Results of a Feasibility and Effectiveness Study

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he Acupuncture Pilot Study for Persons with Dementia is the first study in the United States to examine acupuncture as a treatment for Alzheimer's disease (AD) and vascular dementia (VD). Funded by the Helen Bader Foundation, the study was conducted from 1997 to 1999 at Wellesley College's Center for Research on Women. The study, which included 11 treatment participants and no controls, demonstrated that acupuncture may be a feasible and effective treatment for depression and anxiety in Americans with AD or VD. All enrolled participants completed at least 22 acupuncture needling treatments and every required evaluation. Using paired sample t-tests, statistically significant improvements were found in three of the four scales used to assess the effect of acupuncture on mood.

Key words: acupuncture, Alzheimer's disease, anxiety, complementary therapy, dementia, depression, energy, mood, vascular dementia

The Acupuncture Pilot Study for Persons with Dementia is the first study in the United States to examine acupuncture as a treatment for Alzheimer's disease (AD) and vascular dementia (VD). Funded by the Helen Bader Foundation, the study was conducted from 1997 to 1999 at Wellesley College's Center for Research on Women. The results indicate that acupuncture may be a feasible and effective treatment for depression and anxiety in Americans with AD or VD.¹

BACKGROUND AND PURPOSE

Despite the many recent advances in the understanding of the causes of AD, approximately four million Americans living with AD² continue to experience impairments in cognition, mood, and activities of daily living. Accord-

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ing to the estimates by the Alzheimer's Association, 19 million Americans have a family member afflicted with AD or a related disorder. Over the next 50 years, the prevalence of AD and related disorders is projected to rise to almost 14 million Americans, potentially overwhelming the US health care system. The psychological and physiological illnesses resulting from the stresses of caregiving are well documented.^{3–13}

In addition to the cognitive decline associated with AD, a large percentage of patients experience mood or behavioral problems.^{14–19} Katz²⁰ advanced the theory that depressive disorders represent common comorbidities, components, or complications of dementia, and Teri²¹ estimated that 54% of persons with AD experience depressed mood and 70% anxious mood symptoms. The treatment of depression and anxiety in patients with AD or a related disorder can improve the quality of life of both patients and their caregivers by reducing the frequency or intensity of symptoms.^{22(p143)} However, conventional pharmaceutical treatments for mood and behavioral issues, such as antidepressants,^{15,23–27} antipsychotics, and antianxiety drugs, not only provide mixed results but often have unpleasant side effects.²⁰

The high incidence of depression and anxiety associated with AD and the limitations of the current treatment modalities demand the consideration of alternative or complementary treatments, such as acupuncture. Acupuncture, a core component of traditional Chinese medicine, has been recognized by the National Institute of Health's National Center of Complementary and Alternative Medicine and the World Health Organization as a safe and potentially effective therapy for treating conditions such as postoperative nausea and dental pain, addiction, low-back pain, osteoarthritis, stroke, and asthma.²⁸ The FDA approved acupuncture needling in spring 1996 as "safe and effective."²⁹

Several studies examined the effectiveness of acupuncture in treating both cognitive and mood symptoms in dementia in the elderly, particularly VD.^{30,31} One Chinese matched, controlled study of both cognition and mood symptoms in adults with VD used Western diagnoses and outcome measures to assess the results of acupuncture treatment. The study found substantial and statistically significant improvements in cognition; improvement in mood was noted but not as precisely measured.³² The good response in persons with VD was consistent with positive responses in persons with stroke.³³ More recently, Kao et al³⁴ reported improvement in cognitive function following acupuncture treatment in eight patients with mild and moderate AD.

Several recent studies suggest explanations for the effectiveness of acupuncture in dementia. Gu³¹ advanced the theory that acupuncture improves symptoms of dementia by enhancing perfusion and the oxygen content of the brain. Sun³⁵ described acupuncture as uniquely fighting a deficiency of both Qi (energy)^{36(p11)} and blood. Other traditional Chinese medicine mechanisms³⁷ that we will just mention (their definition is beyond the purview of this article) include excess or stagnation of phlegm (obstruction) in the heart, deficiency of kidneyessence, deficiency of heart and sea, and deficiency of brain (the marrow sea).

