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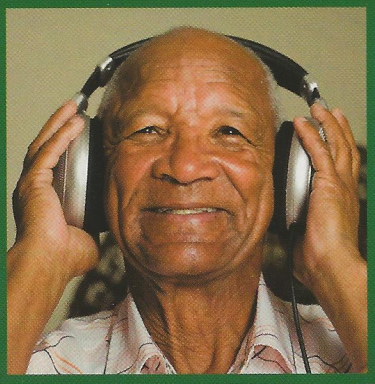


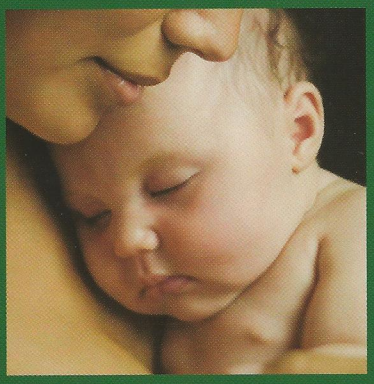
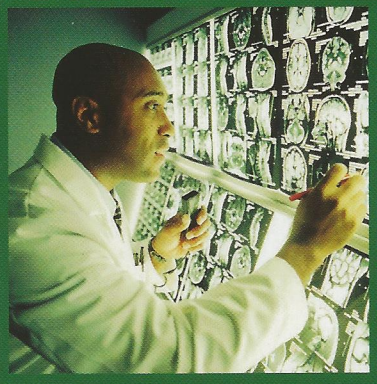
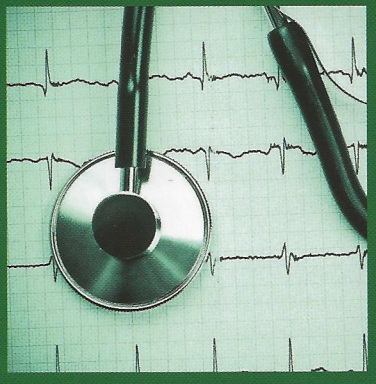


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CLINICAL STUDY

Summary Document

Complete Study Available Upon Request

Coro Health, LLC

2010

The effects of widespread and frequent personalized music programming on agitation and depression in assisted living facility residents with Alzheimer's dementia.

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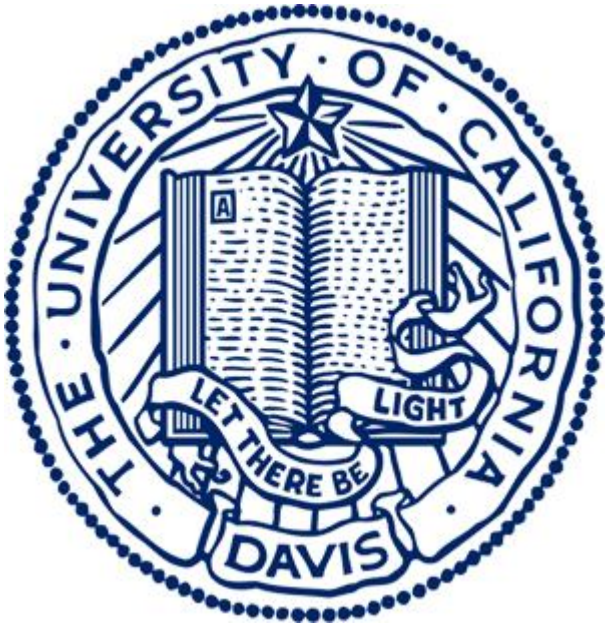
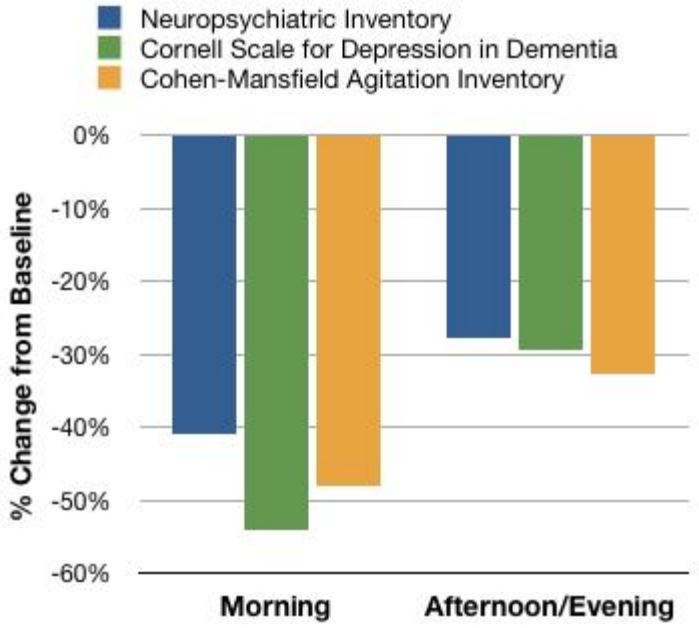


Abstract

A randomized controlled music intervention was performed to examine effects of customized music programming on agitation and depression in a sample of assisted living facility residents with moderate to severe dementia.

