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Short Communication

Prior acupuncture experience among elderly participants enrolled in a clinical trial of acupuncture for chronic low back pain: Implications for future trials

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ABSTRACT

Background: The effectiveness of acupuncture for chronic low back pain (cLBP) has not been studied specifically in the 65-and-older population. To inform the validity and generalizability of future acupuncture studies among older adults, we characterized elderly participants' prior experience with and views toward acupuncture and tested for clinical and sociodemographic differences between acupuncture-naïve and non-naïve participants.
Methods: Data for this study were collected during the baseline telephone interview from the participants enrolled in the Kaiser Permanente Northern California site of an NIH-funded, multicenter clinical trial of acupuncture for cLBP in older adults.
Results: Nearly two-thirds (65.6 %) of participants surveyed reported they had previously received acupuncture treatment with the vast majority seeking acupuncture treatment for pain-related issues (84.8 %). The majority of these participants reported relatively modest levels of exposure to acupuncture with most participants (63.1 %) reporting fewer than 10 treatment sessions over their lifetimes. There were no significant differences in age, sex, race, ethnicity, disability scores, income levels, or pain levels between the acupuncture-naïve and non-naïve groups.
Conclusion: Contextual consideration for prior acupuncture utilization rates is warranted and may be higher than expected or previously reported. We found few differences in baseline characteristics between participants who were acupuncture-naïve and those with prior acupuncture experience; thus, future pragmatic clinical trials might relax previous acupuncture-use considerations in their recruitment criteria. For trials focused on acupuncture-naive patients, it may be more feasible to expand the definition of "acupuncture-naive" based on lifetime acupuncture visits or time since last treatment.
Trial registration: The protocol was registered at clinicaltrials.gov (#NCT04982315).

1. Introduction

Chronic low back pain (cLBP), defined as lumbar pain lasting longer than 3 months, is a significant cause of disability in older adults and is associated with limited physical as well as psychosocial functioning (e.g., depression).[1,2] Approximately one-third of U.S. adults 65 and older experience lower back pain (LBP).[3] With the United Nations estimating the worldwide population of adults older than 65 doubling by 2050, cLBP will only increase its economic and social burden as time passes.[4] Low back and neck pain represent one of the highest healthcare spending categories by payers in the U.S. at $134.5 billion in 2016.[5,6]

Despite considerable healthcare spending, there remains a lack of a single highly effective therapeutic intervention for cLBP. Older adults with new primary care visits for LBP often have persistent symptoms, disability, and interference.[7] In all participants who present with acute low back pain, up to 65 % will develop cLBP that is still present at one year, indicating that a large proportion of cLBP cases do not spontaneously resolve.[8] A multidisciplinary approach to cLBP care may be more effective, where comprehensive pain-care options may be selected or combined based on patient preference and provider recommendation.[9]

Research into nonpharmacologic pain-care options has increased over time. Acupuncture therapy is recommended as part of compre-

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hensive pain care for LBP by the American College of Physicians' 2017 practice guideline for acute, subacute, and cLBP (also adopted by the American Academy of Family Physicians) that recommends nonpharmacologic options as first-line approaches, including acupuncture therapy.[10,11] Acupuncture is widely used for chronic pain, and an individual patient-level-data meta-analysis found acupuncture improved pain and function, with 85 % of treatment effect persisting at one year following a course of care.[12] Systematic reviews from National Center for Complementary and Integrative Health (NCCIH) and the U.S. Agency for Healthcare Research and Quality provide further supporting evidence of the effectiveness of acupuncture for cLBP.[13,14] As of January 2020, the Centers for Medicaid and Medicare Services (CMS) began coverage of acupuncture for LBP for Medicare recipients.[15] This effectiveness, coupled with its well-established safety profile, makes acupuncture a reasonable treatment option for patients experiencing chronic pain.[16,17]

Older patients with cLBP represent a population that is particularly vulnerable to risks associated with conventional medical therapies, such as long-term chronic use of opioids and nonsteroidal anti-inflammatory drugs (NSAIDs).[18] Effective, low-risk nonpharmacologic interventions, such as acupuncture, are especially compelling for this group. However, no acupuncture trials that focus specifically on its effectiveness in the elderly population (>65 years of age) have been published to date (for example, the Cochrane Collaboration meta-analysis of acupuncture for LBP did not perform subgroup analyses for participants >65 years old due to lack of sufficient data).[19,20] In order to inform and ensure the validity and generalizability of future studies among older adults, it is important to describe the characteristics and experience of individuals participating in these trials.