Acupuncture has also been shown in studies in China, the United States, and elsewhere to provide symptom relief for depression38-49 and anxiety41,43,44,50-52 in cognitively intact persons with minimal side effects, and with success rates comparable to or better than those of conventional treatments, including psychotherapy or pharmacotherapy. Of these studies, a few were controlled trials that were at least double-blind.38,41,42 Han55 and Luo54 compared electroacupuncture to amitryptyline, a widely used and established antidepressant. In both studies, acupuncture showed rates of beneficial effects similar to amitryptyline and without the associated side effects. The latter study used double-blind controls, included 133 total participants, and used the Hamilton Depression Scale as the outcome measure. In the United States, Allen and Schnyer38 conducted a NIH-funded wait-list, controlled clinical trial in which acupuncture improved symptoms of major depression in two-thirds of 34 female participants.

The mechanism of acupuncture in treating depression and/or anxiety is now partially understood. Cheng⁵⁵ found acupuncture led to activation of neurotransmitters in the central nervous system, primarily in the hypothalamus, suggesting a direct influence of acupuncture on the pathogenic mechanisms of depression. Chen⁴³ suggested that electroacupuncture increases serotonin and cerebral blood flow. Another study reported that acupuncture stimulates the production of hypothalamic and pituitary neuropeptides-releasing factors, and several hormones (oxytocin, vasopressin, and endorphins), many of which have specific antidepressant properties.⁴¹ Russian scientists Dudaeva et al56 reported neurophysiologic changes using EEG- and visual-evoked potentials during acupuncture treatment of depression. Hui et al⁵⁷ conducted functional MRI studies of the human brain that demonstrated that participants experiencing dequi (mild tugging sensation during acupuncture treatment) but not pain had prominent decreases of functional magnetic resonance



imaging signals in limbic and subcortical regions such as the amygdala, hippocampus, parahippocampus, hypothalamus, septal nucleus, caudate, putamen, nucleus accumbens, anterior cingulate gyrus, anterior insula, temporal pole, and fronto-orbital cortex. The authors suggest that "modulation of this neuronal network by acupuncture could well contribute to its efficacy for the treatment of diverse affective and psychosomatic disorders."

Although several studies report beneficial effects of acupuncture on symptoms of AD or other dementias, many of them were not rigorous or omitted details concerning design, standards of diagnosis, or treatment protocol.²⁸ The study described here was the first in the United States to apply rigorous and established research methods to determine the feasibility and explore the effectiveness of acupuncture in the treatment of AD or VD.¹

We hypothesized that acupuncture would be a safe, feasible, and effective method for reducing the symptoms of anxiety, depression, and cognitive impairment for persons with AD.

METHODS Study design

The study was a simple phase-one study with no controls. Its purpose was to determine if acupuncture could provide additional benefit to persons who had dementia and were receiving concurrent standard medical treatment, a recommended practice in current acupuncture research.⁵⁸ for each diagnostic category.

Eligibility criteria included diagnosis of probable AD or VD, age of 55 or older, and baseline Mini-Mental Status Exam (MMSE)⁵⁹ of 15 or greater. We excluded people with severe AD, poor health, or bleeding diathesis and those who had received acupuncture treatment during the preceding 6 months. Diagnosis of AD or VD was established by a review of the candidates' medical records and confirmed by a thorough neurological exam by one of the project's neurologist.

Participants received acupuncture treatments three times a week for the first 2 weeks, then two or three times a week for an additional 7 to 10 weeks. Because acupuncture treatment is unproven in its effects for persons with dementia, we did not ask participants to discontinue other treatments for either mood disorders or cognitive impairment. Participants were allowed to continue on previously established medical regimens, although they

were asked not to start any new treatment unless under physician's order.

Acupuncture treatment protocol

From the literature, we identified acupuncture points most commonly used in anxiety, depression, and dementia studies. They were confirmed and modified through a series of consensus meetings with our acupuncturists. The main and secondary acupoints agreed upon by our team correlated with the literature and team experience in treating anxiety and depression in senile dementia and memory disorders. The initial 10 main acupoints selected were GB9, GV16, GV20, GV23, GV24, PC6, HT7, SP6, Sishencong, and Yintang. The secondary points selected were ST36, LI4, GB20, GV17, SP4, KI3, SI3, BL62, BL23, GV26, and the cervical and thoracic Huato Jiaji points.

Acupuncturists were asked to diagnose participants according to the six diagnostic categories from the 1991 Official Chinese

Consensus Standards on Traditional
Chinese Medicine Diagnosis and
Treatment of Senile Dementia³¹:
Deficiency of Marrow Sea,
Insufficiency of Liver and Kidney
Yin, Flaring of Heart and Liver Fire,
Insufficiency of Spleen and Kidney
Yang, Stagnation of Phlegm and
Fluid, and Stagnation of Qi and Blood.
Relying on traditional Chinese medicine

texts, the team suggested specific acupoints for each diagnostic category. The chart of subtypes and points was distributed to team acupuncturists as one of our training tools.

