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Is massage therapy effective at reducing negative behaviors in patients with dementia?

Casey Reid
Philadelphia College of Osteopathic Medicine

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Casey Reid, PA-S

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ABSTRACT

Objective: The objective of this selective EBM review is to determine whether or not "Is massage therapy effective at reducing negative behaviors in patients with dementia?"

Study Design: A systematic review of three randomized control trials (RCTs) published between 2014 and 2018.

Data Sources: All three sources were discovered using PubMed. The articles were published in English, in peer-reviewed journals, and selected based on applicability to the clinical question.

Outcome Measured: A reduction in the number of negative behaviors performed by patients with dementia was the outcome measured in all three studies using the Cohen-Mansfield Agitation Inventory-Short Form (CMAI) or Campbell Scores. The CMAI is a 0 to 5 scale that rates how often certain agitated behaviors are performed. The Campbell score is based on anxiety and chronic pain severity ranging from 0 to 6.

Results: In the RCT by Rodriguez-Mansilla, a Campbell score mean change from baseline in the intervention group was -0.57 and the control group was 2.20, with the p-value <0.001. In the RCT conducted by Moyle et al., the mean change from baseline for the CMAI score in the intervention group was 1.28 compared to the control group with 7.82. The p-value was 0.03. Lastly, in the Schaub et al. RCT, the mean change from baseline for the CMAI score in the intervention group was 1.1 and 1.7 for the control group. There was no p-value given for the results reviewed in this study, making the significance of this answer unknown.

Conclusions: Taking into account all three studies in this review, the evidence is inconclusive in determining if massage therapy reduces negative behaviors in patients with dementia. The study by Rodriguez-Mansilla et al. showed that massage therapy did decrease the negative behaviors but the two studies by Schaub et al. and Moyle et al. showed that massage therapy did not decrease the negative behaviors in patients with dementia.

Keywords: dementia, massage therapy

INTRODUCTION

Dementia is a widespread public health concern in the United States and worldwide. It is an essential topic to review because it is estimated that about 47 million people worldwide and five million people in the United States are living with this disease, and these numbers are still increasing.[1] It is also predicted that about 131 million people will have dementia by 2050.[1] The defining features of dementia are experiencing a loss of at least two cognitive abilities that were once able to be done by a patient. These abilities include memory, language, visuospatial, mood, and executive functions.[1] The cause of dementia can be due to brain injury or brain disease and is most commonly seen in patients over the age of 65.[1] About 15% of adults over the age of 68 currently have dementia, which shows that this older population is the one most affected.[1]

Dementia is a considerable health concern worldwide, and comes with many attendant expenses. A study found that one patient with dementia will receive more than $250,000 worth of medical care within five years from diagnosis.[2] The annual estimated cost for all patients with dementia ranges from $157 billion to $215 billion.[3] Another study found that a patient with dementia will have approximately $56,000 more spent on their health care in one year compared to a patient without dementia.[2] These monetary estimates show how extensive the impact of this disease is on the healthcare industry.

Dementia is a complex disease and many patients require multiple types of medical and support services. In addition to standard medical therapies, patients often require services that aid their physical quality of life, social and emotional support, social services, and even caregiver support.[4] The family and caregivers of these patients need their own supporting services for the emotionally draining long hours of care these patients need.[3] There is no exact number given for the amount of healthcare visits a patient with dementia typically requires. However, by seeing

how many different areas of care are needed for one patient with dementia, assumptions can be made that the number of healthcare-related visits is high.

Dementia is a disease that continues to challenge our current medical knowledge. Common causes of dementia include cerebrovascular disease, atherosclerosis, arteriosclerosis, white matter changes, and neocortical Lewy body disease.[5] Most patients will have a mixture of different pathologies, especially older patients.[5] Therefore, in many cases, the etiology is not entirely known due to the mixed pathology nature of this disease. There are also specific, known risk factors that lead to dementia. These risk factors include genetics, sociodemographic and behavioral factors, physical and cognitive activities, diet and nutrition, sleep, psychological factors, and medical factors.[5]

Behavioral and psychological symptoms caused by dementia are a substantial aspect of this disease. These symptoms are typically treated with pharmacological interventions, while isolation and physical restraints are also employed at times.[6] Antipsychotics are used most commonly to treat the negative behaviors and feelings of dementia.[6] Antipsychotic medications are effective; however, they come with adverse side effects such as increased mortality, falls and pill burden.[6] Using physical restraints to decrease negative symptoms presents ethical dilemmas.[6] The treatment method of massage therapy for this patient demographic is being proposed because studies have shown that sensory approaches may work better than pharmacological interventions in those with dementia.[7] Massage therapy is a way to activate these patients' emotional and social areas of the brain through touch to decrease negative behaviors.[7] This therapy rarely has harmful side effects and doesn't involve taking another medication, making it an intriguing player in treating dementia. This paper examines three different randomized control

trials (RCTs) for whether massage therapy is a beneficial management for reducing negative behaviors in patients with dementia.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not "Is massage therapy effective at reducing negative behaviors in patients with dementia?"