Music programs were streamed to the rooms of individuals assigned to a music group for ~3 hours/day across four time windows each day, 7 days/week for 12 weeks.

Ambulatory residents assigned to the control group could come into contact with the music programming in the course of daily living. **Reductions (27–54%) in composite scores on the Cohen-Mansfield Agitation Inventory, Neuropsychiatric Inventory, and Cornell Scale for Depression in Dementia were rapid and sustained in both groups, with more significant reductions observed during the mornings than in the evenings**. Evening depression scores increased less for the group at which the music treatment was directed (see Figure 2). Creating an almost omnipresent musical atmosphere directed at the musical preferences and listening histories of residents reduces average levels of agitation and depression throughout the facility.



Introduction

Among the most significant behavioral and emotional problems confronting dementia patients and their caregivers are those of agitation, aggression, anxiety, and depression. These symptoms signal an unhappy state of the individual and may pose a threat to caregivers and other residents of assisted living facilities. The potential for music to alleviate such symptoms is gaining considerable attention, though considerable variation in treatment approaches and outcomes has been observed

(Bradt & Dileo, 2010; Raglio & Gianelli, 2009; Spiro, 2010; Sung & Chang, 2005; Vink, Birks, Bruinsma, & Scholten, 2003).

The objective of the present study was to examine the efficacy of a music intervention that blends music therapy and music medicine approaches. The intervention is akin to music therapy in that a music therapist designs customized music libraries for each individual based on the individual's music preferences and listening history.

A significant and important difference between this study and previous studies was the amount of music that individuals were exposed to on a daily basis. The range across previous studies spans from relatively little music treatment, e.g. 15 min/d for 5 d (Groene, 1993) or 20 min 1d/wk for 16 weeks (Guetin, et al., 2009), to moderate amounts of treatment, e.g. 30–40 min/day, 2–3 d/wk for 8–12 weeks (Cooke, et al., 2010; Gerdner, 2000) and thirty 30 min sessions across 10 weeks (Raglio, et al., 2008). In this study, music was made available to individuals for 3 h/d, 7 d/wk for 12 weeks. Thus, the amount of music treatment in this study was substantially higher than in previous studies.

Methods

Participants

Residents from Somerford Place Alzheimer's Assisted Living facility in Roseville, CA, were enrolled in the study. Potential participants were excluded if they suffered from hearing impairment that was sufficiently severe to impair hearing speech or music played at a moderately loud listening volume. Table 1 provides further information about the participants, arranged by the group to which they were assigned. For individuals from whom it was not possible to obtain direct informed consent, surrogate consent was obtained according to study procedures approved by the University of California, Davis Institutional Review Board.

Study design

The study was designed as a controlled, randomized, single-site trial lasting 16 weeks between July and November, 2010. Following enrollment of the entire cohort, participants were assigned randomly into one of two groups: a music treatment group, and a non-treatment control group. Group assignment was completely random, i.e. performed without consideration of age, gender, or dementia status

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Timeline

A music therapist from Coro Health LLC performed the assessments necessary to construct an individualized music treatment plan for each participant according to the company's standard playlist development procedures. Following the baseline period, those participants assigned to the treatment group received 12 weeks of music programming. Assessments were performed throughout this period, and continued during a 2-week post-treatment period in which none of the residents received the music treatment.

Music intervention

The music delivery system and music programming were provided by Coro Health, LLC. The system uses wireless technology to stream music from playlists maintained on a centralized server to a player situated in a participant's room at prescribed times. Music players were placed in every resident's room, and disconnected if the resident had not been assigned to the treatment group. For those in the treatment group, four music programs were played in the participant's room each day within specific time windows adjusted to match the daily rhythms of the individual.

Dependent measures

Our choice of measurement instruments and administration frequency was guided by two principles: we wanted to assess as broad a spectrum as possible of behavioral and emotional disturbances that are considered to be of greatest concern among assisted living facility administrators and staff, and we wanted to collect samples sufficiently often that we could readily detect any time-varying changes.