While this initial set of primary and secondary points, together with the dementia subtypes, formed the framework for our acupuncture treatment protocol, individual acupuncturists were given leeway to use their own judgment regarding point selection and treatment method according to traditional Chinese medicine diagnosis and theory. As a result, the initial protocol was flexible and served as a set of guidelines for the individual acupuncturist to consider. Our purpose was to gain experience and use that experience to further develop and standardize the protocol for future clinical trials.

Participant recruitment

We pursued an active recruitment program for about a year to enroll sufficient participants. The Alzheimer's



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Association actively promoted the project through a cover letter to family support group leaders and mentioned it in the list of accepted research projects published on its website. Additional referrals came from acupuncturists and directors of AD specialty units in assisted living facilities or nursing homes. Local newspaper articles, presentations, and personal referrals also generated some participants.

Assessments

After screening and the informed consent process were completed, eligible participants received three rounds of evaluation: a baseline assessment, a midpoint assessment, and a posttreatment assessment. The baseline and the posttreatment assessments consisted of neurological, psychological, and research interviews, while the midpoint evaluation consisted only of the research interview. Both the persons with dementia and their caregivers were part of the interview process. In addition, for the duration of the study, each caregiver was asked to fill out daily logs about the participant's condition. To monitor the acupuncturists' treatments and aid future protocol replication, the study also included three rounds of acupuncture assessment—before the first, thirteenth, and last treatment. Each assessment included a comprehensive medical history, an assessment of a variety of physical and mood symptoms, and a tongue, pulse, and skin examination. Team acupuncturists were required to keep a detailed record of the acupoints they chose to use for each patient at each treatment session and to record the reason for their choices, especially for acupoints that were not among the original recommended options.

Measures

The interviews included both feasibility and effectiveness measures.

Feasibility measures

The research interview incorporated various items that we developed to measure the feasibility aspects of the study, such as participants' acceptance, compliance, perception of pain, adverse reactions, side effects, and adherence to acupuncture treatment as well as caregivers' response to the study. Both participants and caregivers provided feedback. The caregivers' daily logs also provided information on the participants' daily responses in mood and behaviors to acupuncture treatment.

Effectiveness measures

To assess the effect of acupuncture treatment on our primary outcomes, anxiety and depression, as well as to explore the effects on cognitive impairment, vitality, and function, we used the following established and validated measures.

Depression. We used two measures well validated in elderly persons with dementia: the Cornell Scale for Depression in Dementia (CSDD)⁶⁰ a 19-item scale specifically designed for persons with dementia, and the Geriatric Depression Scale (GDS).⁶¹ We used the 30-item version of the GDS as part of the psychologist's interview and the 15-item version⁶² in the caregiver daily logs.

Anxiety. We adapted the Profile of Mood States (POMS) tension subscale⁶³ to create dichotomous response categories for use during the psychologist's interview with the participant, while we used the original version in the caregiver daily logs. We also used the Spielberger State-Trait Anxiety Inventory (STAI),⁶⁴ the most widely used state anxiety measure.

Cognitive Impairment. The Mini-Mental Status Exam (MMSE),⁵⁹ a widely used instrument in assessing memory and other cognitive functions, was used as both a screening tool and as an outcome measure. We also used the FAS,⁶⁵ a reliable test for controlled oral word association and fluency; and the Boston Naming Test (BNT),⁶⁶ a validated measure of naming deficits.

Mood, Vitality, Function, and Overall Health. We used the MOS 36-item Short Form Health Survey (SF-36)⁶⁷ in the research interview as a self-report by participants and as a caregiver report about participants. In this article, we focus on results from the mood and vitality scales of the SF-36. Interviewers reported that participants had no trouble answering the mood- or energy-related items on the SF-36.⁶⁷

Staffing

Our multidisciplinary team included seven licensed acupuncturists, two licensed and board-certified neurologists then affiliated with the Boston University (BU) Medical Center, and three doctorate level gero-psychologists with busy practices at major clinical institutions and



teaching appointments at BU, Harvard, and elsewhere. The team was also linguistically diversified: three acupuncturists and one coinvestigator were bilingual in Mandarin or Cantonese and English, and one psychologist was bilingual in Spanish and English. In addition to the principal investigator, a dementia expert, the Wellesley College Center for Research on Women research team consisted of research assistants from Wellesley College, a research associate from the New England School of Acupuncture, and a clinical coordinator who was both an academic department administrator and a graduate student at Brandeis University and an academic department administrator. Additional statistical analyses were provided by a research associate with a MPH from BU and a MD from Haiti.

