Therapeutic Touch in the Management of Responsive Behaviors in Patients with Dementia

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Abstract
Introduction: This study aimed to investigate the use of therapeutic touch (TT) in the management of responsive behaviors in patients with dementia. Methods: A randomized, double-blinded control trial was used to compare response to TT in a population with responsive behaviors in dementia, in 3 phases, pretreatment, treatment, and posttreatment each lasting 5 days. The participants were divided into three groups: experimental, placebo, and control. The experimental group received regular TT, the placebo group received mimic TT, and the control group received regular routine care. Behavior was observed and recorded by trained research assistants every 20 min during the study time throughout each of the phases. Modified Agitated Behavior Rating Scale (ABRS) and Revised Memory and Behavior Check (RMBC) scores were used to assess the behavioral symptoms of dementia throughout the study. Results: All groups had decreasing RMBC scores during the pretreatment period, however; the experimental TT group was the only group whose RMBC scores continued to decrease during the treatment period. All groups had a similar pattern of rates of change in ABRS scores over the 15-day period, with no differential pattern of results related to experimental TT. Conclusion: Despite limited evidence, TT should be explored as an adjunctive therapy for reducing behavioral symptoms in individuals with dementia. Further research is needed to determine the effects of TT on responsive behaviors in dementia. There is a need for studies with larger sample sizes, equal distribution of participants between groups (in terms of dementia stages), and longer post study follow-ups.

Introduction

In 2015, more than 47 million individuals lived with dementia. That number is projected to double every 20 years in the future [1]. An estimated 90% of individuals with dementia experience various behavioral symptoms over the course of their illness, which greatly affects their quality of life, and takes a physical and emotional toll on...
family and caregivers. Management of those symptoms is important because a lack of treatment can lead to disease progression, functional decline, repeated falls, longer hospitalizations, misuse of medication, and a decline in the individual’s quality of life [2].

Antipsychotics used to treat behavioral symptoms of dementia have many negative side effects, including an increased mortality risk [1]. Studies have shown that even commonly used drugs such as trazodone and benzodiazepines are no safer than other atypical antipsychotics [2, 3]. There have been many initiatives to decrease antipsychotic use, and antipsychotics are no longer recommended as a first choice for treating responsive behaviors in patients with dementia (RBD) [4]. A recent study even found nonpharmacological interventions are more efficacious than pharmacological interventions for reducing aggression and agitation in adults with dementia [5]. Outdoor activities and touch therapy were most effective in reducing verbal aggression [5]. These findings demonstrate the importance of person-centered care in this frail population. Multidisciplinary assessments are the optimal first course of action and persons with dementia and caregivers should be provided with information about the benefits of nonpharmacological interventions [6]. This shift away from pharmacological interventions presents a need for further research into possible nonpharmacological treatments.

Therapeutic touch (TT) was developed by Dolores Krieger and Dora Kunz in the 1970s [7]. It is a modern utilization of ancient healing practices. TT is based on the idea of universal life energies and that a person’s energy field is balanced in health and imbalanced in disease. TT consists of three phases: centering, assessment, and treatment. In the centering phase, the healer achieves inner calmness and prepares to be of service to the patient. This phase can be achieved by quiet meditation or by taking deep breaths to relax the body. During the assessment phase, the practitioner places their hands a few inches away from the client’s body and accesses their energy field, achieving a sense of their field and any possible imbalances. During the treatment phase, the healer uses rhythmical and symmetrical movements of the hands to rebalance any disturbed flows of energy [8].

Recently, TT has risen in popularity, being used to treat wounds, decrease pain in postoperative patients, relieve migraine headaches, reduce anxiety, relieve dyspnea, improve sleep quality, and increase function in patients with arthritis [3–6, 9, 10]. However, limited studies have been conducted on its effectiveness. Although some studies have shown preliminary evidence for the use of TT to reduce agitation in patients with dementia [11, 12], insufficient data exist, and further studies need to be conducted before definite conclusions can be drawn [8]. New knowledge on this subject would address present gaps in the literature, as well as possibly provide evidence-based rationale for the development and implementation of educational materials for this method. This study aimed to investigate the use of TT in the management of RBD.