METHODS

The studies discussed in this review were all found on Pubmed, published in a peer reviewed journal using the exact keywords "dementia" and "massage therapy." Their applicability to the clinical question allowed them to be selected. They include patients with dementia as the population, massage therapy as an intervention, and decreased negative behaviors as the outcomes. They were also chosen because the control groups had routine care with no massage therapy. The articles were all in English, randomized control trials, and were published after 2011. The exclusions for the searches were observational studies and the measurement of only depression. The measurements used to summarize statistics in all three studies were the mean changes from baseline and p-values.

OUTCOMES MEASURED

The studies performed by Schaub et al. and Moyle et al. both used the CMAI (Cohen Mansfield Agitation Inventory-Short Form), which documents the levels of agitation. This form is filled out by the staff working directly with the dementia patients. It rates each patient's agitated behaviors on a scale of one to five with numbers correlating to how often the agitated behavior occurs collectively over a 2 week period. A score of one means the behavior never occurs and the number five means the behavior occurs a few times in an hour or continuously for 30 minutes with numbers in between showing respective amounts of agitated behavior.[8]

Researchers add together the scores for all the different behaviors to calculate the total score. In the Shaub et al. article, a 29-item agitation rating version of the CMAI was used, and in the Moyle et al. article, a 14-item agitation rating version was used.[8,7] Both were completed by nurses working directly with the patients. Schaub et al. used the CMAI scale to measure agitation levels before each massage at 2 pm and for ten minutes post-massage at 5 pm.[8] In the Moyle et al. article, the CMAI scale was used to collect data after each massage between 1 pm and 5 pm.[7] Rodriguez-Mansilla et al. utilized the Campbell scale for anxiety and chronic pain, which were the negative behaviors measured in this RCT.[6] The total score expressed how prominent the negative behaviors were. The score of zero correlated to no negative behaviors, 1-3 points showed mild amounts, 4-6 moderate amounts, and more than 6 showed severe negative behaviors, such as anxiety and chronic pain.[6]

Table 1. Demographics & Characteristics of Included Studies

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Rodríguez-Mansilla[6] (2015)	Pilot RCT	120	67-91	Over 65 years old, institutionalization in residential homes and diagnosis of dementia according to the DSM-VI	Having medical contraindications for ear acupressure and/or massage therapy, for example, deep venous thrombosis, thrombophlebitis or major hemorrhages.	9	Anxiety and chronic pain were measured using the Campbell Scale.
Moyle[7] (2014)	RCT	55	74-103	Patients living in longterm care, 65 years and older, moderate to late stage dementia, a Mini-Mental State Examination score of less than 18, and a recent history of agitation indicated on the Pittsburgh Agitation Scale as greater than 3.	Residents with major illnesses that affected foot anatomy or foot pain were excluded	2	CMAI (CohenMansfield Agitation Inventory-Short Form)
Schaub[8] (2018)	RCT	40	Avg Age: M: 81 F: 83	All patients hospitalized in the service who suffered from cognitive impairment were considered eligible for the study if they had a minimum score of 1 on the French version of the CDR	Major known difficulties with body contact, severe psychical decompensation requiring minimal physical stimulation, or wounded hands prohibiting the performance of hand massage.	10	CMAI (CohenMansfield Agitation Inventory-Short Form)

RESULTS

The studies discussed in this review enrolled patients with dementia that were institutionalized or hospitalized due to their condition. Rodriguez-Mansilla et al. included

patients who were over age 65 and institutionalized due to their dementia.[6] They had 120 participants randomly placed into either the intervention or control groups.[6] This was done by a computer random number generator that put patients into groups in blocks of three.[6] The list at the end was only seen by an independent researcher who was not a part of the study.[6] The participants were also kept blinded to the treatments due to their level of cognitive deficiency, according to this study.[6] The assessors were also kept blind from the interventions given to each patient and the purpose of the study.[6] The participants in the intervention group received relaxing massage techniques performed by professional physiotherapists. The massages were done on the lower back and lower limbs for 20 minutes each session and occurred daily from Monday to Friday for three months.[6] The control group just received their routine care.[6] This study occurred over five months with three months having the intervention performed and a two month follow up. The last two months were used to see if the treatment effects would last after the massage therapy ended.[6] Five patients were lost in the intervention group, and four were lost in the control group due to death.[6] A worst-case analysis was not performed in this study.[6]

