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Feature Article

Slowing progression of early stages of AD with alternative therapies: A feasibility study

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ABSTRACT

This pilot study identified the feasibility and efficacy of the effect of combining healing touch (HT) and body talk cortices (BTC) on the progression of Alzheimer's disease (AD). Both HT and BTC elicit the relaxation response and support cognitive function from two different perspectives. A two-group, repeated measures design was used. Subjects ($n = 22$), 65 or older with early stage (less than four) AD, residing in the community ($n = 2$) or in care agencies ($n = 20$), were assigned to either the HT-BTC group ($n = 12$) or the control group ($n = 10$) randomized by residence. The treatment group received, 6 months of weekly HT and performed the BTC technique daily. The usual medical regimen for all subjects was continued. The control group had no additional interventions. Both groups were assessed at baseline, 3 and 6 months. The groups did not differ significantly at baseline on cognitive reserve, age, gender, and ethnicity, nor on the outcome variables (cognitive function, mood, & depression). Adherence (76%) to the BTC protocol, the major feasibility problem, related to memory deficits. Significant interactions occurred regarding cognitive function and mood. Significant improvements in cognitive function ($p = .008$), mood ($p = .001$), and depression ($p = .028$) were observed in the treatment group which is not the usual course of AD. A decline in cognitive function occurred in the control group typical of AD's usual course. Although the number of subjects in this pilot study was small, and there were feasibility challenges with recruitment and adherence, important trends were noted suggesting areas for future study.

1. Introduction

The progressive degeneration of the neurons in the cortex and hippocampus in persons with Alzheimer's disease (AD) leads to multiple cognitive deficits. AD is also characterized by AD-related behavioral and psychological symptoms of dementia (BPSD), which are associated with caregiver distress.[1] The behavioral and psychological symptoms of dementia exert a major influence on the quality of life (QoL) of patients and their caregivers.[2,3] Social and health interventions are now considering Qol as one of the main outcomes of pharmacological and non-pharmacological treatments.[4] Many studies suggest that the initial severity and rate of disease progression can predict the course of AD, the less sever, the slower the rate of decline (Drachman et al, 1990; Morris ER, 1993; Kraemer et al, 1994; Stern et al, 1994).[5–8] A direct correlation between cognitive impairment and QoL, reported by patients, has been found to be more evident in the early stages of the disease than the later stages, supporting the importance of maintaining cognitive performance in the early phases of the disease.[9,10] The severity of depressive symptoms has demonstrated a strong reverse association both with self-assessed and proxy-rated quality of life in all stages of dementia[11–15] Several studies have found that patient behavioral problems are stronger predictors of caregiver distress than patient cognitive or functional impairment.[16–18] Up to 50% of persons with AD experience anxiety and depression over the course of the disease.[19] A recent study of early stage AD patients with mild cognitive impairment (MCI) found chronic sever anxiety associated with all types of MCI and core mood depression profiles associated with Clinical Dementia Ratings.[20] A strong association has also been noted between levels of depression, diagnosis and progression of AD.[21]

AD leads to over-activation of the hypothalamic-pituitary-adrenal (HPA) axis and has been found to correlate with smaller hippocampal volume, and cognitive decline.[22] Recent developments in neuroendocrinology suggest that changes in the HPA axis

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alter the responses of persons with AD to stress, making them less able to cope with stressors.[23,24]

Of the treatments available today none have been found to slow or stop the death and malfunction of neurons in the brain which cause Alzheimer's symptoms. Therefore, this disease is still perceived as fatal (AAsso, 2013). The U.S. Food and Drug Administration has approved five drugs which temporarily improve the symptoms of Alzheimer's disease by increasing the amount of neurotransmitters in the brain (AAsso, 2013).[25] Non-pharmacological approaches, (i.e., environmental enrichment, cognitive rehabilitation, fitness training, and reduction in psychological stressors) have produced improvement in function of persons with early stages of AD.[21]

Reports from practitioners of healing touch, a noninvasive, nonmanipulative, standardized biofield therapy, indicate that HT reduces anxiety, and enhances relaxation.[26] Research findings, although limited, have noted that HT significantly reduces distress, and fatigue[27]; improves quality of life, emotional role functioning and mental health[28]; improves mood, and relaxation[29];and reduces depression.[30] A recently developed alternative modality, body talk (BT) is reported by practitioners to reduce reactions to external stressors, enable increased focus, concentration and clarity, and improve learning.[31,32] While research with this modality is very limited when thermal imaging, poly-contrast interference photography and gas discharge visualization were used to measure the effects of body talk sessions significant changes in the biofield were found (i.e., clearing of congested areas, and less flaring and biophoton emission leaks) when compared to a control group.[33] A second study, although not with adults, found after eight weeks of using body talk three times per week, a group of young school children ($n = 20$) with attention deficit hyperactivity disorder showed an average of 30% improvement in their organizing, remembering, reading, writing, and spelling abilities.[32] Thus, there are some indications of the ability of the alternative modalities of HT and BT to reduce stress responses and improve cognitive and psychological functions suggesting they may be appropriate for use with individuals with AD.

