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5-1-2016

# Music therapy in patients with dementia and behavioral disturbance on an inpatient psychiatry unit: results from a pilot randomized controlled study.

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#### Citation of this paper:

Thornley, Joanna; Hirjee, Hussein; and Vasudev, Akshya, "Music therapy in patients with dementia and behavioral disturbance on an inpatient psychiatry unit: results from a pilot randomized controlled study." (2016). *Psychiatry Publications*. 29. https://ir.lib.uwo.ca/psychiatrypub/29 doi:10.1017/S1041610215001866

### Music therapy in patients with dementia and behavioral disturbance on an inpatient psychiatry unit: results from a pilot randomized controlled study

#### Background

The prevalence of dementia continues to grow worldwide due to an aging population and is projected to affect 65.7 million people by 2030 (World Health Organization, 2012). Behavioral and psychological symptoms of dementia (BPSD), including agitation, anxiety, aggression, depression, and psychosis, can occur in as much as 80% of the affected population, frequently necessitating psychiatric admission. Traditionally BPSD have been treated using pharmacological approaches. However, such medications could have serious adverse effects and additionally have limited efficacy in reducing such symptoms (Ballard *et al.*, 2009).

There is some evidence that music therapy (MT) may be an effective non-pharmacological treatment for BPSD as it has been shown to reduce aggressive behavioral symptoms and anxiety, while improving mood and quality of life in patients with dementia residing in nursing homes (Chang *et al.*, 2010; Vink *et al.*, 2013). However, there is no evidence of MT offering benefit in this population in a psychiatric unit. The aim of this pilot randomized controlled study is to determine the feasibility and effectiveness of MT on BPSD in patients with dementia in an acute psychiatric inpatient setting.

#### Methodology

Approval was received from the Western University Research Ethics Board. Participants were recruited from patients over the age of 50 years with an ICD-10 diagnosis of dementia admitted to an acute inpatient psychiatric unit within a large academic hospital in Ontario, Canada. Additional inclusion criteria encompassed scores of  $\leq 13$  on the Mini-Mental State Examination, indicating a baseline of moderate to severe cognitive impairment,  $\geq 2$ on the Clinical Dementia Rating (CDR) scale,  $\geq 3$ on distressing behaviors from the Neuropsychiatric Inventory-Clinician version (NPI-C) and  $\geq 45$ on the Cohen-Mansfield Agitation Inventory (CMAI). Participants were recruited for the study by AV, the investigator psychiatrist, who provided the letter of information and evaluated the patient's competency to consent. Of the patients approached, only 3 (19%) were assessed to be competent to provide consent themselves; 13 participants (81%) had consent provided by their substitute decision maker (SDM). In the province of Ontario, the patient's SDM is responsible for understanding the details of a particular treatment and recognizing the consequences of choosing it or not.

Participants were randomized to either a MT treatment group or Active Engagement Intervention (AEI) using an online randomization program. The sequence of allocation was concealed from the inpatient staff and clinical raters. A power calculation was completed using  $\alpha$  of 0.05 and power of 80%, which required 16 participants in each group to identify a difference of one standard deviation between the mean total CMAI scores between the two groups.

Participants in the MT group received up to eight hours of face-to-face MT from an accredited music therapist over four weeks of bi-weekly, hour-long sessions. All MT and AEI sessions were completed individually. The participants were encouraged to actively engage in the musical process and to follow the music therapist's lead. Participants were provided with specific instructions on how to participate by singing and/or playing simple instruments, including maracas and small drums. The music was selected in accordance with participant preferences and was of a calming nature. The music therapist indicated that most participants engaged in a meaningful way. Participants in the AEI group received up to eight hours of active engagement and attention from a social worker, including supportive interviewing and encouragement of expression through simple occupational activities including folding towels and browsing magazines.

Change in severity of BPSD was assessed using the NPI-C and CMAI for each participant, at baseline and weekly, within 24 hours of the last session, for up to four weeks. Raters came from a pool of trained outpatient psychiatric nurses and social workers masked to treatment allocation. Data were analyzed using a mixed model analysis of variance with repeated measures using IBM SPSS 21 (IBM Corp., USA). If patients participated in less than the eight sessions, all outcome data were treated as Last Observation Carried Forward (LOCF).