Materials and Methods

Design

A randomized, double-blinded control trial was used to compare responses to TT in a population of long-term care residents with RBD. All participants were permanent residents of SageCare long-term care dementia institution. Participants were randomized into three groups: experimental, placebo, and control. The experimental group received regular TT, the placebo group received mimic TT, and the control group received regular routine care. When administering the mimic treatment, TT practitioners stimulated the movements of TT; however, made no attempt to achieve inner calmness nor interact with the participant’s energy field.

The study consisted of pretreatment, treatment, and posttreatment phases each lasting 5 days. Behavior was observed and recorded by two trained research assistants every 20 min from 7 a.m. to 5 p.m. throughout each of the phases. This study received approval from the Research Ethics Committee.

Procedure

The Mini-Mental State Exam (MMSE) was used to screen participants for the study, as well as to obtain a baseline level of cognitive impairment. The MMSE was administered to all participants prior to or upon enrollment to the study. The total score ranges from 0 to 30, with a lower score indicating an increased level of cognitive impairment. A participant may either have mild (MMSE score of 21–25), moderate (MMSE score of 11–20), or severe (MMSE score of 0–10) cognitive impairment. Inclusion criteria for participants were a diagnosis of dementia according to the DSM IV criteria confirmed by a physician, MMSE score <20, stabilized on medications for at least 1 month, and resided on the unit for at least 2 months prior to study implementation and for the duration of the study. Exclusion criteria for participants included an acute psychiatric or physical illness diagnosed within a 3-month period.

The research assistant obtained informed written consent was received from each participant’s proxy who was legally responsible for decision making on their behalf. Verbal assent was also obtained by the practitioner from each participant before intervention for the TT and mimic TT groups. If the participant refused, intervention did not proceed. A total of 50 participants were enrolled in the study, one of which refused intervention.

During the treatment phase, the experimental group received regular TT twice daily, between 11–12 a.m. and 3–4 p.m. TT was performed by trained TT practitioners, and each intervention lasted about 5 min. The control group was not approached for TT intervention, instead receiving regular routine care at the same time intervals. The placebo group received a simple touch non-TT
mimic treatment resembling TT twice daily, between 11–12 a.m. and 3–4 p.m. Before placebo intervention, participants were approached in the same manner as the experimental group and intervention also lasted 5 min. Placebo intervention was performed by the same TT practitioners.

TT was administered in three phases: centering, assessment, and treatment. In the centering phase, the TT practitioner achieved inner calmness and prepared to be of service to the participant. This phase was achieved by taking deep breaths to relax the body. During the assessment phase, the TT practitioner placed their hands a few inches away from the participant’s body and accessed their energy field, achieving a sense of their field and any possible imbalances. During the treatment phase, the TT practitioner used rhythmical and symmetrical movements of the hands to rebalance any disturbed flows of energy.

**Outcome Measures**

The modified Agitated Behavior Rating Scale (ABRS) was used throughout the study to measure frequency and intensity of the behavior symptoms of dementia. The scale includes five categories of behavior: manual manipulation, escape of restraints, searching/wandering, tapping/banging, and vocalization. The frequency and intensity of each behavior were recorded. Frequency was given a score from 0 to 5, with higher scores representing a higher frequency of occurrence, while intensity was given a score from 0 to 3, with higher scores meaning the behavior was present to a more extreme degree. A total score range of 0–15 was possible for each behavior, by multiplying the frequency score by the intensity score.

The Revised Memory and Behavior Check (RMBC) was used throughout the study for assessing behavior symptoms of dementia, in addition to identifying mood changes and suspected depression. It is a 24-item checklist where the score for each item ranges from 0 to 4; a higher rating indicates more frequent problems. A total score ranges from 0 to 96. Only total scores were used for analysis.

Both ABRS and RMBC have been shown to be valid tools for measuring behavioral response. Studies have shown the ABRS to be predictive of change in cognitive status [8] and able to differentiate confusion and inattention [13, 14]. The RMBC is recommended as a reliable and valid tool for the clinical and empirical assessment of the presence of behavior problems in dementia patients. Both ABRS and RMBC have been shown to be consistent with the Cohen-Mansfield Agitation Inventory, another commonly used tool for measuring agitated behaviors in persons with dementia [9].

**Analysis Methods**

Descriptive summaries of the data include means and standard deviations (SDs) for continuous variables and proportions for categorical data. Analysis of variance was used to compare groups for continuous variables such as age and baseline RMBC. Length of stay and ABRS have skewed distributions, so the nonparametric Kruskal-Wallis test was used. Fisher’s exact test was used to compare categorical variables such as sex and dementia severity.