Coinvestigators providing expertise and services in each of their respective fields included an epidemiologist, an acupuncturist who assisted with the original project design, an MD-PhD geriatric-psychiatrist and clinical trial specialist from a local Veterans Administration Medical Center (VAMC) and Boston University Alzheimer's Disease Center (BUADC), and a gerontology PhD candidate with a degree in public health and a long-term interest in AD and complementary therapies. Later, a neuropsychologist from the VAMC and BUADC joined the research team.

Cost

As the investigators and project consultants donated some or all of their time to the study, the primary (and considerable) expenditures were associated with recruitment; acupuncture treatments; the clinical coordination of evaluations and treatment appointments; and data entry, cleaning, and analysis. The 22 to 26 acupuncture treatments per participant, valued at \$50-\$60 per session, totaled \$1,300 to \$1,560 per participant. Team acupuncturists accepted a reduction to half of their usual fees (\$650-\$780) as their contribution to research. The two neurological evaluations, at \$100 per session, totaled \$200 per participant; the two psychological evaluations, at \$75 per session, totaled \$150 per participant; and the three research interviews, at about \$100 per session, totaled \$300 per participant. Total study costs for treatments and evaluations, not including scheduling and coordination costs, averaged about \$1,500 per person.

RESULTS

Study participants

We recruited 20 people in just over a year. Seven of them were determined ineligible or lost interest before enroll-

ment and baseline evaluation. Two were tested and successfully completed treatment and testing but were omitted from study results because one did not meet diagnostic eligibility requirements and the other had a MMSE of 2. The 11 participants who met all the eligibility criteria had an average age of 76 years (range 53-92). Eight (73%) were female and 3 (27%) were male (see Table 1). All participants had some level of mood and/or behavioral symptoms, 10 (91%) had a diagnosis of AD, and 1 (9%) had a diagnosis of VD. Baseline MMSE⁵⁹ scores ranged from 15 to 30, with a mean of 22.4. Three (23%) participants were married, 5 (45%) had completed high school, and 6 (54%) had completed at least some college. Ten (91%) were Caucasians born in the United States and one was of Asian descent from Burma. Four (36%) rated their physical health as excellent, 4 (36%) as very good, 1 (9%) as good, and 2 (18%) as fair. As for mental health, 3 (27%) rated theirs as very good, 5 (45%) as good, 3 (27%) as fair, and none as poor or excellent.

Most participants were taking multiple medications before and during the course of the study. Of the 11 participants at baseline, many had been taking, for several months prior to the study, the following: 7 (64%) were on a cholinesterase inhibitor, 8 (73%) were on antidepressant or antianxiety drugs, 7 (64%) were on vitamin E, 6 (55%) were on Gingko biloba, and 5 (45%) were on estrogen hormone replacement therapy.

Acupuncture treatment

The acupuncturist assessments took 5–10 minutes, and the treatment sessions lasted approximately 30 minutes. Each participant received an average of 25.8 acupuncture treatments (the range was 22–29 treatments). The average number of weeks of treatment was 14.6 (range 10–21), and the average number of treatments per week was 1.9. Treatment gaps varied among participants: eight (73%) had no more than a 2-week gap, while three (27%) had gaps ranging from 3 to 6 weeks. Six participants (55%) were treated in the acupuncturist's office, three (27%) in assisted living facilities, one in a nursing home, and one initially at her private home and then in an assisted living facility.

Ten acupuncture points emerged as the most frequently used points: GV20 (in 68% of treatments), Taixi/Ki3 (60%), Zusanli/ST36 (58%), Sishencong (48%), Yintang (48%), Sanyinjiao/SP6 (47%), Shenmen/HT7 (40%), laser stimulation of the occiput (base of skull) (40%), GB9 (35%), and GV23 (19%). As the points were either on the head or on the four limbs, they required minimal



Table 1.

	Subject Demographics and Characteristics ($N = 11$)							
ID	Age (years)	Sex (M/F)	Married (Y/N)	Education*	Race	Birth Country	Years in US	
Α	80	F	Ν	SC	W	US	80	
В	76	F	Ν	HS	W	US	76	
С	78	F	N	HS	W	US	78	
D	81	F	N	HS	W	US	81	
Е	53	М	Υ	CD	W	US	53	
F	59	F	N	GD	A†	Burma	40	
G	82	F	N	SC	W	US	82	
н	74	М	Υ	CD	W	US	74	
ı	92	F	N	HS	W	US	88	
J	81	F	N	GD	W	US	81	
К	77	М	Υ	HS	W	US	77	

^{*}HS = high school; SC = some college; CD = college degree; GD = graduate degree.

or no undressing of the participants. The most frequently used six points became the core points for a subsequent study. Four of these six points had been designated as "primary points" and two as "secondary points" at the start of this study.