Rodriguez-Mansilla et al. used the Campbell Scale to measure anxiety and chronic pain as negative behaviors.[6] This scale was used to measure the patient's negative behaviors at baseline, each month during the intervention, and for two months follow-up.[6] The mean scores recorded initially and after five months were used to find the total mean change from baseline. The intervention group's pretreatment score was 7.3.[6] The score after five months was 6.8 with a mean change from baseline calculated to be -0.50.[6] Results for the control group were a pretreatment scoring of 6.6 and 8.8 after five months.[6] The mean change from baseline was calculated to be 2.20.[6] The p-values for the intervention group and control group separately were both <0.001, showing that the mean change from baseline for both groups were significant.[6]

Massage therapy alone did decrease negative behaviors and routine care alone increased negative behaviors. The p-value comparing the two groups was <0.03 which is also significant. This means that massage therapy did decrease negative behaviors compared to routine care.[6] The mentioned scores are also shown below in Table 2.

Table 2. Mean Change Campbell Scores from Baseline for Massage Therapy and Control Groups (Rodriguez-Mansilla et al. 2015)

	Mean Campbell score at Baseline	**Mean Campbell score at 5th month**	**Mean change from Baseline**	**P-value**	**Comparison**
Massage Therapy	7.3	6.8	-0.50	<0.001	<0.03
Control Group	6.6	8.8	2.20	<0.001	

The article by Moyle et al. conducted a randomized control trial with patients aged 65 and older who had moderate to late-stage dementia and living in a long-term care facility.[7] The intervention this article examined was foot massages to decrease agitation in patients with dementia.[7] The 55 patients included in this study were randomized using a computer program to put them either in the intervention group or the control group.[7] Therefore, allocation concealment was present.[7] At the end of the three weeks, there were 25 participants in the intervention group and 28 in the control group, due to one patient from each group passing away before interventions started.[7] A worst-case analysis was not performed.[7] The intervention group received foot massages for five minutes on each foot between 1-5 pm Monday through Friday for three weeks.[7] The control group received quiet presence with no conversation or contact during the ten minutes.[7] This interaction was conducted for three weeks when the intervention group was receiving massages.[7] The screening research assistants, data collectors, families, and other care staff were all kept blind. However, nurses giving the foot massages and the patients were not blinded for apparent reasons.[7]

The effectiveness of foot massages on levels of agitation in patients with dementia after three weeks was recorded using mean changes from baseline CMAI scores.[7] The mean score at baseline for the intervention group was 26.48, and the mean score post-treatment after three weeks for the intervention group was 27.76.[7] Therefore, the mean change from baseline for the intervention group was 1.28.[7] The mean CMAI score at baseline for the control group was 28.28, while the mean CMAI score after the three weeks was 36.07.[7] A mean change from baseline was calculated to be -7.82.[7] These values were significant, with the p-value being 0.03 for both groups individually.[7] The 95% confidence intervals given at baseline for both massage therapy and quiet presence show that each group started out very similar. The 95% confidence intervals given posttest show that foot massage did not increase or decrease negative behaviors and quiet presence simply increased negative behaviors.[7] Therefore, based on the mean changes from baseline, the significance of the p-value, and the 95% confidence intervals, this article showed that foot massage did not decrease the level of agitation in patients with dementia.[7] These results are also shown below in Table 3.

Table 3: Change in CMAI Scores from Baseline to 3 Weeks Post Intervention for Foot Massage and Quiet Presence (Moyle et al. 2014)

	Mean CMAI score at Baseline	**95% CI at baseline**	**Mean CMAI score post test**	**Mean change from Baseline**	**95% CI post test**	**P-value**
Foot Massage	26.48	23.05, 29.91	27.76	1.28	23.78, 31.74	0.03
Quiet Presence	28.28	25.05 ,31.45	36.07	7.82	32.30, 39.84	0.03

Lastly, Shaub et al. enrolled about 40 individuals hospitalized with moderate to severe dementia to participate in a three-week study to see if hand massage would decrease their levels of agitation.[8] The 40 participants were randomly allocated using a block randomization size of four to the hand massage intervention group or the control group, which included just the

patient's usual care.[8] There were 20 participants assigned to the intervention group and 20 to the control group.[8] Five patients from each group dropped out during the three-week study, for a total of ten patients lost.[8] This kept 15 participants in the intervention group and 15 in the control group, making them equal at the end.[8] A worst-case analysis was not performed.[8] There was also a slight difference between the Cognitive Impairment Scores among the two randomized groups.[8] The scores for cognitive impairment were higher in the intervention group than in the control group, which shows that they had more severe levels of dementia altogether.[8] The patients and the nurses who performed the hand massages could not be kept blind from the interventions because they could tell if they were getting or giving the massage.[8] In the intervention group, each patient received a total of seven massages during the three weeks. Each massage lasted for eight minutes on each hand and was performed at 2 pm, when the unit was the quietest.[8] The control group received the standard care that they would have any other day.[8]