Daily dependent measure

The expression of agitation behaviors during the late afternoon and evening is commonly referred to as "sundowning" (Bachman & Rabins, 2006). Although no formal sundowning assessment tool exists, to our knowledge, many "sundowning" symptoms are captured by the Cohen-Mansfield Agitation Inventory (CMAI; Jiska Cohen-Mansfield, et al., 1989). We therefore developed an 8-item "Sundowning Severity Assessment" based on relevant items from the CMAI together with a few additional items (Appendix A). Each item was associated with a 5-point scale for indicating the severity of the symptom (Absent, Mild, Moderate, Severe, Very Severe). The intent of this scale was to provide a quick assessment of the participant's sundowning symptoms based on the preceding 3-4 hour period.

Weekly dependent measures

Neuropsychiatric Inventory (NPI)

The Neuropsychiatric Inventory is widely used in clinical settings and clinical trials (Cummings, et al., 1994). This instrument consists of a 12-item questionnaire and assesses a broad range of psychiatric disturbances associated with: delusions, hallucinations, agitation or aggression, depression or dysphoria, anxiety, elation or euphoria, apathy or indifference, disinhibition, irritability or lability, motor disturbance, nighttime behaviors, and appetite and eating. Each item is scored whether it is present, and if so, how severe it is on a 3-point scale. In addition, this instrument assesses (on a 6- point scale for each item) the distress to the caregiver. The caregiver aspect of the NPI was of considerable interest. To the extent that music therapy interventions are effective in relieving behavioral and emotional problems in the residents, these changes may in turn affect the well being of their caregivers.

Cohen-Mansfield Agitation Inventory (CMAI)

This Cohen-Mansfield Agitation Inventory (Jiska Cohen-Mansfield, et al., 1989) is a 29-item questionnaire that assesses the frequency of a variety of disruptive behaviors across a number of timescales ranging from "several times per hour" to "never". It is

intended to be a retrospective assessment of behaviors over the past 14-day period, with one of the options being “less than once a week”, though in the present context the time span of interest was one week.

Cornell Scale for Depression in Dementia (CSDD)
The Cornell Scale for Depression in Dementia (Alexopoulos, et al., 1988) is a 19- item scale that assesses the severity of each item that the observer is able to evaluate on a 3-point scale.

Other dependent measures
The Mini Mental State Exam (MMSE; Folstein, Folstein, & McHugh, 1975) is one of the most widely used scales for assessing cognitive functioning in dementia. Here we used it as a reference point for purpose of comparison with other studies as well as to assess whether any general cognitive changes occurred as a result of the music treatment program. Because the primary focus of this study was on behavioral and emotional disturbances rather than specific cognitive functions, we did not pursue more detailed assessment of cognitive functions.

Results

The treatment and control groups were well matched in age, gender, diagnosis type, and their MMSE scores (Table 1). A mixed-model ANOVA of the MMSE scores found no significant difference between groups [$F(1,36)=1.57$, n.s.], no significant effect of time point and no interaction of group and time. The range of MMSE scores in both groups showed that the range of dementia was severe to moderate, but the mean scores were indicative of severe dementia.

Behavioral measures
Changes in mean composite scale scores for the NPI, CSDD, and CMAI across the study period are shown in Figure 1. Three primary effects are evident in the data. First, composite scores were lower for the AM observations than for the PM observations. Second, scores decreased during the intervention period relative to the pre-intervention baseline. Especially in the case of the AM observations, the reductions in scores were rapid, beginning in the first week of the intervention. Third, there were no clear differences between treatment groups in general. That is, those assigned to the control group exhibited reductions in symptom severity that were comparable to those assigned to the music treatment group. As indicated in the Discussion section, the strict distinction between “treatment” and “control” groups was blurred on account of the amount of exposure to music that control group residents could receive incidentally by wandering around the facility or entering the rooms of residents whose music they liked. Thus, the groups might be better characterized as “direct” and “indirect” treatment groups, and are referred to as such in the figures.

Discussion

The objective of this randomized controlled study was to assess the impact of a large-scale 12-week music intervention deployed in a single assisted-living residential facility specializing in memory care. We hypothesized that those residents who were played customized music programming in their rooms several times per day (~3 hours/day) every day would show reductions on measures of anxiety, agitation, and depression, whereas those who did not receive music programming would not. Overall, we observed strong reductions (27–54%) in symptom severity in both groups. The reductions were noticeable shortly after the onset of the music intervention in the facility (Figure 1.). Thus, a music treatment program that provides multiple different music streams throughout a facility several times a day appears to have a positive impact on all of the residents, even those who have not been directly designated to receive music.