Feasibility outcomes

All participants, once enrolled, remained in the study. Data from the satisfaction questionnaires showed overall satisfaction from both participants and caregivers. Of the 11 caregivers, 9 (82%) were satisfied with the treatment results, 1 CG said it took too much time, and 2 (18%) responded negatively. Seven participants (64%) reported that acupuncture treatment was enjoyable, and 4 (36%) found it tolerable; all of the participants liked their acupuncturists. Only three (27%) participants reported there was pain present during their treatment, but they all reported that the pain was tolerable.

Effectiveness outcomes

Anxiety and depression

Using paired sample *t*-tests, we found statistically significant improvements in three of the four scales used to assess acupuncture effect on mood (Table 2). For the

depression measures, the total mean scores of the CSDD⁶⁰ declined from 6.4 at baseline to 3.1 at posttest (p < .05), while the 30-item GDS⁶¹ showed a decline in mean summary scores from 7.4 to 6.7, but the decline was not statistically significant.

For anxiety measures, both scales showed statistically significant results: the STAI⁶⁴ showed a decline in mean number or intensity of anxiety symptoms from 49.5 at baseline to 40.1 at posttest (p < .01), and the POMS⁶³ tension subscale showed a decline in mean number and intensity of symptoms from 8.8 to 4.5 (p < .05).

Cognition

No significant change was noted on measures of cognitive function. We used paired t-tests for all measures; the p values were all .6 or greater (Table 2). Participants declined from an average MMSE⁵⁹ of 21.9 at baseline to 21.3 at posttest. They also declined slightly from a mean of 37.5 to 36.1 on the BNT,⁶⁶ but they improved slightly from 25.4 to 25.5 on the FAS fluency test.⁶⁵

Energy and vitality

We found statistically significant caregiver-reported improvements in participants' energy as measured by the



[†]Asian.

Table 2.

Results of Paired t -Tests of Anxiety, Depression, and Cognition ($N = 11$)								
	Anxiety		Depression		Cognition			
	POMS	Spielberger	Cornell	GDS	MMSE	BNT	FAS	
Baseline Mean (SD)	8.8 (6.3)	49.5 (8.4)	6.4 (5.0)	7.4 (3.9)	21.9 (5.2)	37.5 (12.6)	25.4 (17.1)	
Posttest Mean (SD)	4.6 (3.4)	40.1 (8.0)	3.1 (3.0)	6.7 (7.0)	21.3 (4.9)	36.1 (13.9)	25.5 (17.9)	
p-Value Paired t-Test*	.050	.005	.011	.358	.646	.639	.968	

Key: POMS = Profile of Mood State; GDS = Geriatric Depression Scale; MMSE = Mini-Mental Status Exam; BNT = Boston Naming Test; FAS = Controlled Oral Word Association Test

vitality subscale of the SF-36 (Table 3). For the four items measuring vitality or energy levels, caregivers reported a significant perceived increase in vitality, with mean scores decreasing from 4.0 at baseline to 3.5 at posttest (p < .01). We also found statistically significant improvement in SF-36 caregiver-reported anxiety (two items, 6-point Likert), with a decline in the scale from 3.2. to 2.5 (p < .01); caregiver-reported depression did not change significantly. The participants reported small improvements in energy, anxiety, and depression that were not statistically significant (Table 4).

DISCUSSION

The initial data suggest that acupuncture is a feasible alternative or complement to conventional medical treatments for the mood comorbidities of AD. We were able

to recruit and retain 11 participants, and all of them stayed in the 4-month study and completed the minimum number of 22 treatments. No serious adverse effects were reported. Acupuncture treatment was well received by both the participants and their family caregivers. We were able to train acupuncturists to treat AD patients and document their treatments. Some participants reported they enjoyed the treatments while others said they tolerated them. Some were more sensitive to pain than others, but none found the minor pain unbearable.

The Bader-Wellesley study found strong pre- and posttreatment differences in measures of depression and anxiety. Since multiple measures of anxiety and depression showed improvements and data were collected from both the participants directly as well as their primary caregivers, the findings are particularly robust for such a small study.

Table 3.

Mood and Vitality Subscales for SF-36: Caregiver Report (N = 11)						
	Vitality†	Anxiety‡	Depression§			
Baseline Mean (SD)	4.1 (1.2)	3.2 (.7)	2.8 (.7)			
Posttest Mean (SD)	3.4 (.9)	2.5 (.8)	2.7 (1.0)			
p-Value Paired t-Test (2-tailed)	.003	.006	.394			

[†]Four items averaged; range 1-6.

