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Research Article

Application of Auricular Point Acupressure for Pain in Patients with Alzheimer's Disease and their Caregivers

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Abstract

Objective: To explore the feasibility of Auricular Point Acupressure (APA) to self-manage pain among patients with Alzheimer's disease and related disorders (ADRD) and their caregivers (patient-caregiver dyads).

Methods: A two-phase study design was used. Phase 1 was designed to explore the experiences of the dyads in using APA to manage chronic pain. In Phase 2, we examined the revised intervention protocol to manage pain. All of the study activities were conducted at the participants' homes.

Results: In Phase 1, five dyads (patients and caregivers) who received the APA treatment reported marked and immediate outcomes but there were challenges in applying APA to manage pain for ADRD patients, including how to remind the patients to stimulate the ear points, and the access issues (i.e., when the participants lived far away, home visits were not feasible). In phase 2, the intervention protocol was revised by including the reminder text message, caregiver training to self-administer APA training; the caregiver also received APA treatment for their pain/symptoms to motivate their willingness to adhere to APA practice. Among 7 dyads enrolled, the patients' worst pain had decreased 31% after completing the 4-week APA treatment compared to T1. Caregivers who received the training though APA stated that the treatment was easy to learn and easy to administer.

Discussion: Preliminary data demonstrate positive outcomes from the use of APA to manage pain in ADRD patients as well as feasibility in delivering caregiver training for both self- and patient-administration of APA. Further studies are warranted to examine the efficacy of APA on ADRD patients and their caregiver to manage their pain in a larger clinical trial.

Keywords: Alzheimer's disease and related disorders; Caregiver; Chronic pain; Auricular point acupressure

Introduction

Alzheimer's Disease and Related Disorders (ADRD) are characterized by progressive neurodegeneration that results in cognitive decline and eventual loss of function [1]. ADRD affects almost 5.8 million Americans, causing a significant negative impact on individuals and society [2-4]. Behavioral and Psychological Symptoms of Dementia (BPSD), including agitation, aggression and psychosis, as well as depression and apathy, are particularly common in ADRD, affecting 90% of individuals at some point in their condition [5,6]. The combination of BPSD and physical dysfunction is the major reason for seeking help and institutionalization [7]. Associated health care expenditures for ADRD are over $234 billion annually, including estimated unpaid caregiver hours [2,3,8].

Pain is common among older adults, including those with ADRD [9,10], which is predominantly, but not exclusively, related to musculoskeletal symptoms [11]. Assessing pain in older adults with ADRD is challenging due to the progressive cognitive and functional decline [12,13]. Evidence has shown that up to 64% of older adults with ADRD experience bothersome pain and 43% have pain that limits their activities [9]. It is considered one of the most important contributing factors of BPSD, such as agitation and aggression [14]. BPSD are frequent symptoms of under-

recognized pain in ADRD and often treated with antipsychotic medications, yet these medications are associated with significant adverse effects including increased cerebrovascular events, falls, and mortality [15,16]. Pain is an important determinant of neuropsychiatric symptoms, quality of life, mortality, and antipsychotic prescriptions in people with ADRD [17].

The goal of managing chronic pain is to decrease pain intensity, disability, and BPSD among patients with ADRD [14,18]. To accomplish this, analgesics and opioids are the most common methods to decrease pain and facilitate activity, but they are associated with adverse side effects (confusion, drowsiness, constipation, gastrointestinal bleeding, and potential addiction) [19,20]. Untreated pain is associated with BPSD [17,21], decreased daily activity [22], depression [23], cognitive dysfunction, and decreased quality of life [22]. Furthermore, ADRD patients usually have multiple medical conditions that require multiple medications. Polypharmacy may further aggravate symptoms and lead to additional problems such as harmful drug reactions and interactions [24]. Improved non-pharmacological pain management is strongly needed.

Due to the adverse effects of the current pharmacological treatments, Auricular Point Acupressure (APA), a non-invasive procedure, can be a viable non-pharmacological treatment or adjunct pain management among older adults with ADRD. APA provides acupuncture-like stimulations on ear points using small pellets instead of needles. Therefore, we have gathered substantive evidence on the significant impact of APA to effectively self-manage pain in many chronic conditions [25-36]. With origins stemming from Traditional Chinese Medicine, auricular therapy was developed into a science in the 1980s by Paul Nogier [37-39]. Nogier mapped a somatotopic representation of the human body onto the ear, indicating that specific ear points correspond to specific body parts and organs. Once ear points are identified according to the body parts affected by pain, the ear points can then be stimulated, and symptomatic body parts can be treated. The stimulation is done using acupuncture needles, pellets/seeds, or electric stimulation [40,41]. With APA, a needleless system of auricular acupuncture, small pellets (i.e., metals, magnets, or Vaccaria plant seeds) are taped onto the ear points and pressed by the patient throughout the day, anytime and anywhere, to manage pain symptoms [40,42]. The underlying theory of APA posits that the ear nerve system represents/mimics the entire body as a microsystem; these areas have a reflex connection with specific parts of the body [40,41] and have been validated by fMRI [43,44].