The levels of agitation in the Shaub et al. article were measured using the CMAI with a 29-item agitation rating completed by the nurses directly caring for the patients.[8] The mean change from baseline for the CMAI scores reported each week in both the intervention and control groups was used to determine if negative behaviors were decreased.[8] In the intervention group receiving the hand massages, the mean CMAI score recorded on the first day of week one was 3.5.[8] The post-treatment mean CMAI score recorded at week three was 4.6.[8] Therefore, the mean change from baseline was 1.1 after three weeks of hand massage therapy.[8] The CMAI mean score for the control group was 2.3 on the first day of week one. The post-treatment mean score at three weeks was 4.0, resulting in a mean change from baseline of 1.7.[8] These results are complicated by the fact that the study did not give a p-value, making it difficult to determine the significance of the results. The agitation levels went up in both groups, which is shown below in

Table 4.[8]

Table 4. Mean Change from Baseline CMAI Scores from Hand Massage and Control Group (Data from Schaub et al. 2018)

	Mean CMAI score at Baseline	Mean CMAI score post test	Mean change from Baseline	P-value
Hand Massage	3.5	4.6	1.1	Not given
Control Group	2.3	4.0	1.7	Not given

DISCUSSION

Most patients hospitalized or institutionalized with moderate to severe dementia are usually under significant pill burden. Taking an antipsychotic for their agitation, anxiety, or uncontrolled behaviors can add to this burden, while also potentially causing harmful side effects. On the other hand, massage therapy may be thought of as a burden of its own due to the treatment requiring more direct intervention by the caregiver. Massage therapy requires the staff to be fully trained in that discipline and adequate time must be included in the schedule to permit massages of sufficient duration for clinical effectiveness.

Two of the articles reviewed in this study showed that negative behaviors were not decreased with the use of massage therapy. In the Schuab et al. article both the intervention group and the control group had increasing levels of agitation noted.[8] In the article by Moyle et al. there was no decrease in agitation in both groups at the end of the study.[7] Even though the control group had an increase in agitation while the intervention group kept the negative behaviors the same, the agitation levels did not decrease in this study.[7] However, in the article by Rodriguez-Mansilla et al., there was an actual decrease in negative behaviors noted in the intervention group.[6] This is compared to the patients in the control group who had increased

negative behaviors.[6] This article's data is significant as shown by the p-value and proved that the massage therapy did decrease negative behaviors in the patients in this study.

The validity of these articles is essential for determining the success or failure of massage therapy in the reduction of negative behaviors. In all three articles, the assignment of patients to either the intervention group or control group was randomized and concealed from the participants, making the groups as even as possible. However, even with randomization, there can be differences in the two groups that can significantly change the outcomes. Specifically, in the Schaub et al. article, the intervention group had higher ratings of cognitive impairment using Clinical Dementia Rating scores.[8] This means that more patients receiving the massage therapy had severe dementia than those in the control group, which could have skewed the results. Another factor contributing to the lack of validity in the Schaub et al. article, was that patients and staff were not blind to the groups receiving each treatment. This was due to the nature of the treatment being physical touch and the CMAI forms being recorded by the staff member giving the massage.[8] Blinding also was unable to be done in the Moyle et al. RCT due to those reasons as well.[7] The assessors in the Rodriguez-Mansilla study were kept blind, unlike the other two articles.[6] This helps increase the study's validity. Lastly, none of the RCTs reviewed did a worst case analysis to account for the patients lost throughout the study.

CONCLUSION

According to the systematic review data, it is not able to be determined if massage therapy decreases negative behaviors in patients with dementia due to conflicting evidence. In the articles by Schaub et al. and Moyle et al., negative behaviors did not decrease over the course of the study making these treatments unsuccessful. However, the Schaub et al. study had no p-value, make it challenging to interpret the results. This study also demonstrated noteworthy

differences in the cognitive impairment levels of the patients in the intervention group, which is an essential factor that should be considered. The article by Rodriguez-Mansilla et al. did show a decrease in negative behaviors in the intervention group with an increase in negative behaviors in the control group. With significant p-values, this successfully shows that massage therapy did decrease negative behaviors in the patients with dementia. By having one strong study show that massage therapy is effective and two other studies show that massage therapy is not effective, it is inconclusive if massage therapy should be implemented in decreasing negative behaviors in patients with dementia.

To increase the validity of the outcomes and reduce bias, future studies should consider extended periods of treatment and recorded observations, to gauge the long-term effects of massage therapy on dementia patients. Using a larger sample size would also increase the accuracy of the RCTs. Lastly, it would be more beneficial if those who were rating the level of negative behaviors performed by the patient was always someone who was unaware of the treatment performed.

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