Table 4.

Mood and Vitality Subscales for SF-36: Patient Self-Report in Interview (N = 11)						
	Vitality†	Anxiety‡	Depression§			
Baseline Mean (SD)	2.7 (.8)	2.5 (.7)	2.6 (1.0)			
Posttest Mean (SD)	2.6 (.9)	2.1 (.6)	2.2 (.7)			
p-Value Paired t-Test (2-tailed)	.416	.441	.350			

[†]Four items averaged; range 1-6.

^{*}One-tailed test for mood (predicted improvement), two-tailed for cognition (no prediction).

[‡]Two items averaged; range 1–6.

[§]Three items averaged; range 1-6.

[‡]Two items averaged; range 1–6.

[§]Three items averaged; range 1–6.

All of our measures of anxiety showed statistically significant results. Although our various measures of depression showed improvement in symptoms, only the CSDD showed statistically significant improvements. Improvements in measures such as the GDS or the depression items on the SF-36, whose items reflected primarily sad or depressed mood as opposed to somatic symptoms, differences in measures were not statistically significant.

of depression and The Bader-Wellesley study, the first acupuncture study published in English to anxiety. examine effects on anxiety symptoms in persons with dementia, found stronger effects on depression in persons with dementia than previously published Asian studies. Chen's study reported mixed results in treating depression in persons with AD and VD. Chen found that 45 acupuncture treatments focused on treating cognition also improved depressive symptoms (based on clinical judgment, not on formal measures) in 29% of the 7 people in the study with both AD and depressive symptoms and in 55% of the 11 people in the study with both VD and depressive symptoms.

The findings of many other acupuncture studies document a beneficial effect of acupuncture in cognitively intact people with depression^{38-46,51} and in cognitively intact persons with anxiety.41,43,44,50-52 Our findings thus add support to the conclusion that acupuncture is effective in treating anxiety and possibly depression, even in people with dementia. This is particularly relevant since anxiety and depression are such common comorbidities in AD and VD.

The significant increase in energy as measured by the vitality subscale of the SF-36 is an intriguing finding given that one major purpose of acupuncture in traditional Chinese medicine is to increase health by stabilizing Qi, which would include restoring energy. Also, a majority of participants said they felt calmer (64%) and had more energy (64%) after acupuncture treatments, a few said there was no change, and none reported getting worse (although there was one "didn't know" for this latter question).

The study did not replicate the finding that acupuncture actually improves cognitive function—a finding reported by Jiang,32 Chen,30 and Kao.34 It would be difficult for Americans to follow the Kao protocol (21 scalp acupuncture treatments in 30 days), and even he lost two thirds of the initial study participants. However, our study results are encouraging, and the cognitive scores could be interpreted as staying constant, on average, during the 4month study period. Cognitive decline was mild and far from being statistically significant (p values greater than 0.6 for the MMSE, FAS, and BNT).

> The addition of acupuncture to standard medical treatment may ultimately improve the quality of life of those with AD or VD and their caregivers by improving mood and other comorbidities. Randomized, controlled studies with larger numbers may also show that acupuncture helps slow cognitive and functional decline.

One caveat is that the baseline mean scores on all four scales for anxiety and depression outcomes were below typical cut-

offs for mild depression or anxiety. While four participants had scores of depression measures (CSDD and GDS) that correspond to mild or moderate depression and/or anxiety and a fifth had scores that correspond to moderate anxiety, the scores for the remaining six indicated a very mild level of depression and/or anxiety. However, all participants or their caregivers reported symptoms of depression or anxiety prior to enrollment in the study, and eight participants were taking antidepressants or antianxiety medicines months before and during the study. Thus, prior to receiving acupuncture treatment, these participants' depression or anxiety symptoms persisted despite medical treatment. It is an open question whether the observed improvement in anxiety and depression symptoms resulted from the acupuncture treatment alone or represented a potentiating effect of acupuncture on the antidepressants and antianxiety agents.

While results are promising, we need to keep in mind some limitations. As a phase I trial, there was no control arm. Thus, the observed positive effect of acupuncture on measures of anxiety and depression may be due to either the experience of being in a study, the positive interaction with the acupuncturist, or regression to the mean. The concomitant use of mood-altering medications, such as antidepressants and antianxiety drugs, could introduce potential confounding factors.

Future studies should have tighter inclusion and exclusion criteria to achieve more reliable and robust results. For example, future studies should screen rigorously and require scores above stated cutoffs on standard measures for mild depression and/or mild anxiety. Different measures could then be used as outcome measures.