In APA, small seeds are taped on specific ear points by a skilled provider; patients press on the seeds to stimulate ear points three times daily, three minutes per time, for a total of nine minutes per day. ADRD patients with decreasing cognitive and memory function may have challenges to self-administer APA to manage their pain. Thus, we report how APA was adapted to manage pain for ADRD patients utilizing their caregivers.

Methods and Analysis

Design Overview

To explore the feasibility of APA for pain among ADRD patients and their caregivers (patient-caregiver dyads), we conducted a two-phase study. Phase 1 was a development phase. The aims for this phase were to: (1) examine the feasibility of recruiting dyads into the APA study, (2) explore the experiences of our dyads in using APA to manage chronic pain, and (3) develop an APA protocol that was specific to the ADRD population-based on ADRD patients and caregivers. Based on the experiences of our dyads, we revised our protocol for improvement. Phase 2 was aimed at pilot testing the revised intervention protocol. An open trial with a longitudinal study design was used to explore the feasibility of recruiting ADRD patients for APA and examine participants' experiences with the study protocol. All study appointments and activities took place at the homes of the ADRD patients.

Phase One

Participants

Participant dyads included ADRD patients and their caregivers.

Inclusion Criteria

Patients were eligible if they: (1) were 50 years of age or older, (2) had a diagnosis of ADRD based on the National Institute of Aging and Alzheimer's Association Guidelines [45], (3) had mild to moderate stages (Montreal Cognitive Assessment score $\geq$ 8); (4) had pain that persisted for at least three months and pain on at least half of the days for the previous six months [46], (5) had an average pain intensity $\geq$ 4 on a 10-point numerical pain scale in the past seven days, (6) were willing to receive APA for their pain, and (7) had a caregiver who was 18 years or older, willing to participate, and able to help manage the APA treatment.

Exclusion Criteria

Patients were excluded if they had: (1) a concurrent major psychiatric disorder (e.g., major depressive disorder, bipolar disorder, schizophrenia) or drug and alcohol abuse, or (2) severe illness or pain that would lead to significant deterioration in health, or that would limit participation in the interventions (e.g., metastatic cancer). Caregivers were included if they: (1) were 18 years or older, (2) were able to speak/read English; and (3) were the primary caregiver for the ADRD patient.

Recruitment Setting

Patients were recruited from the Johns Hopkins Memory and Alzheimer's Treatment Center (JHMATC), a multidisciplinary clinic with close to 23,000 patients per year, and the Clinical Core of the Johns Hopkins Alzheimer's Disease Research Center

(JHADRC). Two health practitioners referred patients to the research team. A study coordinator then reached out to the referred patients and caregivers to screen them for interest and eligibility in the study. When potential participants contacted the research office, the study coordinator discussed the study and screened for eligibility.

APA Treatment Protocol

Comprehensive details on our APA protocol are provided in our previous manuscripts [36,42,47-49]. Auricular diagnosis [42] was used to locate ear points for treatment that included the Chinese Standard Ear-Acupoints Chart [50] as a guide to locate the ear points for treatment. The search of ear points (probing) began within an ear zone area (recognized internationally) [41] corresponding to the affected body locations. The points were confirmed when the patient felt a tenderness or sharp pinch on their ears during probing. The points that received acupressure were: (1) points corresponding to the body pain location, and (2) three points known for alleviating stress and pain (i.e., *shenmen, sympathetic,* and *nervous subcortex*) [50]. After the points were located, the outer ears and ear lobes were cleaned with 75% alcohol. Vaccaria seeds were applied to the ear points and the seeds were taped securely. These steps took 10 to 15 minutes.

Patients received one treatment each week for four weeks. ADRD patients and their caregivers were instructed to apply pulsing pressure to the seeds taped on the patient's ear with the thumb and index finger without rubbing side to side (to avoid adverse effects of skin irritation and possible injury at the acupressure point). Patients were expected to press all seeds for three minutes, three times daily (nine minutes total), even if they did not experience pain. The tape and seeds remained on the ear points for five days. Patients were instructed to remove all the seeds at the end of the fifth day and let the ears rest for two days to allow the acupoints to restore sensitivity before the next weekly treatment. Patients and caregivers were instructed to contact the study center immediately if any of the tape pieces fell off the ears or if any adverse effects occurred.

Procedure

After Institutional Review Board approval, participants were recruited from Alzheimer's caregiving events or referred by healthcare providers (physicians and nurse practitioners) at JHMATC. A phone screening was conducted to determine participant eligibility and a home visit was scheduled for those who were eligible. All study measures and surveys were administered to the dyads on paper or through Research Electronic Data Capture (REDCap), a paperless survey database installed onto the research team's iPads.

At the first home visit (T0), informed consents, demographics, and baseline data were collected from the dyad. An activity-tracking Fitbit watch was also given to the ADRD patients to collect physical activity data (daily step counts). Dyads were then waitlisted for one month so that the ADRD patients first received the 4-week APA treatment. Data were collected in person for the baseline visit (T0), four weekly APA treatment visits (T1-T4), and post-APA visit (T5). At the post-intervention visit, a brief interview was conducted to explore the patients' and their caregivers' experiences of using APA.