Healing touch (HT) utilizes the electromagnetic field of the practitioner's hands to clear, energize, and balance the patient's energy field enabling access to their innate healing ability.[34] With all HT techniques the practitioner uses a conscious, intentional process of directing energy through their hands to the patient either by contacting the patient's energy field close to the body and/or lightly touching the body.[34] HT is based on Roger's holistic nursing theory that states that all persons are highly complex fields of various forms of life energy which are in constant interaction and exchange with surrounding energy fields, thereby changing each other.[35]

Effects of biofield therapies on disease processes are hypothesized to occur via a variety of pathways. Biofield therapies usually induce relaxation, which results in blunting of the neuroendocrine stress response. Stress-related information is processed via the central nervous system and ultimately results in activation of the sympathetic nervous system and the HPA axis.[36] The relaxation response has been shown to result in blunting of neuroendocrine stress hormones, and in enhancement of immune function, and other bodily systems.[37,38] A second mechanism includes pathways not mediated by the neuroendocrine stress response. For example, biofield therapies are thought to release blocks to circulation of "vital energy" within the patient.[39] Modulation of a person's energy which recreate flow and balance throughout the body are thought to affect multiple systems, and ultimately support greater resistance to disease and more rapid recovery. These different mechanisms may also work together.[39]

The body talk cortices (BTC) technique, a noninvasive, nonmanipulative light tapping of the head and sternum, is believed to re-establish brain function under a corrected system.[40] The BTC technique is hypothesized to produce a "standing scalar wave."[31,32] While standing scalar waves have been proven to exist they are not well understood.[41] These waves run at one and half times the speed of light, can "tunnel" through matter, and are not absorbed by their surroundings. Some scientists consider them the basis of both classical and quantum energy fields.[42] Clinical trials of standing scalar waves suggest they are associated with a variety of health benefits, including improvement of symptoms of chronic fatigue syndrome, fibromyalgia, cognitive impairments, and sleep disorders.[43]

Based on a review of previously published decline rates in early to moderate AD patients[44] the AD 2000 Collaborative Group,[45] identified the mini-mental state examination (MMSE) (a 30 point scale) value of 1.4 points as the mean AD 6-month cognitive decline. The AD 2000 Collaborative Group was composed of clinicians from twenty-two clinics in the West Midlands of the UK who conducted the largest clinical trials of cholinesterase inhibitors in terms of number of randomized patients and person-years of placebo controlled treatment (Molinuevo et al, 2011).[46] Han and Colleagues[47] found the average rate of cognitive decline using the MMSE to be 3.3 points per year, a slightly faster decline than the AD Collaborative Group's measure. A comprehensive review by Behl and Colleagues[48] found yearly cognitive decline ranged from .8 to 4.0 points on the MMSE.

Individual differences in the rate of decline, in spite of the AD pathology, may be explained by innate intelligence or aspects of life experience like educational or occupational attainment. Such reserves, in the form of a set of skills or repertoires may allow them to function, better than those with less reserve. It has been found that AD patients with greater cognitive reserve (CR) cope with AD pathology longer before expressing it clinically. Ultimately, when signs of AD do present a more rapid decline occurs than seen with those with less CR.[49]

This feasibility study assessed whether an integrated treatment program combining two alternative modalities, thought to have specific impact on brain processes, would 1) be feasible to complete, and 2) have the efficacy to slow the progression of Alzheimer's disease (AD) in persons with early stage AD. The feasibility aim of this study related to the study processes of recruitment, randomization, retention and adherence. The efficacy aim addressed the effect of six months of weekly sessions of healing touch (HT) combined with the daily use of body talk cortices (BTC) on cognitive function, mood states, and depression levels of persons with early stage AD. The study was approved by the University of Iowa Institutional Review Board.