Conclusions

The present study found significant amelioration of agitation and depression among assisted living facility residents with moderate to severe dementia in response to customized music programs streamed throughout the facility several times per day on a daily basis. Music programs designed to directly impact individuals assigned to a music treatment group also had a positive effect on individuals assigned to a non-music control group due to the overall presence and easy accessibility of music in the facility. Further experiments are warranted to confirm that a pervasive culture of music throughout a facility leads to generalized reductions in agitation, anxiety, and depression.

Table 1. Participant summary information

Treatment	**Control**	**Music**
#participants	19	19
Age (y)	81.7 (7.5) [69-97]	80.9 (9.6) [56-93]
Diagnosis		
Alzheimer's Dementia	14	12
Frontotemporal Lobe Dementia	1	1
Lewy Body Dementia	2	2
Vascular Dementia	2	2
Early onset Alzheimer's Dementia	0	2
MMSE (pre)	4.9 (5.4) [0-19]	7.5 (5.8) [0-19]
MMSE (during)	4.2 (5.5) [0-16]	6.5 (5.3) [0-16]
MMSE (post)	4.5 (6.4) [0-19]	6.7 (6.2) [0-19]

Note: Values in parentheses are standard deviations. Values in brackets are ranges. Values for #participants and diagnosis types are counts, other values are means.

Table 2. Percentage reductions in least-square mean estimates of composite scores on three behavioral assessments collected both in the morning (AM Shift) and late evening (PM Shift).

	AM Shift			PM Shift		
Behavioral Measure	Baseline (Wk 1–2)	Weeks 11–14	Change (%)	Baseline (Wk 1–2)	Weeks 11–14	Change (%)
Neuropsychiatric Inventory	7.04	4.16	-40.87	7.58	5.49	-27.57
Cornell Scale for Depression in Dementia	4.67	2.15	-54.03	5.22	3.69	-29.42
Cohen-Mansfield Agitation Inventory	21.82	11.36	-47.93	18.79	12.67	-32.56

Figure 1.