To address this research gap on the effectiveness of acupuncture for cLBP in this population, the National Institutes of Health (NIH)-NCCIH, through its Helping to End Addiction Long-term (HEAL) initiative, funded a large, multicenter, randomized clinical trial of acupuncture for cLBP among individuals 65 and older.[19,21] As one of four trial sites for the Acupuncture for Chronic Low Back Pain in Older Adults trial (BackInAction), we leveraged our clinical trial data to better characterize participants' prior experience with and views toward acupuncture. As acupuncture use becomes more widespread, it will become increasingly difficult to recruit large samples of acupuncture-naïve participants who are most appropriate for explanatory trials and that are optimized to demonstrate the efficacy of an intervention in a highly selected patient group whereas pragmatic trials comparing acupuncture to usual care or an active control generally do not require participants who are acupuncture-naïve (i.e., having never had acupuncture). Identifying any major differences between acupuncture-naïve and non-naïve participants will inform the design of future trials.

2. Methods

The BackInAction study is a pragmatic three-arm, parallel-group, four-center randomized clinical trial of two approaches to acupuncture treatment for older individuals with cLBP.[19] Eligible participants are at least 65 years old with at least 3 months of uncomplicated low back pain (with or without radicular features) who have seen a healthcare provider for back pain within the prior year and scored at least 3 on the General Activity question from the Pain, Pain Interference with Enjoyment, and General Activity (PEG) scale at baseline.[22] Patients who reported having received any acupuncture in the prior 6 months were excluded as were patients who had lower back surgery within the past 3 months. Participants are provided usual care for their LBP and are randomized to a no-acupuncture usual care arm, "Standard Acupuncture" (up to 15 treatments over 3 months), or "Enhanced Acupuncture" (Standard Acupuncture followed by an additional 4–6 treatments over the following 3 months). The acupuncture intervention is restricted to needling only and for the three west-coast sites, is delivered in the offices of experienced independent community practitioners recruited for the study who are provided with updated safety and study-specific training. An evidence-based, expert-consensus manualization process created a responsive acupuncture protocol of session parameters and acupoint options from which acupuncturists could select according to their clinical judgement.[23]

The primary outcome is back-related disability as measured by the change in the Roland-Morris Disability Questionnaire from baseline to the 6-month post-randomization timepoint.[24] This trial is funded by NCCIH (UH3 AT010739), conducted under Kaiser Permanente Northern California (KPNC) IRB approval # 1474280 (FWA# 00002344) and is registered on clinicaltrials.gov (#NCT04982315). All participants provided written informed consent.

All data for this ancillary study are from the participants enrolled in the KPNC site of the BackInAction study (N = 286); participants were generally recruited from the area in and surrounding Oakland, California. Data were gathered by experienced research personnel via a telephone interview at baseline just prior to randomization between December 2021 and October 2022. Baseline trial data collected included sociodemographics, the Roland-Morris and PEG scales, prior treatments for LBP, and a 0-to-10 scale assessing expectations for the impact of acupuncture treatment on their pain (with 0 defined as "no change or worse" and 10 defined as "back pain no longer impacts my life"). Additional variables collected for this sub-study included questions about prior use of, indication for, and response to acupuncture. Respondents who reported no prior acupuncture use were asked if they had ever desired to have acupuncture treatments in the past. Participants' perceptions of their response to prior acupuncture treatment were measured on a 0-to-10 scale with 0 defined as "no change or made worse" and 10 as "complete relief."

Only data collected at baseline were used in these analyses. Descriptive data are presented as means or medians for continuous variables and percentages for categorical variables along with 95 % Confidence Intervals (CI's; based on the normal distribution for means and with the Clopper-Pearson exact method for proportions[25]) or the interquartile range. Associations with continuous baseline measures were analyzed with *t*-tests; levels of significance were verified with Wilcoxon rank-sum tests that require no distributional assumptions. Associations among categorical baseline measures were analyzed with Fisher's exact tests. All analyses were conducted with Stata, version 18.[26]

3. Results

3.1. Baseline characteristics

Of the 286 participants at the KPNC site, 276 (96.5 %) completed the short acupuncture-experience survey in addition to the baseline questionnaire (Table 1). The median age of the participants was 72 years, most were retired (76.7 %), and 64.0 % had annual household income below $150,000. Although this was a predominantly white sample (62.6 %), a significant proportion of the participants identified as Black/African-American (18.7 %). Most participants had at least some level of college education (88.7 %).