2. Method

A randomized two-group control trial repeated measures design was used. Persons with a diagnosis of early stage (less than stage 4) AD (institutionalized [$n = 20$] and community dwelling [$n = 2$]) were assigned by chance (coin toss) to either the intervention (HT + BTC) group or a comparison control group. Due to the nature of the group activity and disclosure of the purpose of the study the subjects were not blinded to whether they were receiving a treatment.

The treatment group received a weekly HT session. These subjects were also to complete the BTC technique daily for 6 months or have their caregiver do it to them. All subjects continued with their usual medical regimen. No other interventions were added to the control group's care regimen. Cognitive reserve was measured at baseline as this is a trait measure. Cognitive function was measured at baseline, and 6 months as this is the earliest usual

time period drug studies use to observe cognitive decline.[45,46] Mood states and depression level were measured at baseline, 3 and 6 months, as these outcomes are known to change more rapidly over time.

2.1. Procedure

2.1.1. Recruitment and group assignment

Participants were recruited both from care facilities and from the community. Administrators of two local long term nursing care facilities provided twenty one names of potential subjects from their facility who were willing to talk with the study's principal investigator (PI) about participating in the study. Twenty one agreed to participate, but 18 of these did not meet the inclusion criteria of being in the early stages of AD. The supervising nurses from two assistive living facilities provided twenty names of persons willing to talk about participation. While all met the inclusion criteria, only nine agreed to participate. The other eleven felt they could not commit to the 6 months the study required. Most had other competing activities already scheduled. One became very anxious just about committing to that amount of time. The mangers of two Independent Living facilities recommended 16 names to the study. Three did not meet the criteria of early stage AD and five did not think their schedules would allow them to commit to a six month participation. Eight of these residents, met the inclusion criteria, and agreed to participate. Community participants were reached through the mass email system of The University of Iowa to their retired faculty and staff. While 500 emails were mailed only 5 persons responded to the mass email. Two of these five did not meet the early stage criteria and one felt the distance for weekly winter travel for the treatment was too far. Two who agreed to participate, met the inclusion criteria.

Sixty two persons were approached and screened based on the following inclusion criteria: 65 years or older, had a designation of early AD (information regarding their doctor's diagnosis was acquired from the subjects, their caregivers, or nursing staff), living in the community, independent living, assistive living, or a nursing home and with a life expectancy of more than 12 months past study entry. Exclusion criteria were: age 64 and younger, AD stage 5 and above, can't read or speak English, and history of strokes, Parkinson's disease, dementia with Lewy bodies, Huntington's disease, and Wernicke–Korsakoff syndrome. Twenty two persons consented to participate. The twenty two subjects were assigned to one of two groups: HT ($n = 12$) and control ($n = 10$). One subject from the assistive living withdrew from the control group after 4 weeks due to scheduling problems (see cohort Fig. 1).

Since funding for this pilot project was limited, to reduce the travel expenses of the practitioners, subjects who resided in the same agency were assigned to the same group. Thus the coin toss assignment related to assignment of the agency's subjects to one of the groups. An advantage to this type of assignment was prevention of cross group contamination. The two community subjects were both assigned by coin toss to the treatment group.

2.2. Treatments

2.2.1. Intervention group

The intervention group continued with their usual medical and care regimen. In addition the following HT and BTC protocols were received for the 6 month treatment period.