Measures

ADRD Patient Outcomes

Pain Intensity

Brief Pain Inventory (BPI)-Short Form [51] was used to assess pain intensity (severity) during the past seven days on an 11-point numeric rating scale (0=no pain to 10=pain as bad as you can imagine). BPI has established reliability and validity [51]. A 30% improvement was considered the threshold for identifying clinically meaningful improvement in pain intensity [52]. In this study, single score of "average" pain intensity were used in the final data analysis.

Pain Interference

The BPI [51] was also used to assess the impact of pain on seven domains of daily functioning (general activity, mood, walking ability, normal work, relations with others, sleep, and enjoyment of life) during the past seven days. Patients rated the level of interference that pain had on each domain on a numerical scale from 0-10 (0=pain does not interfere to 10=pain completely interferes). All seven ratings were summed and averaged with a range of scores from 0 to 70; higher scores indicated more pain interference with daily functioning.

Physical Function

Patients' physical function was measured by a self-report survey (4-item subscale) from the PROMIS-29 [53] and by using objective measures (Fitbit). PROMIS-29 has established reliability and validity [53] and is widely used in the United States. The range of scores were 4-20; higher scores indicated more difficulty with daily physical functioning. Fitbit data were measured in average daily step counts.

Neuropsychiatric Symptoms

Neuropsychiatric Inventory Questionnaire (NPI) [54] was used to assess the severity of 12 neuropsychiatric symptoms. Caregivers completed the NPI by rating the severity of the symptoms that their ADRD patients exhibited in the last month on a Likert scale from 1-3 (1=mild, 2=moderate, 3=severe). The 12 symptom scores were summed as a total score. The range of scores were 12-36; higher scores indicated more symptom severity.

Cognitive Function

The Montreal Cognitive Assessment (MOCA) was used to assess mild cognitive dysfunction by testing several cognitive domains (i.e., attention, memory, and visuospatial skills) [55]. The assessment was administered to the patient by the same study team member at the baseline visit (T0) and post-APA visit (T5) to ensure consistency without introducing interrater reliability. The range of scores were 0-30; a score of 26 and higher was generally considered normal.

Quality of Life

The Quality of Life in Alzheimer's disease **(**QOL-AD) [56] caregiver-administered version, was used to assess the patient's quality of life in 13 domains (i.e., emotional, mental, and physical health). Caregivers completed the QOL-AD by rating the QOL of the ADRD patients using a scale of 1 (poor) to 4 (excellent). Scores ranged from 13 to 52; higher scores indicated a better overall quality of life for the patient.

Caregiver Distress

It was measured by Neuropsychiatric Inventory Caregiver Distress [57]. Caregivers rated the distress they experienced, due to the 12 neuropsychiatric symptoms exhibited by the ADRD patients, on a Likert scale from 0 to 5 (0=no distress to 5=extreme distress). Scores ranged from 0 to 60; higher scores indicated more distress experienced by the caregiver.

Caregiver Burden

Caregiver burden was measured using the Zarit Burden Interview [58]. Caregivers answered 22 interview questions about their feelings of burden using a Likert scale from 0 to 4 (0=never to 4=nearly always). Scores ranged from 0 to 88; higher scores indicated greater caregiver burden experienced due to their caregiving duties.

Demographics Survey

This included questions about race, age, socioeconomic status, educational level, living situation, and pain medication use.

Brief Interview

A brief qualitative semi-structured interview was conducted for each dyad at the post-intervention home visit (T5). The initial opening question was "how did you feel about APA?" and then the direction of the interview was based on the participants' concerns and questions. The caregivers and ADRD participants were interviewed together. The semi-structured interviews were audio-recorded and transcribed for analysis.

Data Analysis

Descriptive analyses (e.g., means, standard deviations) were used to examine the scores in all of the outcomes. Intent to Treat (ITT) analysis using the data of all participants was used. Missing values on the outcome variables were replaced by "last value carried forward" for ITT. For the qualitative interviews, transcripts of the audio-recording with field notes were analyzed using conventional content analysis to explore the dyads' experiences in more depth with the APA treatment and other study procedures. Common suggestions and concerns were extracted to address issues with the feasibility of APA.

Results

Feasibility of Recruiting ADRD Patients for APA

As shown in Figure 1, 19 dyads were identified and screened for eligibility. Fourteen dyads were excluded for various reasons: no longer interested in the program (n=2, 10.5%), did not meet inclusion criteria (n=4, 21.1%), were unreachable (e.g., did not return the call, phone was disconnected) (n=4, 21.1%), and lived far away (travel time from research facility > 30 min drive) (n=4, 21.1%) (Figure 1). In effect, five dyads were enrolled. One dyad dropped out at the fourth week because the patient had a health emergency, unrelated to the APA that required hospitalization. Four dyads completed the 4-week intervention program (80% treatment retention).

Participant Characteristics

Table 1 presents the demographic characteristics of the ADRD patients. Patient ages ranged from 65 to 83 years (mean=75.8), with four females (80%) and three whites (n=3, 60%). The mean age for the caregivers was 63.5 (SD=3.42).