PERSONAL ANECDOTES

Each participant came with multiple comorbidities and health challenges, yet during and after the study each



The study

found strong pre-

and posttreatment

reported a unique experience with acupuncture treatment, each reported a genuine interest in acupuncture treatment, and some reported benefits from the treatment.

Case studies and direct reports from participants and their caregivers are of special interest in this early stage of exploring the feasibility of acupuncture as a treatment for the comorbidities of AD and VD. Following is a sampling of such stories.

Participant J, age 81, suffered from severe and painful arthritis, but her history of hemorrhagic strokes limited her options for pain relievers. Even though she refused to allow body acupuncture, the auricular acupuncture treatments mitigated her pain and allowed her more freedom of movement.

The caregiver of participant A, age 80, stated this at the time of the treatments: "There are flashes of clarity. Six months ago I might have expected it, but since there's a decline, the clarity is more startling." This participant has continued acupuncture treatments, at this writing, for over a year beyond the end of her study participation, and she agreed to be featured in a syndicated medical news report.

Participant B, 76, had been very anxious about leaving her home of many decades despite being treated by her physician for several weeks prior to the move. Her caregiver reported that, with acupuncture treatment, her mother's anxious mood lifted, she became calmer, and she quickly adjusted to her new life in assisted living. Her daughter also reported that participant B was glad to have another caring person, her acupuncturist, come see her during her first 2 months in assisted living. As a result of her improved status, her doctor discontinued all antianxiety medications.

Participant D, age 81, had a history of severe depression resistant to antidepressants. She had VD while all other participants had AD. Participant D refused to see a psychiatrist, despite the advice of her primary care physician, and then refused to take any more antidepressants. Concerned, her caregiver daughter sought acupuncture as an alternative treatment her mother might accept (and did). The daughter reported that before acupuncture, her mother thought everything was centered around her: "She was in a pit and could not see outside of her own deep situation." However, the caregiver felt that, with acupuncture, her mother became understanding and less self-centered: "She really started to understand that I have three kids and that things might be difficult for me. . . . Her ability to get beyond her own issues is the change. She will also cry more often. Before she was just mad. She was very stoical and would not let her feelings out. Now

she will tell you what is wrong." The caregiver stated that this is "a big shift." The daughter also said that, on the phone, her mother's conversations are better and that she has seen some surprising memory changes: "I would test her and I'd be surprised she remembered. . . . I said, "The acupuncturist is coming," and she responded, 'Yes, I only have a few sessions left."

Participant D experienced an above-average response to the acupuncture sessions. Her greatly improved mood (reflected in decreases on the POMS tension subscale from 15 to 2, on the STAI from 62 to 47, and on the CSDD from 18 to 8) was accompanied by a 5-point improvement in her MMSE score (from 15 to 20), an increase from 31 to 39 on the BNT, and an increase from 5 to 19 on the FAS. That her GDS scores increased, from 16 to 22, was consistent with her daughter's observation that her mother was expressing her sad feelings more openly.

Participant F, age 59, thoroughly enjoyed the acupuncture sessions and liked to have the needles manipulated vigorously. She said her friends had noticed an improvement in her memory, conversation, and other cognitive tasks. She said, "Occasionally I will remember and surprise my friends." The acupuncturist noted a great decrease in anxiety, including confidence in dressing herself. At baseline, according to her son and her medical records, participant F suffered from severe anxiety unrelieved by pharmaceutical treatment. Acupuncture relieved her anxiety and depressive symptoms (all scores improved substantially). Her cognitive scores on some tests also improved (e.g., her MMSE score improved from 17 to 21). She continued her treatment intermittently for almost 2 years after the conclusion of the study.

Before developing AD, participant G, age 82, was described by her daughter as an "up person," but AD caused her to shut down emotionally and dulled her mood—she had become "flat and apathetic." Her daughter stated that, after the acupuncture treatment, her mother's personality was restored. She reported that her mother is "much brighter, more aware, more involved, and has regained her sense of humor" and that her conversation has improved. Participant G displayed humor in her posttest interview, saying, "Getting stuck with needles is not my idea of fun." She also told the researchers, "I can't say I enjoyed having needles stuck into me but I was anxious to see what would happen."

Only one participant experienced substantial declines in outcomes. Acupuncture treatment was going well with participant E, age 53, for the first two thirds of the treatment sessions. Then, just a few weeks before the posttest



evaluation and with only a couple acupuncture treatments left, his medical doctor discontinued done pezil medication precipitously, and he suffered a dramatic decline in cognitive function, together with a substantial increase in mood distress. His MMSE plummeted from 28 to 17 and his BNT from 46 to 19.