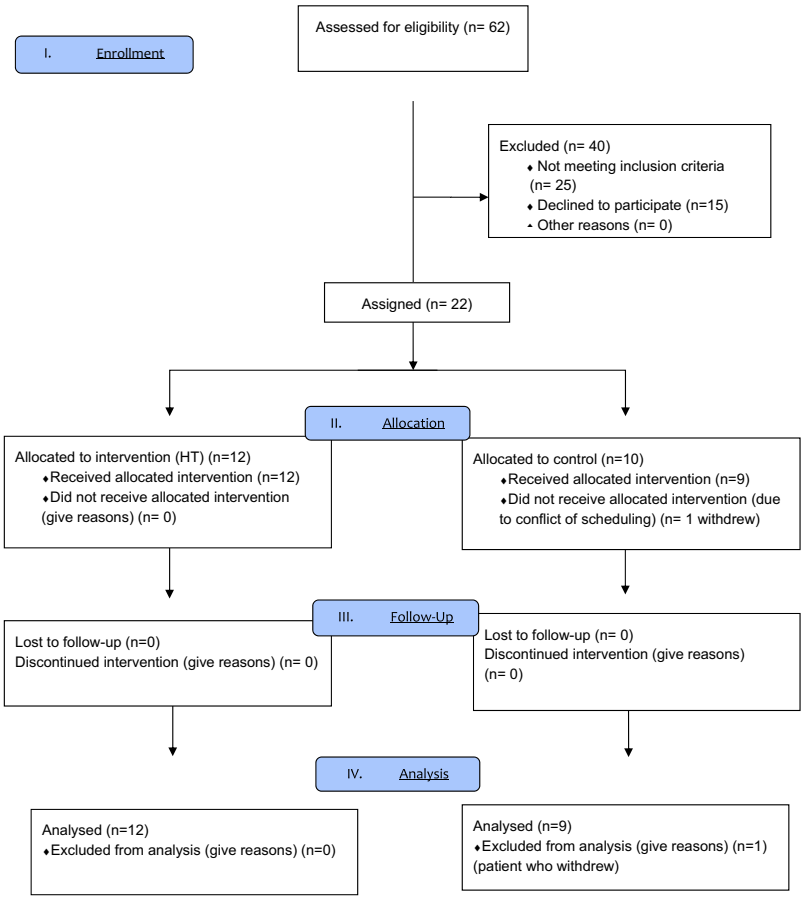

Fig. 1. Consort allocation.

Table 1
Healing touch techniques used in every HT session.

Technique	Purpose	Description	Rationale for use
Pain drain (energetic siphon)	Clearing (reduces local energetic congestion)	Left hand over area of congestion. Right hand held lower and away from body to drain congestion. Then hands reversed to refill void of draining	Reduce energetic congestion, promote comfort & normal pattern of energy flow
Chakra connection	Balancing-open & connect major & some minor energy centers (EC)(joints)	Hands placed sequentially over EC from feet to head-remaining at each EC until energy flow is noted	Re-establish normal pattern of energy flow-supporting flexibility & mobility
Magnetic clearing	Clearing-full body cleanse energy fields of congested energy & toxins (physical & emotional)	Hands pass through energy field, with fingers curled, 12 inches above the body, at least 30 times, until field is smooth and light	Clear energy fields of debri—supporting relaxation, comfort & mobility
Mind clearing	Clears and focuses the mind-reset energy flow in head	Fingertips are placed on points on the head, neck & face in 11 sequential positions	Relaxation which occurs supports interruption of negative thought patterns with the emergence of more positive emotions

2.2.1.1. HT session protocol. Ten of the subjects received HT sessions at their residences, in a quiet room, while sitting in a recliner. Two subjects received their HT sessions while lying down on a treatment table in the office of the HT therapists. The subjects were clothed, but not wearing shoes. HT sessions were delivered by two teams of two certified HT practitioners (all four were nurses). The subjects always received their sessions from the same practitioner team. The sessions always included the following techniques: 1) liver drain, 2) chakra connection, 3) magnetic clearing, and 4) mind clearing. See Table 1 for descriptions of these techniques.[50] Additional techniques were included when warranted by the subject's presentation. An example of an additional technique used was the use of a headache relieving technique when the person presented with a headache.

2..2.1.2. BTC protocol. During BTC, one hand is used to systematically bridge the two hemispheres of the brain from the occipital area to the forehead. While one hand is bridging the hemispheres, the other hand is tapping on the top of the head, over both hemispheres, and then tapping on the sternum, for the duration of two normally-paced breaths for each hand position. The procedure concludes with the hands over each temporal lobe. The entire procedure usually takes under 1 min to perform.[40] The patient and a caregiver were taught how to performed BTC by the study PI. During the HT weekly sessions the HT practitioners observed the subject or their caregiver perform the BTC to verify accuracy.

2.2.2. Control group

Subjects in this group continued with their usual medical and care regimens. No other interventions were added to their care regimen.

3. Assessments

The subject's characteristics were measured at baseline and outcome variables at baseline and again at 3 and/or 6 months.

3.1. Demographic characteristics

Age, gender, race, marital status, type of residence, was gathered by a nurse interviewer from the subject and/or caregiver during baseline assessment.