APA Effects on ADRD Patient Outcomes

Pain Intensity

Table 2 presents the pain intensity (worst and average) scores. Pain intensity scores from baseline (T0) to pre-intervention (T1) were similar, indicating that ADRD patients' chronic pain was stable and their pain intensity did not change due to time in study. After four weeks of APA treatment, the average pain intensity scores decreased 24% at post-intervention (T5) compared to pre-intervention (T1) (Figure 2a).

Pain Interference and Physical Function

Pain interference and physical function scores had a pattern similar to the pain intensity scores. Pain interference and physical function improved from pre- to post-APA (T1 to T5), indicating less pain interference (19%) and better physical functioning (22%) (Table 2). Figure 2b shows the weekly changes on patterns of pain interference and Figure 2c shows physical function. Daily step counts collected from the Fitbit data showed an increase in average daily steps by 25% after the end of the 4-week APA treatment.

Neuropsychiatric Symptoms, Quality of Life, and Cognitive Function

Table 2 shows the change patterns from baseline (T0) to post-intervention (T5). The average neuropsychiatric symptom severity scores remained constant from baseline (T0) to pre-APA (T1) and increased by 7% at post-intervention, indicating slightly more symptom severity compared to pre-intervention (T1) (Table 2). The average quality of life scores stayed constant from baseline to pre-APA (T0 to T1) and throughout the month of treatment (T1 to T5) (Table 2). The average MOCA scores slightly decreased from baseline (T0) (mean=12.40, SD=3.58) to post-intervention (T5) (Mean=12.00, SD=4.24).

Caregiver Outcomes

Caregiver's Burden and Distress

Average caregiver burden and distress scores increased between pre-APA (T1) and post-APA (T5), indicating higher levels of burden and distress regarding their caregiving duties. Table 3 shows the burden and distress scores through time.

Qualitative Interview Data: Dyads' APA Experiences

The following interview data from the dyads revealed common themes on APA treatment effects, usability, and barriers.

Theme 1: APA Treatment Effect and Feasibility

Dyads reported immediate outcomes that surpassed their expectation. They found that the pain was significantly less severe. Two caregivers said that the patients did not ask for pain medication during the night, did not complain about the pain, and were able to walk more than before the treatment. One patient reported perceiving only a small difference, but the patient reported better mobility when bending down immediately after the treatment. All caregivers expressed that the APA treatment had immediate effects which were observable. One caregiver said that the pain came and went, and the symptoms were significantly less severe. All caregivers also expressed that the treatment was very easy to enact. Other comments about the treatment included: (1) one patient did not like to keep the seeds/tapes on, (2) annoyance with the seeds led patient to try to take them off, and (3) seeds easily fell off (n=1).

Theme 2: The Need to Remind the Patients to Stimulate the Ear Points

Participants stated that they did not stimulate the ear points as suggested because they forgot. Most of them had their caregiver remind them or press the ear points for them. A caregiver who did not live with the patient had a busy work schedule and was not able to remind the patient to press the seeds regularly. The same situation arose with another patient who went to the day care center during the day.

Lessons Learned from Phase 1

Based on our study findings, it was feasible to recruit ADRD patients and their caregivers and to administer APA to manage ADRD patients' pain. Caregivers expressed their observations that APA was an effective treatment for pain; this qualitative assessment was corroborated by a positive trend of improvement in patient pain intensity, pain interference, and physical function. In this phase of the study, the caregivers played a critical role in managing the health of the ADRD patients. They took responsibility for reminding the patients to press the seeds, or they pressed the seeds for the patients. However, given caregivers' work schedules or patients' activities, caregivers may not have been able to be with the patients all the time. Home visits were only feasible for participants who lived close to the research facility (i.e., traveling time about 30 minutes driving distance, one way). Hence, the recommended pressing times may not have been adhered to consistently. In this phase of the study, we also learned that caregivers had their own health issues (i.e., chronic pain); as such there was an opportunity for caregiver to benefit from APA training and self-treatment as well.

Phase Two

Based on the lessons learned and feedback from Phase 1, we revised the intervention protocol to make it more feasible for ADRD patients and their caregivers. The APA protocol was revised as follows:

1. Reminder Text Message: A text message (three times per day: morning, noon, and evening) was sent to the caregivers and ADRD patients simultaneously to remind them both about pressing the seeds. Due to the limited cognitive function of ADRD patients, a simple, easy-to-use phone with bigger buttons and a simple menu (e.g., Jitterbug Flip phone) was provided for those who did not have a phone. The phone was programmed with a loud sound and vibrate setting so that the patients were easily made aware when they received the reminder texts. Caregivers received the same reminder messages as the patients on the same schedule.

2. Reminder Sign Photo: We made a large sign with the words "When in pain, press the seeds" on a photo of an ear wearing APA ear seeds so that caregivers could post them throughout the house to help patients remember that the seeds were meant to help with pain. We taught the ADRD patients that the sign was a reminder to press the ear seeds when they were experiencing pain.

3. Caregiver Training: In-person APA caregiver training was provided for those who lived more than 15 miles from the study site and offered to any caregiver who wished to receive the training. The interventionist administered the first week of APA treatment for the ADRD patient; caregivers then completed the remaining three weeks of APA treatment. An APA kit (including seeds and probe) was provided. Ear seed placements for both the patient and caregiver were photographed and given to the caregiver to use as a reference guide to administer APA on the ADRD patients. The caregiver was called each week for the purpose of weekly data

collection and to allow opportunity to answer any questions about the APA treatment.