3.2. Previous acupuncture use

Nearly two-thirds of our sample reported they had previously received acupuncture treatment more than 6 months before trial enrollment (65.6 %, 95 % CI: 59.6 % to 71.2 %; Table 2). Typical of most patients seeking acupuncture,[27,28] the vast majority sought treatment for pain-related issues (84.8 %), with nearly half of that pain being cLBP (42.6 %). While prior acupuncture experience was common, the majority of participants reported relatively modest levels of exposure with most participants reporting fewer than 10 treatment sessions over their lifetimes (63.1 %) and nearly 90 % reporting receiving 25 or fewer total lifetime acupuncture treatments. Approximately 80 % of those with prior acupuncture experience had their most recent treatment more than 2 years previously and nearly half (44 %) had not had

Table 1
Baseline demographic and clinical characteristics of all participants, and stratified by history of prior use of acupuncture.

CHARACTERISTIC	All Participants (n = 276)	Prior Acupuncture (n = 181)	No Prior Acupuncture (n = 53)
Age *[years]*			*p = 0.047*
Median (IQR)	72 (68 – 77)	72 (68–77)	73 (68–79)
Mean (SD)	73.2 (5.6)	72.8 (5.05)	74.2 (6.4)
Sex assigned at birth			*p = 0.20*
Female [*N (%)*]	167 (60.5 %)	115 (63.5 %)	52 (54.7 %)
Race [*N (%)*]			*p = 0.74*
Black / African-American	51 (18.7 %)	32 (17.8 %)	19 (20.4 %)
Asian	20 (7.3 %)	10 (5.6 %)	10 (10.8 %)
Hispanic	21 (7.7 %)	15 (8.3 %)	6 (6.5 %)
White	171 (62.6 %)	116 (64.4 %)	55 (59.1 %)
Other / Multiple	10 (3.7 %)	7 (3.9 %)	3 (3.3 %)
Education [*N (%)*]			*p = 0.07*
Less than high school	2 (0.7 %)	2 (1.1 %)	0 (0 %)
Completed high school / trade school	29 (10.6 %)	19 (10.5 %)	10 (10.6 %)
Some college, Associate's degree	71 (25.9 %)	40 (22.2 %)	31 (33.0 %)
Completed Bachelor's degree	64 (23.4 %)	44 (24.4 %)	20 (21.3 %)
Some graduate or professional school	21 (7.7 %)	19 (10.6 %)	2 (2.1 %)
Completed graduate or professional school	87 (31.2 %)	56 (31.1 %)	31 (33.0 %)
Marital status [*N (%)*]			*p = 0.80*
Married	144 (53.5 %)	94 (53.7 %)	50 (53.2 %)
Domestic partner	20 (7.4 %)	13 (7.4 %)	7 (7.5 %)
Never married	22 (8.2 %)	12 (6.9 %)	10 (10.6 %)
Divorced / Separated	51 (19.0 %)	33 (19.4 %)	17 (18.1 %)
Widowed	32 (11.9 %)	22 (12.6 %)	10 (10.6 %)
Annual household income [*N (%)*]			*p = 0.25*
<$35,000	33 (12.0 %)	23 (12.7 %)	10 (10.5 %)
$35,000 – $74,999	70 (25.5 %)	53 (29.3 %)	17 (17.9 %)
$75,000 – $149,9999	73 (26.5 %)	48 (26.5 %)	25 (26.3 %)
$150,000 or more	32 (11.6 %)	20 (11.1 %)	12 (12.6 %)
Declined to answer or unknown	68 (24.6 %)	37 (20.4 %)	31 (32.6 %)
Employment status [*N (%)*]			*p = 0.20*
Working full-time	28 (10.2 %)	18 (10.0%)	10 (10.5 %)
Working part-time	31 (11.3 %)	26 (14.4 %)	5 (5.3 %)
Retired	211 (76.7 %)	131 (72.8 %)	80 (84.2 %)
Other	5 (1.8 %)	5 (2.8 %)	0 (0 %)
Roland-Morris Disability Questionnaire			*p = 0.80*
Baseline score [Median *IQR)*]	12 (8.0 – 16.3)	12 (9 – 16)	12 (8 – 17)
Numerical rating scale for pain			*p = 0.90*
Baseline score [Median *(IQR)*]	5.3 (3.7 – 7.0)	5.3 (3.7 – 7.0)	5.3 (3.7 – 7.0)

IQR, interquartile range; SD, standard deviation.

Table 2
Prior experience with and views of acupuncture among trial participants.