3.2. The wide range achievement test-4 reading subtest (WRAT-4) blue form

The WRAT-4 has a 70 point reading subtest, was used at baseline to assess cognitive reserve.[51] The WRAT-4 has an internal consistency between .92 and .98.[51] Cognitive reserve is associated with the ability to cope with AD pathology.[49] The WRAT4 blue form age score mean (standard deviation) for the age group of 65–74 are 60.4 (5.9), and for the age group of 75–84 are 55.1 (10.9).[52]

3.3. Functional Assessment Staging (FAST)

To validate that the subject met the eligibility criteria for early stage AD (less than stage 4), criteria from the FAST global scale were used. FAST stages have a correlation of .9 with global deterioration scale (GDS) stages.[53] The reliability of FAST, calculated by intraclass correlation coefficient, is .87.[54] The PI used the FAST assessment criteria during an interview with the subject's primary caregiver prior to interviewing the potential subject. During an approximately 30 min interview with the potential subject, to verify admittance criteria, the nurse interviewer observed the subject's communication skills, orientation to day and time, and gathered information regarding self care function (e.g., can they dress and feed themselves), and the amount of assistance needed to manage their daily activities. Behaviors which indicate stages 1–4 scaling include: (stage 1) no difficulty, (stage 2) forgetting location of objects, (stage 3) decreased job functioning (evident to co-workers), (stage 4) decreased ability to perform complex tasks (planning dinner for guests, handling personal finances).

3.4. Montreal Cognitive Assessment test (MoCA)

The MoCA, a 30-point cognitive screening test designed to measure cognitive function, was used at baseline and repeated after 6 months. The MoCA is more sensitive ($p < .001$) than the mini-mental state examination (MMSE) in distinguishing persons who are normal from ones who have a mild cognitive impairment (MCI).[55] The MoCA has a Cronbach's alpha internal consistency of .74, and test–retest reliability of .88 ($p < .001$).[55] Content validity for the MoCA test was established by its close correlation with MMSE ($r[274] = .87$ $p < .001$). The majority of persons who are normal or are AD patients are scored in the same range by both tests. Compared to the MMSE the MoCA will score many more in the MCI range.[55] The following ranges of MoCA scores indicate different levels of cognitive ability: between 25.2 and 29.6 normal; 19.0–25.2 mild cognitive impairment; and 11.4–21.0 Alzheimer's disease.[55]

3.5. Profile of Mood States-Brief Form (POMS-BF)

This list of 30 adjectives was used by subjects to identify their moods over the past week, at baseline and every 3 months. Each item is rated on a 5-point scale, from (0) "not at all" to (4)

"extremely." Cronbach's alpha ranges from .78 to .91 for each of the six subscales.[56,57] The following emotions are measured by this tool: tension–anxiety, depression–dejection, anger–hostility, fatigue–inertia, and confusion–bewilderment for negative aspects and vigor–activity for positive aspects. Agitation, often related to the distress measured by the POMS, is the most frequent and persistent AD related behavioral and psychological symptom in later stages of AD.[58]

3.6. Patient Health Questionnaire (PHQ-9)

The PHQ-9, developed in 1999 as a self-report version of the primary care evaluation of mental disorders (PRIME-MD), was used at baseline and every 3 months.[59] The PRIME-MD includes criteria used to diagnose mental disorders commonly seen in primary care. Scores of 1–4 indicate no depression; 5–9 mild depression; 10–14 moderate depression; 15–19 moderately severe depression, and 20–27 severe depression. The test–retest reliability of the PHQ-9 has been reported with an intraclass correlation coefficient (a reliability measurement) of .92 when administered twice within a 7-day period.[59]

4. Statistical analysis

Descriptive analysis was used for demographic characteristics and for recruitment, randomization, retention and adherence characteristics related to the study's aim of feasibility. Outliers were examined for accuracy and possible entry errors. To address the study's second aim of efficacy independent *t*-tests were used to test for differences between groups at baseline. Repeated-measures ANOVAs (MANOVA) were used to compare changes in the outcome variables over time. Significant interactions were followed up by between group comparisons and paired *t*-tests of within group changes. Effect sizes of within group changes and between group comparisons regarding outcome variables were also calculated. The alpha level used to identify significant differences was $p < .05$. Data were analyzed using SPSSWIN 20.0.[60]

5. Results

5.1. Subject characteristics

Subjects ranged in age from 68 to 94 with a mean age of 84. As can be seen in Table 2, the groups did not differ significantly at baseline regarding cognitive reserve (measured by WRAT-4), age, gender, ethnicity, or marital status. More participants in the treatment group resided in the community and in independent living agencies than did participants in the control group. The control group subjects primarily resided in nursing homes or assisted living agencies.

5.2. Feasibility

The first aim of the study was to determine the feasibility of carrying out a study which could provide a well founded answer to the efficacy of the tested interventions.