4. Caregiver APA Treatment: Recognizing that some caregivers also suffered from chronic pain, caregivers then received the APA treatment for their own pain/symptom as applicable to ease their burden and relieve their pain/symptoms. Caregivers were instructed on how to self-administer APA. The same auricular diagnosis procedure was used to locate and activate the caregivers' ear points for treatment. Caregivers receiving the APA treatment completed weekly pain surveys identical to those of their patients and received a Fitbit activity tracker.

5. One-month Follow-up Added: A follow-up phone call to caregivers was added to assess whether effects of APA were sustained one month after completion of the treatment (M1 time point).

Approach

Participants, recruitment setting, and procedures were similar as in phase 1 apart from changes noted in the protocol as above. Similar measures as those used in Phase 1 were also used in Phase 2 and descriptive analyses were conducted in analyzing the data.

Results

Recruitment

To examine feasibility and pilot test outcomes of the adjusted APA protocol, we screened 34 dyads; 27 were excluded for the following reasons: patients were uninterested (n=5), had no chronic pain or at the levels insufficient for eligibility (n=13), or did not respond to the team's outreach (n=9) (Figure 1).

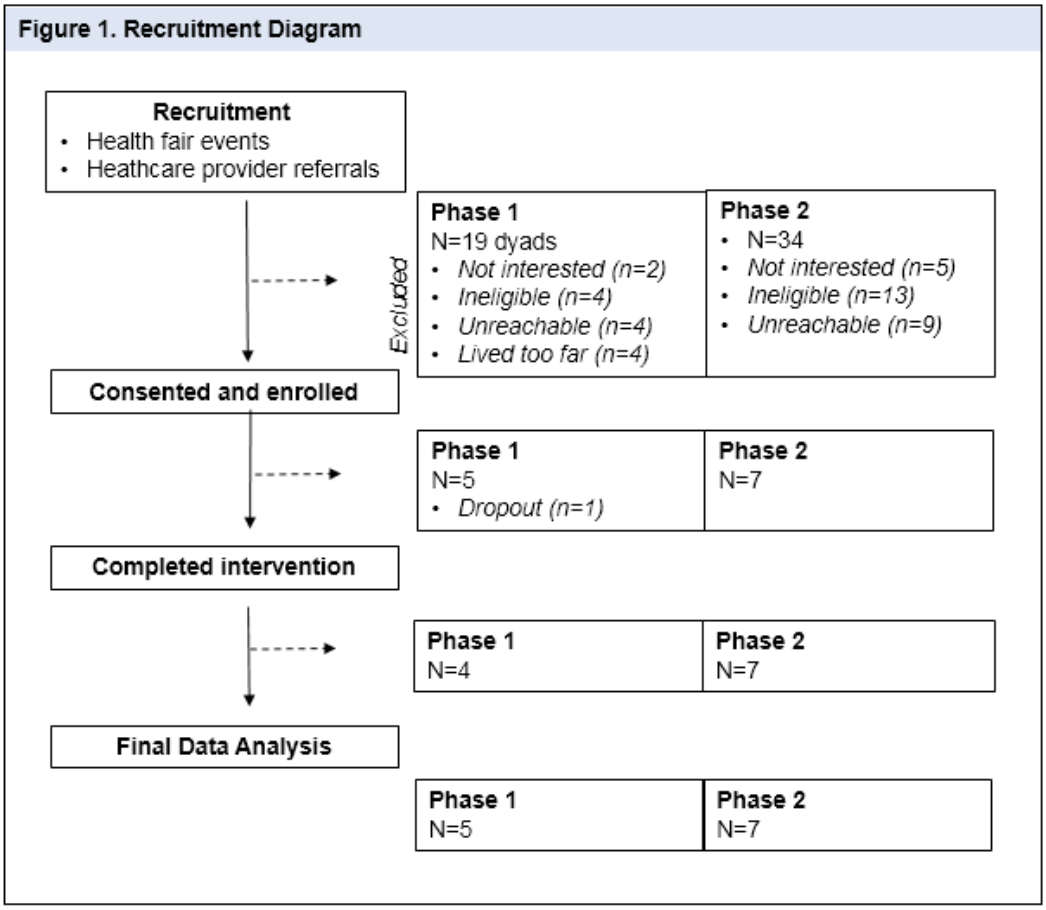


Figure 1: Recruitment Diagram.

Participant Characteristics

Table 1 presents the demographic characteristics of the seven ADRD patients. The patients ranged in age from 73 to 91, (mean=83.0), including five females (71%) and five whites (71%). The caregivers' ages ranged from 30 to 88 (mean=65.7), including four females

(57%) and five whites (71%). Of the seven dyads enrolled, five caregivers chose to receive APA alongside their ADRD patients. Three caregivers received the in-person APA training, 2 caregivers received the APA treatment from the interventionist.

