] Razali N, Wah YB (2012) Power comparisons of Shapiro- Wilk, Kolmogorov-Smirnov, Lilliefors and Anderson- Darling tests. *J Stat Model Anal* 2, 21-33.
[47] Geisser S, Greenhouse SW (1958) An extension of box's results on the use of the F distribution in multivariate analysis. *Ann Math Statist* 29, 885-891.
[48] Cohen J (1988) *Statistical Power Analysis for the Behavioural Sciences*, 2nd ed., Erlbaum, Hillsdale.
[49] Livingston G, Kelly L, Lewis-Holmes E, Baio G, Morris S, Patel N, Omar RZ, Katona C, Cooper C (2014) Non-pharmacological interventions for agitation in dementia: Systematic review of randomised controlled trials. *Br J Psychiatry* 205, 436-442.
[50] Ballard C, Corbett A (2010) Management of neuropsychiatric symptoms in people with dementia. *CNS Drugs* 24,729-739.
[51] Kong EH, Evans LK, Guevara JP (2009) Nonpharmacological intervention for agitation in dementia: A systematic review and meta-analysis. *Aging Ment Health* 13, 512-520.
[52] Staal JA, Sacks A, Matheis R, Collier L, Calia T, Hanif H, Kofman ES (2007) The effects of Snoezelen (multi-sensory behavior therapy) and psychiatric care on agitation, apathy, and activities of daily living in dementia patients on a short term geriatric psychiatric inpatient unit. *Int J Psychiatry Med* 37, 357-370.
[53] van Weert JC, van Dulmen AM, Spreeuwenberg PM, Ribbe MW, Bensing JM (2005) Behavioral and mood effects of snoezelen integrated into 24-hour dementia care. *J Am Geriatr Soc* 53, 24-33.
[54] Sung HC, Chang AM (2005) Use of preferred music to decrease agitated behaviours in older people with dementia: A review of the literature. *J Clin Nurs* 14, 1133-1140.
[55] Park H (2013) The effect of individualized music on agitation for home-dwelling persons with dementia. *Open J Nurs* 3, 453-459.
[56] Youn JC, Lee DY, Jhoo JH, Kim KW, Choo IH, Woo JI (2011) Prevalence of neuropsychiatric syndromes in Alzheimer's disease (AD). *Arch Gerontol Geriatr* 52, 258-263.
[57] Figueiro MG, Hamner R, Higgins P, Hornick T, Rea MS (2012) Field measurements of light exposures and circadian disruption in two populations of older adults. *J Alzheimers Dis* 31,711-715.
[58] Figueiro MG, Plitnick BA, Lok A, Jones GE, Higgins P, Hornick TR, Rea MS (2014) Tailored lighting intervention improves measures of sleep, depression, and agitation in persons with Alzheimer's disease and related dementia living in long-term care facilities. *Clin Interv Aging* 12, 1527-1537.
[59] Seignourel PJ, Kunik ME, Snow L, Wilson N, Stanley M (2008) Anxiety in dementia: A critical review. *Clin Psychol Rev* 28, 1071-1082.
[60] Ozdemir L, Akdemir N (2009) Effects of multisensory stimulation on cognition, depression and anxiety levels of mildly-affected Alzheimer's patients. *J Neurol Sci* 283, 211-213.
[61] Sakamoto M, Ando H, Tsutou A (2013) Comparing the effects of different individualized music interventions for elderly individuals with severe dementia. *Int Psychogeriatr* 25, 775-784.
[62] Suzuki M, Kanamori M, Nagasawa S, Tokiko I, Takayuki S (2007) Music therapy induced changes in behavioral evaluations, and saliva chromogranin A and immunoglobulin A concentrations in elderly patients with senile dementia. *Geriatr Gerontol Int* 7, 61-71.
[63] Poza J, Gómez C, Gutiérrez MT, Mendoza N, Hornero R (2013) Effects of a multi-sensory environment on brain- injured patients: Assessment of spectral patterns. *Med Eng Phys* 35, 365-375.
[64] De Oliveira TC, Soares FC, De Macedo LD, Diniz DL, Bento-Torres NV, Picanço-Diniz CW (2014) Beneficial effects of multisensory and cognitive stimulation on age- related cognitive decline in long-term-care institutions. *Clin Interv Aging* 14, 309-320.
[65] Vasionyte˙ I, Madison G (2013) Musical intervention for patients with dementia: A meta-analysis. *J Clin Nurs* 22, 1203-1216.
[66] Appollonio I, Gori C, Riva G, Spiga D, Ferrari A, Ferrarese C, Frattola L (2005) Assessing early to late stage dementia: The TSI and BANS-S scales in the nursing-home. *Int J Geriatr Psychiatry* 20, 1138-1145.
[67] Collier L, McPherson K, Ellis-Hill C, Staal J, Bucks R (2010) Multisensory stimulation to improve functional performance in moderate to severe dementia–interim results. *Am J Alzheimers Dis Other Demen* 25, 698-703.
[68] Laurienti PJ, Burdette JH, Maldjian JA, Wallace MT (2006) Enhanced multisensory integration in older adults. *Neuro- biol Aging* 27, 1155-1163.
[69] Freiherr J, Lundstro¨ m JN, Habel U, Reetz K (2013) Mul- tisensory integration mechanisms during aging. *Front Hum Neurosci* 7, 863.
[70] Chung JCC, Lai CKY (2002) Snoezelen for dementia. *Cochrane Database Syst Rev*, CD003152.