5.2.1. Recruitment

Subjects were recruited from the community, long term care facilities, and assistive living and independent living facilities. Sixty two persons agreed to be approached by the recruiter to discuss participation. Twenty three persons (37%) did not meet the eligibility criteria of being in the early stages of AD. Sixteen persons (27%) refuse participate either because they felt the commitment time of 6 months was too long or they had other competing activities already planned, such as trips. Only 10% of persons from long term care facilities meet the inclusion criteria of early stage AD. All the persons in the assistive living facilities meet this criteria while only 80% in the independent living agencies and 60% in the community who agreed to discuss participation, met the early stage criteria. In summary 65% of persons interviewed for participation did not qualify or refused to participate. The primary reason for refusal (27%) was length of time commitment required.

5.2.2. Randomization

Randomization of the subjects provided a challenge due to grant funding financial restraints. This resulted in subject assignment to groups by their place of residence in order to reduce practitioner travel costs.

5.2.3. Retention

Only one person (4.5%) withdrew from the study after one month due to scheduling problems.

5.2.4. Adherence

In the treatment group, there was a subgroup of subjects (4) who were much less compliance with the use of the BTC technique. Three of them resided in the same assistive living facility. These three only received the BTC weekly with their HT sessions. One refused to do the tapping although allowed the therapists to do it

Table 2
Baseline comparison of groups characteristics ($N = 21$).

Variable	Treatment ($n = 12$)	Control ($n = 9$)	*t* test	*p*
	Mean (SD)	Mean (SD)		
Age (years)	83 ± 8.54 (68–93)	85.22 ± 8.63 (68–94)	−.588	.564
Reading word recall (WRAT-4)	44.17 ± 10.96	39.89 ± 7.42	1.007	.326
	Frequency (%)	**Frequency (%)**	X^2	***p***
Gender				
Male	3 (25)	2 (22.2)	.022	.88
Female	9 (75)	7 (77.8)		
Ethnicity				
Caucasian	12 (100)	9 (100)	–	–
Living type				
Community	2 (16.7)	0	9.77	.021
Nursing home	0	3 (33.3)		
Assist living	3 (25)	5 (55.6)		
Marital status				
Independent living	7 (58.3)	1 (11.1)		
Married	3	3		

weekly. Her score remained the same. The other two could not remember to do the BTC and the caregivers in the agency did not assist them with this. Their scores decreased by two points. The fourth subject, who resided in an independent living residence, was able to remember, or be reminded to do the BTC only half the time (three to four times per week). Her score improved by three points. Based on the expectation that the BTC were to be done daily for 24 weeks by the 12 subjects in the treatment group 2016 BTC treatments were to be completed. However, as noted above 516 BTC treatments were missed resulting in an adherence level for the BTC of 76%.

Ten of the weekly healing touch sessions were missed due to scheduling conflicts. One persons who lived in an independent living facility missed 6 sessions due to conflicting activity scheduled and one person from the community missed four sessions due to out of town travel. Of the 288 HT sessions ten were missed giving HT sessions an adherence level of 96%.

5.3. Efficacy

5.3.1. Cognitive function

The cognitive function scores of the subjects at baseline, measured by MoCA (16.75 & 16.22), were in a typical range of persons with early AD (AD range = 11–21). The groups did not differ significantly in cognitive function at baseline (see Table 3). After 6 months of treatment a repeated measures ANOVA found a significant interaction by time between groups: $F(1,19) = 7.864$, $p = .011$ (see Fig. 2). A follow up paired t-test found a significant improvement in the treatment group's cognitive function (an increase of 2.58 points, $p = .008$). The MoCA score of the control group had a non significant decline (−.89 points, $p = .383$). The between group comparison, while finding the groups were not significantly different, indicated a trend toward a difference in the groups ($p = .086$).

5.3.2. Mood states and depression level

At baseline the groups did not differ significantly in mood states, as measured by POMS, (see Table 3). A repeated measures ANOVA regarding POMS scores revealed a significant interaction by time between the groups ($F[2,18] = 8.357$, $p = .001$) (see Fig. 3). Follow up paired t-tests showed a significant improvement in mood in the intervention group both at 3 months ($t = 4.71$, $p = .001$) and 6 months ($t = 4.76$, $p = .001$). Significant changes did not occur in the control group ($p = .569$) (see Table 3). Follow up between group comparisons found the groups did not significantly differ ($p = .135$).