Variable	Phase 1 *(n=5)*	Phase 2 *(n=7)*
Age		
Mean (Range)	75.8 (65-83)	83.0 (73-91)
Gender		
Male	1	2
Female	4	5
Race/ethnicity		
White	3	5
Black/African American	2	2
Marital Status		
Single	1	0
Married	3	5
Widowed	1	2
Employment Situation		
Unemployed	1	1
Disabled	2	2
Other	2	4
Highest Completed Education Level		
8th grade or less	0	2
9th to 11th grade/High School/GED	5	2
College or above	0	3
Estimated Income Before Taxes		
<19,999	1	0
$20,000 to $39,999	1	3
> $60,000 to $100,000	3	3
Living Situation		
Owns home or apartment	4	5
Lives in family household	1	2
Current Pain Medication Use		
Yes	1	3
No	4	4

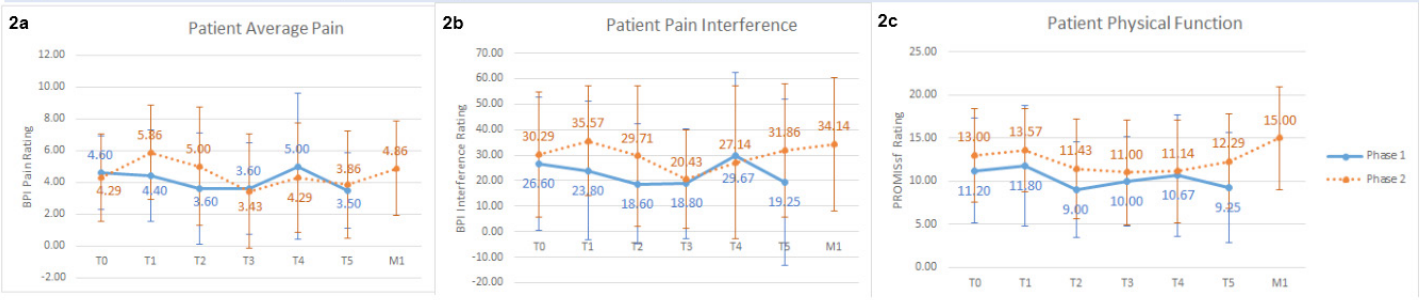
Table 1: Demographic characteristics of ADRD patients.

APA Effects on ADRD Patient Outcomes

Pain Intensity

Patients reported an overall decrease in pain intensity (31% decrease in average pain intensity) after completing the 4-week APA treatment (T5), compared to T1 (pre-intervention). Pain reduction was felt most strongly after two weeks of APA, with average pain decreasing by 41% at T5 compared to T1 (Figure 2a).

Figure 2. Effects of APA on patients' pain intensity, pain interference, and physical function.



Note: The Phase 1 and 2 changes at pre-APA (T1), weekly during intervention (T2, T3 and T4), post-APA (T5), and 1-month follow-up (M1) are shown in (2a) for average pain intensity, (2b) for pain interference, and (2c) for physical function. Graphs show mean scores ± standard deviation. BPI, Brief Pain Inventory; PROMIS-29sf Physical Function, Patient-Reported Outcomes Measurement Information System Short Form.

Figure 2: Effects of APA on patients' pain intensity, pain interference, and physical function.

Pain Interference and Physical Function

Compared to pre-intervention (T1), patients only reported slight improvement (10%) in pain interference or physical function after 4-weeks of APA treatment. Fitbit data revealed that patients experienced an overall decrease in average daily step count by 34.8% at the end of the 4-week treatment (Table 2).

Variables	Phase 1 *(n=5)* (M±SD)				Phase 2 *(n=7)* (M ±SD)		
	T0	T1	T5	T0	T1	T5	M1
Pain Intensity							
Average Pain (BPI)	4.60±2.30	4.40±2.88	3.50±2.38	4.29±2.75	5.86±2.97	3.86±3.39	4.86±2.97
Physical Function							
Pain Interference (BPI)	26.60±26.28	23.80±27.14	19.25±32.59	30.29±24.47	35.57±21.58	31.86±26.06	34.14±26.21
Physical Function (PROMIS)	11.20±6.06	11.80±7.01	9.25±6.40	13.00±5.42	13.57±4.83	12.29±5.47	15.00±5.94
Average Daily Steps (Fitbit)	1,151± 321	1,232±866	1,442±0	3,602±2,957	3,467±3,702	2,349±1,650	-
Neuropsychiatric Symptoms							
Severity (NPI)	9.80±8.96	9.80 ± 9.28	10.5 ±12.79	7.57±7.50	5.00± 5.77	5.57±7.59	5.14±6.84
Cognitive Function							
MOCA	12.40±3.58	-	12.00±4.24	16.86±6.23	-	17.43±5.47	-
Quality of Life							
QOL-AD	30.20±9.65	30.60 ± 8.96	30.25 ± 4.27	32.57 ± 6.35	34.00±7.02	33.71±8.24	30.71±6.42

M: Mean; SD: Standard Deviation; BPI: Brief Pain Inventory; PROMIS-29sf Physical Function: Patient-Reported Outcomes Measurement Information System Short Form; NPI: Neuropsychiatric Inventory; MOCA: Montreal Cognitive Assessment; QOL-AD: Quality of Life in Alzheimer's Disease

Table 2: Patient Study Outcomes.