#### Results

A total of 25 participants were screened, of whom 9 did not meet eligibility criteria. Of the 16 participants recruited to the study, 10 were allocated to the MT group and 6 to the AEI group. From the sample, 11 (69%) were diagnosed with Alzheimer's Dementia, 3 (19%) with Vascular Dementia, and 2 (13%) with Dementia with Lewy Bodies. The mean  $\pm$  SD age of participants in the MT group was 83.5  $\pm$  7.7 years and 68.4  $\pm$  5.2 years in the AEI group (p < 0.05). Other than the age of participants, treatment arms did not differ significantly with respect to gender, education, marital status, type of residence at admission, number of past psychiatric admissions, smoking status, and extent of medical comorbidities. All of the participants received at least one psychotropic medication during their hospital admission. The commonest psychotropics, used by 25% or more participants, included Haloperidol, Quetiapine, Risperidone, and Trazodone. At baseline, the mean  $\pm$  SD MMSE score was 7.3  $\pm$  6.3 in the MT group, and 5.7  $\pm$  3.4 in the AEI group (p = 0.59), while the mean  $\pm$  SD CDR score was 16.7  $\pm$  2.4 in the MT group and 17.0  $\pm$  0.8 in the AEI group (p =0.80).

The baseline mean  $\pm$  SD CMAI score was 67.8  $\pm$  17.1 in the MT and 64.2  $\pm$  19.5 in the AEI groups. We observed a non-significant decrease in the CMAI scores in both the MT (54.3  $\pm$  12.8) and AEI (56.2  $\pm$  20.4) groups after the first week (p > 0.05). However, there was subsequent deterioration on the CMAI scores over the following three weeks; at the end of study period, scores were 84.3  $\pm$  28.7 in the MT group and 79.0  $\pm$  34.1 in the AEI group.

Mean total NPI-C and Caregiver Distress scores were higher for the MT group at both baseline (MT =  $38.2 \pm 24.3$ ,  $11.8 \pm 5.9$  vs. AEI =  $32.8 \pm 12.9$ ,  $8.8 \pm 5.8$ ) and after one week (MT =  $30.2 \pm 15.9$ ,  $6.9 \pm 5.3$  vs. AEI =  $25.3 \pm 12.5$ ,  $6.2 \pm 1.6$ ) but there were no significant differences (p > 0.05) between treatment groups at any of the time points. Some of the individual behavior items, including delusions, elation, and motor disturbances, showed differences between the treatment groups; however, these were inconsistent in both direction of effect and relationship with time.

#### Discussion

It is realistic to offer MT to patients with BPSD on a busy inpatient psychiatry unit; however, our pilot data suggest that it may not be superior to active engagement. These results seem to contradict current evidence showing the benefit of MT for individuals with BPSD in nursing home settings. The lack of benefit of MT in our study could be related to the more severely affected sample as reflected by the high baseline CMAI and NPI-C scores. We suspect participants were unable to meaningfully engage in the intervention.

The major limitation of this study is the small sample size, as only 16 participants were recruited before human resource changes in the psychiatric inpatient unit made further recruitment untenable. It is possible that the study was further underpowered as previous research indicates effect sizes of MT equal to approximately half an SD (Ueda et al., 2013), requiring a sample of 55 participants in each arm. However, we felt that a single SD difference would be considered more clinically relevant. Regardless, future studies aiming to investigate MT in acute psychiatric inpatient settings would likely need to be multi-centered due to the difficulty in recruiting sufficient eligible participants. A second limitation was the varying duration of patient stay and treatment. A number of the patients enrolled in this study were hospitalized for two to three weeks, which limited the amount of data that could be collected. Finally, the intention of this controlled trial was to have participants engage with one another during treatment sessions. However, due to the small sample size and availability of patients who met the eligibility criteria, MT sessions occurred individually on all occasions.

Additional large scale RCTs are needed to assess if MT does improve BPSD in patients with dementia in acute psychiatric care. There were no adverse events experienced by the participants in either group, which supports the future potential for therapeutic benefits gleaned from additional RCTs. Subsequent studies should consider increasing the frequency of therapy sessions to see if the initial benefits of the therapy are sustained. Our results can be considered preliminary evidence of the feasibility of MT interventions in acute care settings.

#### **Conflict of interest**

None.

#### **Acknowledgments**

We would like to thank the Behavioral Supports Ontario program for providing us some seed money to complete this project. Additionally, we are indebted to all the raters and participants without whom this study could not have been accomplished.

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