Both groups at baseline were mildly depressed (intervention: 6, control: 4.11) as measured by PHQ9. After 3 months both groups PHQ9 scores had moved to the non-depressed range. While the score of the intervention group was above the control group's at the baseline and below the control group's after 6 month, the interaction did not reach a level of significance ($F[2,18] = 1.867$, $p = 183$) (see Table 3).

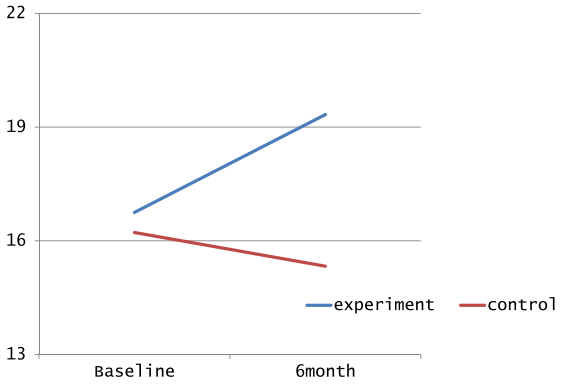

Fig. 2. RMANOVA of MoCA scores (cognitive function).

6. Discussion

A number of challenges were found regarding study's feasibility aim. The criteria of being in the early stages of AD restricted the recruitment of the largest number of persons who would have been willing to participate. Persons in all types of residence posed this challenge except for those in the assistive living agencies. Those in independent living agencies and in the community, where the expectation regarding function would be greater, had 20% & 40% of these groups not meeting the early stage criteria. A second recruitment challenge was to find ones who would commit to participation which last 6 months and requires daily and weekly interventions. This challenge was no doubt accentuated due to the novelty of the interventions. Recruitment and retention might both be increased by using a two step recruitment process. Step one could include just a brief visit to allow the potential subject to become familiar with the recruiter and begin establishing a trust relationship. Step two could be having the flexibility of dividing the screening and consent process into multiple smaller time periods. This would reduce the fatigue factor as well as subject anxiety regarding sustaining focus and performance.

Adherence to the protocol was challenged by the subject's ability to remember to carry out the daily body talk technique. This raises the question of relative contributions of the two modalities, and of techniques for increasing adherence to a self- or caregiver-administered intervention.

Although the number of subjects in this pilot study was small, important trends regarding efficacy of the interventions were

Table 3
Group comparisons over time.

Variable	Baseline			3 months		6 months		Baseline to 3 month change				Baseline to 6 month change			
								Within		Interaction		Within		Interaction	
	N	*M* ± SD	*p*	*N*	*M* ± SD	*N*	*M* ± SD	*t*	*p*	*F*	*p*	*t*	*p*	*F*	*p*
MOCA															
Healing touch	12	16.75 ± 3.42	.70			12	19.33 ± 5.38					3.259	.008	7.864	.011
Control	9	16.22 ± 2.44				9	15.33 ± 4.44					−.922	.383		
POMS															
Healing touch	12	20 ± 16.14	.21	12	5.92 ± 8.67	12	4.5 ± 9.55	−4.71	.001	8.927	.008	−4.76	.001	8.357	.001
Control	9	11.22 ± 13.7		9	10.67 ± 15.89	9	12.89 ± 15.10	−.164	.873			.593	.569		
PHQ9 total															
Healing touch	12	6 ± 5.97	.41	12	3.08 ± 3.17	12	2.33 ± 1.88	−1.938	.079	1.568	.226	−2.54	.028	1.867	.183
Control	9	4.11 ± 3.52		9	3.89 ± 4.83	9	3.89 ± 3.26	−.152	.883			−.258	.803		

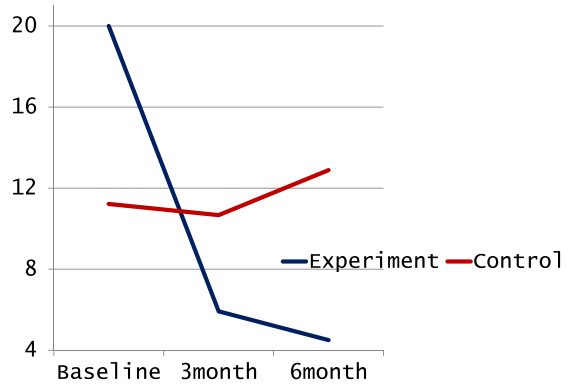

Fig. 3. RMANOVA of POMS scores (mood states).

visible. Significant improvements were seen in cognitive function, mood and depression between baseline and six months in the treatment group whereas the control group showed no significant changes in these outcome variables.