Neuropsychiatric Symptoms, Quality of Life, Cognitive Function

As noted in Table 2, compared to pre-intervention (T1), the average neuropsychiatric symptom severity increased slightly (11%) after 4-weeks of APA treatment. The average quality of life scores remained the same after 4 weeks of APA treatment and decreased slightly (8%) at 1-month follow-up (T5). MOCA scores increased slightly (3%) from baseline (T0) to post-APA (T5) (Table 2).

Caregiver Outcomes

Burden and Distress

There were decreasing trends for caregiver burden and distress from pre-intervention (T1) to post-intervention (T5), and 1-month follow-up (1M) (Table 3). From T1 to T5, caregiver's burden decreased by 4%. Distress decreased by 11%, and continuously decreased by 14% for caregiver's burden and by 21% for caregiver's distress at the 1M follow-up.

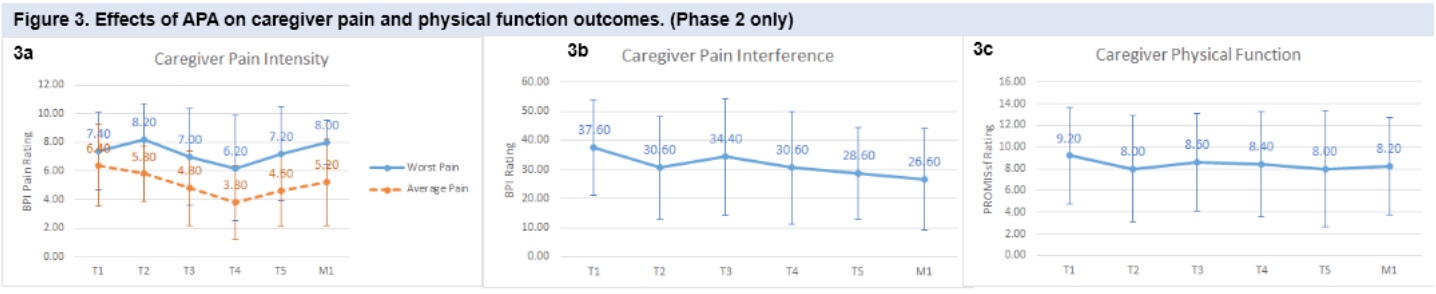
Variables	**Phase 2 *(n=7)* (M ±SD)**			
	T0	T1	T5	M1
Pain Intensity				
Average Pain (BPI)	-	6.40±2.88	4.60±2.51	5.20±3.03
Physical Function				
Pain Interference (BPI)	-	37.60±16.53	28.60±15.77	26.60±17.40
Physical Function (PROMIS)	-	9.20±4.44	8.00±5.34	8.20±4.49
Average Daily Steps (Fitbit)	3,941±3,101	3,764±3,064	3,476±3,078	-
Quality of Life				
Burden (ZBI)	33.57±22.07	33.00±24.92	31.86±28.81	27.43±24.20
Distress (NPI)	6.50±11.03	6.75±10.90	6.00±12.00	4.75±9.50

M: Mean; SD: Standard Deviation; BPI: Brief Pain Inventory; PROMIS-29sf Physical Function: Patient-Reported Outcomes Measurement Information System Short Form; NPI: Neuropsychiatric Inventory; ZBI: Zarit Burden Interview

Table 3: Caregiver Study Outcomes.

Pain Intensity

Caregivers experienced an overall decrease in average (28%) pain intensity from pre- to post-APA (T1 to T5), with the largest reduction felt after three weeks of APA (Figure 3). The average pain decreased more than worst pain from pre- to post-APA (T1 to T5). The average pain intensity decreased by 13% at the 1-month follow-up or M1 (Table 3). Figure 3 shows the worst and average pain intensity change patterns from pre-APA (T1) to 1-month follow-up (M1).



Note: The changes at pre-APA (T1), weekly during intervention (T2, T3 and T4), post-APA (T5), and 1-month follow-up (M1) are shown in (3a) for worst and average pain intensity, (3b) for pain interference, and (3c) for physical function. Graphs show mean scores ± standard deviation. BPI, Brief Pain Inventory; PROMIS-29sf Physical Function, Patient-Reported Outcomes Measurement Information System Short Form.

Figure 3: Effects of APA on caregiver pain and physical function outcomes (Phase 2 only).

Pain Interference and Physical Function

Caregivers reported an overall decrease in pain interference (24%) and improved physical function (13%) from pre- to post-APA (T1 to T5), indicating easier physical functioning. From T5 to 1M (month of follow-up), pain interference and physical function remained lower than pre-APA levels, showing sustained effects at the 1-month follow-up (Figure 3). Figure 3 shows the change patterns for pain interference and physical function from pre-APA (T1) to the 1-month follow-up (M1). The Fitbit data for caregivers showed an overall decrease in average daily steps by 11.8% from pre- to post-APA (T1 to T5) (Table 3).