A spline regression model was used to explore average daily total scores for each outcome measure and compare groups across the 15-day period. The truncated power function basis with a degree of 1 was used in the spline modeling of day with knots at day 5 and 10. This model allows for the comparison of intercepts and linear slopes (or the rate of change in the outcome) within and across the 5-day periods. Random intercepts and a variance component correlation structure were used to adjust for repeated measures within study participant. The models also included a main effect for group with the placebo control group the reference category.
egory and an interaction term of group and day. There were no model adjustments made for other patient characteristics. Contrast statements were used to test group differences in rate of change or switching of rates of change within and across pre-, during, and posttreatment periods, respectively.

The study outcomes were mostly complete. One patient was missing the outcome measures for 2 of the 15 days. All recorded measures were included in the spline regression models, and there were no additional sensitivity analyses to assess impact of missing data. There was no adjustment made for multiple testing. The data analysis for this paper was generated using SAS/STAT software version 14.1 and the SAS System for Windows version 9.4. Copyright © 2012 SAS Institute Inc.

Results

Analysis was completed on 49 participants after dropping the case that refused intervention. All participants were admitted to the institution from 2012 to 2018, and their demographic characteristics are depicted in Table 1. Participants had average age of 88.7 (SD = 6.8) years with the majority being female (84%) and Asian (98%). About 63% were widowed, while the remaining 37% were married or divorced. The average age was 88.7 (SD = 6.8). The majority of participants had severe dementia (67%; Fig. 1), with the remaining categorized as moderate (22%) and mild (10%).

The most frequent descriptions of type of dementia were “dementia in Alzheimer’s” (45%, Fig. 2), “unspecified Alzheimer’s” (31%), and “unspecified dementia” (14%). Less frequent descriptions (<5% each) (Fig. 2) were “vascular dementia,” “FTD,” “multi-infarct dementia,” and “dementia in Parkinson’s.” A large proportion of participants were receiving antidepressants (45%) and antipsychotics (47%). There were no observed group differences for each drug type (Table 1). These treatments could be received in combination.

RMBC Scores

The baseline RMBC scores were significantly higher for experimental TT group (mean score 9.0, SD = 1.4, p < 0.0001, Table 1), who had a larger proportion of participants with severe dementia (77%). The mean baseline RMBC scores for all of the groups were relatively low (compared to the maximum score of 96). These low scores may have been related to the participant’s behavior being controlled by medications. All participants in this study were stabilized on medications for at least 1 month, which may have reduced their responsive behaviors. Furthermore, these low scores could be attributed to severe cognitive impairment, especially in the experimental group.

Modeling results indicate that the control and mimic TT groups had a significant decline in RMBC scores in the pretreatment period (p < 0.0001 and p = 0.002, respectively, Table 2; Fig. 3). The experimental group also had a nonsignificant decline (p = 0.16) in RMBC scores. The control and mimic TT groups switched from decreasing
scores in the pretreatment period to increasing scores in the treatment period ($p < 0.0001$ and $p = 0.01$). The experimental TT group continued to have decreasing scores over both these periods and the rates of change are not significantly different ($p = 0.20$). The experimental TT group switches from decreasing scores to increasing scores from the treatment period to the posttreatment period ($p < 0.0001$). But there is no significant switch in rates for the other two groups ($p = 0.07$ and $0.66$, respectively). These group patterns were significantly different ($p = 0.0004$).

**ABRS Scores**

The baseline ABRS scores were the highest for experimental TT group (mean score 1.3, SD = 1.6), but these group differences were not significant ($p = 0.22$). Similar to the RMBC scores, the mean baseline ABRS scores were also relatively low. Once again this could be attributed to the participant’s behavior being controlled by their medications, as well as severe cognitive impairment, especially in the experimental group may contribute to the highest baseline ARBS. All participants in the study were stabilized on medications for at least 1 month, based on the inclusion criteria prior to study initiation which may control their responsive behaviors.