AD is a syndrome of acquired deficits in multiple domains of cognition which may progress to interference with everyday life deteriorating to inability to carry out activities of daily living. The profusion of cognitive, behavioral and psychiatric changes occurring during the course of the disease, are of clinical and practical importance as they may distress both the patients and caregivers, often precipitating institutionalization.[58] Clinical drug trials conventionally report their results in terms of the differences between active and placebo treatments on a measured outcome together with its 95% confidence interval and statistical significance (p value $< .05$). Because neither the observed difference nor its statistical significance may indicate clinical significance, the minimum clinically important difference (MCID) has been suggested as a more useful measure of effectiveness.[61] The MCID has been defined as "the smallest difference that patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management."[62] Cohen's effect size is a distribution-based method to identify a clinically important change. Using this method a medium effect size of .5 is conventional. Norman, Solan and Wyrwich[63] suggested that the value of .5 be used as a default for defining important patient and clinician perceived change. The FDA suggested as early as 1989 that a reversal of the natural history of cognitive decline over 6 months constituted an MCID and that 1.4 MMSE points corresponds to the expected mean 6-month rate of decline in AD.[44]

The MoCA test was used in this study to measure cognitive function because of its high correlation ($r = .87$) with the MMSE and its greater sensitive than the MMSE in distinguishing normal controls from ones who have a mild cognitive impairment (MCI).[55] Both are thirty point scales and both tests score the majority of normal and AD patients in the same score range.[55] The average cognitive change which occurred in the control group was a decline of .89 points on the MoCA while an improvement of 2.58 points occurred in the treatment group. Although the decline in the control group did not fall within the average 6-month rate of decline identified by Burback et al,[44] it did fall within the range noted by Behal et al[48] of .4–2.0. The treatment appears to have reversed the natural history of cognitive decline and has no troublesome side effects. According to Jaeschke, Singer & Guyatt,[62] this suggests a mandate for change in patient management. It must be noted that while the MoCA and MMSE tests are very similar, the expected decline relates to points on the MMSE test.

Recent developments in neuroendocrinology suggest that changes in the HPA axis alter the responses of persons with AD to stress; making them less able to cope with stressors.[23,24] It should be noted that one individual in each of the study groups experienced a major life stressor. With such a small sample, it could be argued that these individuals may have unduly influenced the findings. In the control group one subject faced a major financial decision regarding her home and also had a serious chronic skin ulcer on her lower leg at baseline. These stressors resolved by the 6 month assessment and her cognitive function score increased by four points. In the treatment group one of the subjects fell and broke her hip during the last month of the study and was in considerable pain during her 6 month assessment. Her cognitive function declined two points. Thus it is possible that the findings are an underestimate of the actual effects of the treatment.

6.1. Limitations

There are a number of factors in this study which limit the ability to generalize from these findings. The small sample size of this study, the small number of males, and inclusion of only Caucasians and randomization via residence limits the generalizability of these findings. Certainly the small number of subjects limits the inferences which can be drawn from the data. However, these findings have a moderate to large effect size (range between .53 and .99) suggesting that with a larger sample size, robust effects would be observed.

Additionally, the treatment group started out with greater distress and more depression than the control group. Although these differences at baseline were not statistically significant, the treatment group had more room for improvement. Thus it is not clear to what extent regression to the mean vs. treatment effects may have contributed to study findings.

Group assignment by place of residence may have biased the findings. Although cognitive scores did not differ between the two groups at baseline, it is possible that some confounding factor related to living arrangements may have affected the findings. A larger study with subject randomized assignment will be necessary to fully eliminate such confounds.

The design of the study could not delineate the relative contributions of each of the modalities and in addition the weekly visit may have added a social benefit. These factors could be addressed in future studies by adding a placebo treatment such as a social visit as well as separating the interventions.

7. Conclusion

The progression of AD typically leads to increasing cognitive deficits accompanied by increasing behavioral and psychological symptoms related to dementia. A treatment that has the ability to reduce the progression of cognitive decline has enormous potential for improving the quality of life for patients and caregivers. In spite of the limitations discussed above, the positive effects found in this pilot project suggest this work should be expanded. The following needs to be investigated: intervention frequency (dosage), relative contributions of each of the modalities, mechanisms of action, ability of caregivers to deliver the treatments and cost effectiveness.

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