LESSONS LEARNED AND RECOMMENDATIONS

This study suggests that acupuncture may be useful as a short- or long-term alternative therapy for treating certain comorbidities in persons with dementia, since it is minimally invasive and has no significant side effects.

Treatments for persons with dementia (or their caregivers!) should be performed under the auspices of a licensed, well-trained, experienced acupuncturist. To ensure that the patient stays oriented and safe, the acupuncturist should not leave the treatment room (except if the patient is in the very early stages of the disease). Also, it is best to have appointments scheduled at the same time and day of the week to minimize confusion and missed appointments. In addition, while the Wellesley acupuncturist team believe that three times a week might produce larger and faster results, we found it logistically impractical and often impossible to arrange treatments more than twice a week. For

average consumers, the cost of more than one or two treatments a week might be prohibitive.

Based on the project team's

collective experience, the acupuncturist should not leave ideal candidates for acupuncture treatment would include the treatment room. persons who have AD or VD and are experiencing certain comorbidities that have not been or cannot be sufficiently resolved with current allopathic modalities, either because the modalities have proven ineffective for this person or are not well tolerated. Acupuncture has the advantage of helping relieve the side effects of other drugs rather than adding to them and thus may be acceptable to persons who prefer not to take more pharmaceutical pills. Comorbidities that acupuncture may be useful in treating include anxiety, depression, pain, joint swelling, nausea, and perhaps behavioral issues that other nonpharmaceutical techniques have not resolved. Other considerations include whether there are supportive family members willing to help the person with dementia make and keep appointments and provide transportation. The prospective acupuncture patient should also not experience

excessive bleeding tendencies. In addition, for practical logistical reasons, well-qualified acupuncturists should be available within 30-40 minutes travel time.

Many elderly persons with AD or VD also suffer from painful diseases such as arthritis. This study suggests that acupuncture can serve as pain relief for these persons, just as it does for many cognitively intact persons.68-75 Acupuncture could also be useful in alleviating sleeping problems, especially when conventional medicine is not working or is accompanied by unacceptable side effects or when exercise is not an option.

Acupuncture could be used as complementary or adjuvant therapy in clinical settings. For instance, it could be used to reduce anxiety and agitation in persons with dementia who are being prepared for physical therapy or health care activities, such as dental visits and MRI and other brain scans. It could also be used to supplement other nonpharmacological methods to reduce sundowning and other behavioral issues that may arise. It is well established as an effective means of minimizing nausea from multiple causes, including chemotherapy.²⁸ It remains to be seen if acupuncture, as part of a package of treatments, can also help slow cognitive and functional

Anyone seeking treatment should consider interviewing candidate acupuncturists by phone in order

to discover their licensing, training, and experience treating the elderly as well as discuss the ailpatient stays oriented and safe, the ments of concern. If an acupuncturist is licensed, has substantial relevant experience (e.g., treating depression), but has not treated persons with

dementia, the family should expect to

teach the acupuncturist the proper way to interact with the person with dementia. This article can be shared as a guide to treatment protocol. The acupuncturist should also be asked about cost and location, whether he or she travels to patients' residences, and whether senior or "quantity" discounts are available. In addition, the acupuncturist may be able to inform the family which insurance companies are offering coverage in the area. General information about licensure, training [and certified acupunctants] is provided online by the National Certification Commission for Acupuncture and Oriental Medicine at www.nccaom.org. A list of local acupuncturists is also available on the website of the American Association of Oriental Medi-cine (www.aaom.org) or by calling the association at 888-500-7999.



To ensure that the

In the future, long-term care settings may employ resident acupuncturists who pay daily or weekly visits to patients in need of pain therapy, reduction of nausea, or relief of agitation or mood disorders. The addition of acupuncture services in assisted living facilities, nursing homes, and other residential facilities may ultimately improve the quality of life of those with AD or a related disorder and their caregivers by improving mood and stabilizing behavior. Facilities could negotiate package rates with acupuncturists, thereby lowering treatment costs. In addition, some health plans might offer coverage for acupuncture treatment.

CONCLUSION

Funding from the Helen Bader Foundation and the national Alzheimer's Association has enabled the development and completion of the first scientific pilot study in the United States of acupuncture as a treatment for anxiety and depression in persons with AD and VD. The results of the study revealed that acupuncture treatment was both feasible and safe for persons with dementia. The exploration of effects was encouraging. The purpose of the study was to provide relief to mood distress in addition to that already obtained with conventional treatment, and that purpose was achieved in this small pilot. Future research on acupuncture as a treatment for persons with dementia is merited.

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