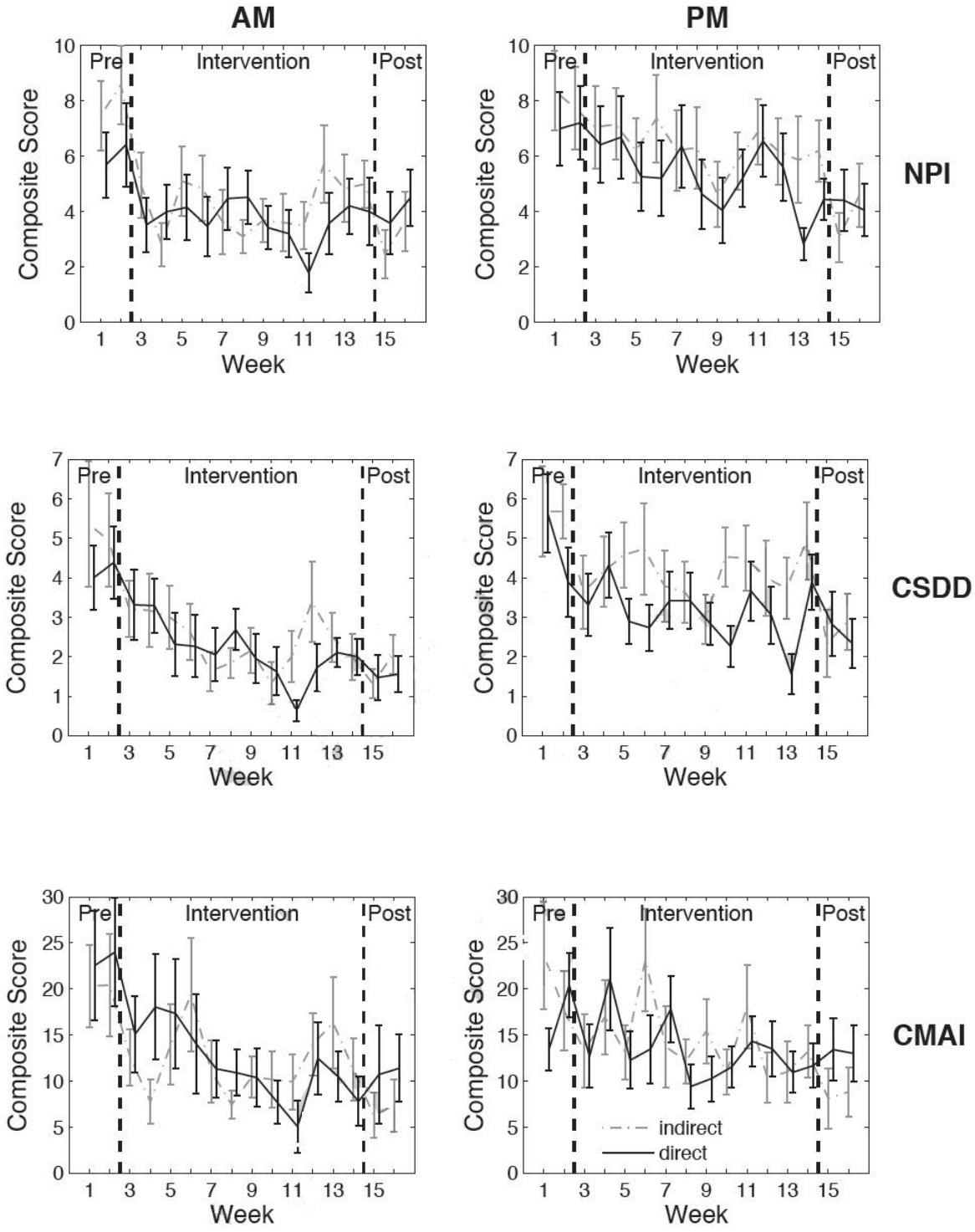
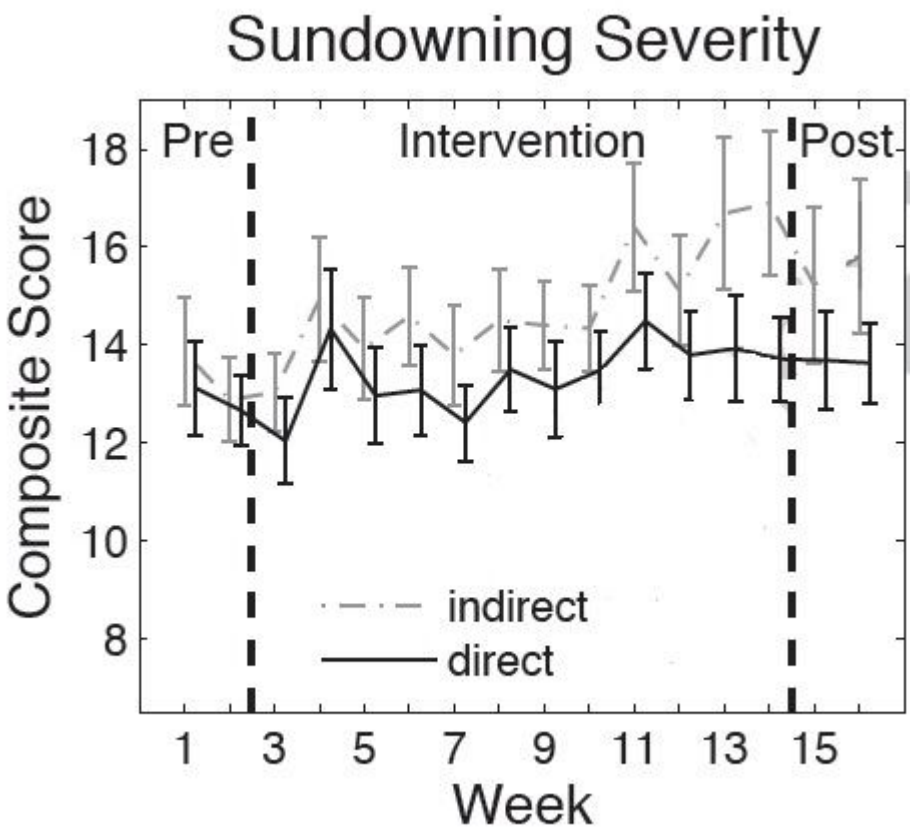

AM
PM
NPI
CSDD
CMAI
Pre
Intervention
Post
Composite Score
Week
indirect
direct

Figure 2.


Sundowning Severity
Pre
Intervention
Post
Composite Score
18
16
14
12
10
8
indirect
direct
1
3
5
7
9
11
13
15
Week