Qualitative Interview Data: Dyads' APA Experiences

Overall APA Treatment Effect and Feasibility

All ADRD patients and caregivers found that the APA provided significant pain relief. Patients observed that the treatment was very quick and easy to perform (pressing the ear points three times per day, three minutes per time) with immediate effects. A caregiver stated the following: "It was manageable. . . It definitely helped with the pain. . . It solved her problem. She immediately got used to it on the first day, which was surprising." Another caregiver said that the first week was challenging since pressing the seeds was a new routine but they were able to adapt and get used to the APA. Another caregiver who received the APA in-person training was amazed that the pain and numbness decreased immediately after she performed the treatment on the patient. This caregiver also expressed, "that the pain and numbness did not totally disappear, sometimes it [APA] worked immediately, sometimes it worked gradually." One caregiver who received the APA treatment indicated that she did not know what happened, but the pain was completely relieved.

Reminder Sign Photo

Patients found the ear photos were helpful to remind them to press the seeds on their ear. The seeds on the ear have minimal effect on the participants' appearance but one patient did not like how her ear appeared during the treatment. Nevertheless, the patient continued with the APA treatment.

Reminder Messages and Technology Issues

There were mixed comments about the reminder messages. Among 7 caregivers, 4 used the study phone. One caregiver felt it took time to get familiar with the device. Another caregiver found that the cell phone required time to adjust while another caregiver observed that the smartphone was very easy to implement. Among ADRD patients, most (6/7) were frustrated with the Jitterbug phone and did not find it useful. They reported that it would have been easier to have their caregivers receive all the text messages reminding them when to press the seeds. Both caregivers and patients thought the Fitbit activity tracker was easy to use since it was a low-maintenance device; however, most participants and caregivers wore the Fitbit regularly on their first and second week of the program. Two participants reported that they often forgot to wear or charge the band.

Caregiver Training

Three caregivers who received the APA training included two (ages 70 and 56 years) who lived too far from the study site; one who was a student and would not be able to keep the weekly study visits. Three caregivers thought the APA treatment was easy to learn because the APA treatment protocol was straightforward and simple. Caregivers observed that the interventionist gave the first treatment and kept an ear diagram to use as a reference when placing the seeds each week. The APA treatment was easy to teach to the caregivers because the treatment was straightforward and simple. Two caregivers struggled to learn how to place the seeds on themselves; however, the weekly phone calls proved extremely helpful in these situations. The caregivers found it helpful when the interventionist answered their questions over the phone and marked up the ear photos to let the caregivers know whether they had placed the seeds correctly.

Discussion

We describe our process implementing APA for pain management in ADRD patients and their caregivers. Our study shows that it is feasible to employ APA to self-manage pain in ADRD patients, furthermore, that it is possible to provide the caregiver training to self-administer APA. All caregivers were pleased to observe their patient's immediate pain relief and agreed that APA was an easy treatment. APA presents an exciting opportunity to self-manage pain without using pharmacological treatments and intensive office visits, which will significantly ease patients' and caregivers' burden. The Institute of Medicine (IOM) [59] has recommended for a focus on non-pharmacological, self-management strategies to manage chronic pain. Although the current non-pharmacological treatments (i.e., exercise, physical therapy, mindfulness-based stress reduction, tai chi, yoga, cognitive behavioral therapy and spinal manipulation) have demonstrated efficacy to manage pain [60,61], these treatments have not been broadly implemented in ADRD patients with limited cognitive abilities and their overburdened caregivers. Additionally, the non-pharmacological treatments suggested (i.e., exercise, yoga, cognitive behavioral therapy, or physical therapy) usually have delayed benefits. This can limit treatment and contribute to patient and caregiver frustration and suffering. Hence, pain relief modalities that incorporate self-management feasibly are valuable. Self-management is described as the performance of tasks and skills with self-efficacy to activate patients to make appropriate decisions and engage in health-directed behaviors [62-64]. Self-management plays a central role in the control of chronic pain and maximization of function [65-68], especially since the "cure" for

chronic pain is not a realistic expectation [59]. It is for this reason that the IOM calls for the promotion of pain self-management [59]. However, self-management alone is not sufficient to manage pain efficiently and is challenging, particularly among vulnerable populations [64,69-71].

APA-a combination of Traditional Chinese Medicine acupressure with a rapid effect and self-management-is a powerful treatment to manage pain in many chronic pain conditions including those with ADRD and their caregivers. The foundation of APA as a pain treatment is consistent with evidence-based chronic pain theory (e.g., self-management and empowerment as proactive approaches) [72]. It has been well documented that patients with chronic pain who participate actively in their treatment achieve superior outcomes compared to those who engage in more passive approaches [73,74]. That is, those who are offered only passive interventions, such as medications, acupuncture, massage, without effective self-management, have poorer prognosis for experiencing sustained improvement in physical function. Based on this feasibility and pilot study, we were able to demonstrate that APA is a feasible pain self-management tool for both ADRD patients and their caregivers and provide evidence for preliminary efficacy [75]. APA presents an exciting and promising treatment that ADRD caregivers and patients can incorporate into a self-management plan to manage chronic pain as a part of their daily routine. The next step is to test the APA protocol with a larger sample size to determine the impact of APA for pain management among ADRD patients and their caregivers and to track the long-term effects.

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