Modeling results indicate that the control, experimental, and mimic TT groups switched from decreasing scores in the pretreatment period to increasing scores in the treatment period ($p = 0.03$, $p = 0.03$, and $p = 0.13$, respectively, Table 3; Fig. 4). These group patterns were not significantly different ($p = 0.82$). Then all groups nonsignificantly switched from increasing scores in the treatment period to decreasing scores in the posttreatment period ($p = 0.62$, $p = 0.26$, and $p = 0.30$). These group patterns were not significantly different ($p = 0.94$).
Discussion

The results of this study are mixed. All three groups had a decline in RMBC scores in the pretreatment period. The experimental TT group was the only group to continue to have a decline in RMBC scores during the treatment period and then switch to increasing scores in the posttreatment period. The experimental TT group’s rate of change in RMBC scores into a decrease of −0.80 in the mean RMBC score over the 5-day treatment period. When standardized by the SD for the experimental TT group at baseline, this is considered a medium effect size of −0.57 standardized units over 5 days. Using similar calculations for ABRS, the experimental TT group had an increase of 0.13 standardized units (a small effect size) during the same 5-day treatment period.

It is important to consider why only the experimental RMBC scores declined during the treatment period. While this may have been due to TT intervention, the RMBC scores for the experimental TT group were higher at baseline (likely due to a larger proportion of participants with severe dementia) and may have had more opportunity to decrease over time. However, similar studies have also found a decrease in responsive behaviors shortly after TT intervention [11] indicating this decrease may have been due to immediate effects of TT.

For the experimental TT group, the RMBC scores began increasing in the posttreatment period. Other studies have also observed an increase in responsive behaviors in the 1–1.5 days postintervention [12, 15], suggesting there are minimal residual effects of TT after treatment. This suggests a need for ongoing supportive treatment to effectively reduce behavior using this nonpharmacological approach. It is also possible that the experimental TT RMBC scores may have continued to decrease if treatment had continued past the 5-day treatment period, as these scores only began increasing when treatment stopped.

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Limitations
The generalizability of this study was limited by the small sample size of this cohort and short follow-up, as well as the characteristics of the participants, specifically that the vast majority of participants were female and Asian. The experimental group also had the largest proportion of participants with severe dementia and had the highest baseline RMBC and ABRS scores. Based on these differences in RMBC scores at baseline the reported outcomes of this study could be questioned.

Further Research
Additional research is needed to overcome some of the limitations of this study. Future randomized controlled studies with larger sample sizes, equal distribution of participants between groups (in terms of dementia stages), and longer post study follow-ups are necessary to draw concrete conclusions on the impact of TT in the management of responsive behavior in dementia patients. Additionally, exploring the relationship between the behavioral response to TT of different subtypes and severity of dementia in the presence or absence of medications and the impact of sex, age should be considered. Specifically, future research should focus on the isolated impact of TT to participants with mild, moderate, and severe dementia to differentiate and assess the value of TT on different severities of cognitive impairment.

Conclusion
While the results for this study were mixed, they suggest a need for further research into the effects of TT and its long-term impact. Other studies have shown preliminary evidence for the potential use of TT in reducing agitated behaviors in individuals with dementia. Specifically, TT may be beneficial for reducing common behaviors of agitation such as wandering, restlessness, and vocalizations.

TT can be taught to family members, staff, and even volunteers and can be used as a supportive therapy in any setting. Using TT may help to calm agitated individuals with dementia and enhance communication with staff, especially as it is a nonpharmacological intervention associated with the absence of negative sequelae. As such, despite the limited evidence TT should be explored as an adjunctive therapy (with or without pharmacological intervention) for reducing behavioral symptoms in individuals with dementia.

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Statement of Ethics
The manuscript complies with guidelines for human studies and was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. This study protocol was reviewed and approved by Baycrest Research Ethics Board, REB approval number 16-56. Written informed consent was obtained from participants and their proxies to participate in the study.

Conflict of Interest Statement
The authors have no conflicts of interest to declare.

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Author Contributions
Helen Senderovich contributed to the conception and design, interpretation of data, drafting of paper, critical revision, final approval, and accountable for all aspects of the published work. Sandra Gardner contributed to the data collection, analysis and interpretation of data, drafting of paper, and critical revision of the manuscript. Anna Berall contributed to the analysis and interpretation of data, drafting of paper, and critical revisions of the manuscript. Rosanne Aleong contributed to the conception and design of the manuscript. Vincent Santaguida contributed to the data collection, interpretation of data, drafting of paper, and critical revision of the manuscript.

Data Availability Statement
All data generated or analyzed during this study are included in this article. Further enquiries can be directed to the corresponding author.
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