Outcome	Response	95 % CI for percentages
All participants	276 (100 %)	-
Prior acupuncture use	181 (65.6 %)	59.6 % - 71.2 %
Among participants with prior acupuncture use:		
Used acupuncture for any pain (n = 177)	150 (84.8 %)	78.6 % - 89.7 %
Used acupuncture for chronic low back pain (n = 169)	72 (42.6 %)	35.0 % - 50.4 %
Total lifetime number of acupuncture treatments (n = 176)		
<10	111 (63.1 %)	55.5 % - 70.2 %
10 – 25	45 (25.6 %)	19.3 % - 32.7 %
26 – 50	14 (8.0 %)	4.4 % - 13.0 %
51 – 100	4 (2.3 %)	0.6 % - 5.7 %
>100	2 (1.1 %)	0.1 % - 4.0 %
Years since last acupuncture treatment (n = 180)		
<1	12 (6.7 %)	3.5 % - 11.4 %
1 - <2	21 (11.7 %)	7.4 % - 17.3 %
2 - <5	42 (23.3 %)	17.4 % - 30.2 %
5 - <10	26 (14.4 %)	9.7 % - 20.4 %
10 - <20	36 (20.0 %)	14.4 % - 26.6 %
≥20	43 (23.9 %)	17.9 % - 30.8 %
Change in pain level with acupuncture treatment[1] (n = 167)		
Mean (SD)	4.1 (3.5)	
0–3	56 (33.5 %)	26.4 % - 41.2 %
4–7	53 (31.7 %)	24.8 % - 39.4 %
8–10	58 (34.7 %)	27.5 % - 42.5 %
Among participants with no prior acupuncture use: desire for acupuncture among respondents (n = 83)	53 (63.9 %)	52.6 % - 74.1 %

SD, standard deviation.
[1]Measured on a 0-to-10 numerical rating scale of change in pain level.
Denominators (noted in parentheses) vary due to missing responses.

an acupuncture treatment for at least 10 years prior to enrollment in the trial.

Participants' reported responses to prior acupuncture varied, with roughly one-third of the sample having experienced no-to-mild relief of symptoms (defined as a response of ≤3 points on the 0-to-10 point numerical rating scale), one-third reporting moderate relief (response range of 4–7 points), and one-third reporting significant relief (response range of 8–10 points). Participants with prior acupuncture experience were slightly younger than those with no prior exposure on average (72.8 years vs. 74.2 years, $p < 0.05$). Otherwise, there were no statistically significant associations between prior use of acupuncture with participants' sex, race, ethnicity, disability scores, income levels, or pain levels. Participants with previous acupuncture experience had higher expectations for treatment effectiveness (expectancy score = 6.20) compared to those who were acupuncture-naïve (expectancy score = 5.64), though this difference did not reach conventional levels of statistical significance (difference = 0.56 points, 95 %CI: −0.01 to 1.14, $p = 0.055$). Among these participants, those who had received more than 25 lifetime acupuncture treatments reported greater pain relief (mean change score = 6.6 points) than those with fewer prior acupuncture treatments (mean change score = 3.7; difference = 2.9 points, 95 % CI: 1.3 to 4.5, $p < 0.001$). However, there was no significant difference in acupuncture expectations among participants with more than 25 treatments compared to those with fewer treatments (mean scores = 6.2 vs. 6.3; difference = −0.1 points, 95 % CI: −1.2 to 1.0, $p = 0.86$).

Among participants who were acupuncture naïve, a majority (63.9 %) expressed the desire to have tried acupuncture therapy in the past, and these participants had significantly higher expectations for acupuncture effectiveness (expectancy score = 6.08) than participants who did not express a desire to have tried acupuncture previously (expectancy score = 4.72; difference = 1.4 points, 95 % CI: 0.3 to 2.4, $p = 0.01$). Among this group, there were no statistically significant associations between desire to try acupuncture with participants' age, sex, race, ethnicity, disability scores, income levels, or pain levels.

4. Discussion and conclusion

In this study, we examined prior acupuncture use in adults 65 and older from the Northern California region enrolled in a large NIH-funded clinical trial examining the effectiveness of acupuncture for cLBP.

We found that approximately two-thirds of participants had previously received acupuncture, predominantly for reasons related to pain. However, the majority of these participants received fewer than 10 total treatments, and nearly 90 % received 25 or fewer lifetime treatments. Among those with no previous experience with acupuncture, nearly two-thirds wanted to try acupuncture therapy. There were no significant associations between prior acupuncture use or desire to try acupuncture in both groups or with pain levels or any sociodemographic characteristics with the exception of age for which a small, statistically significant difference was observed. The only other borderline significant difference between acupuncture-naïve and those with previous acupuncture experience was a slightly higher treatment expectation among participants who had received prior acupuncture treatments.

Our results have important implications for the design of future acupuncture trials. First, at least in the Northern California Bay Area, a majority of older adults with cLBP who are willing to enroll in an acupuncture trial have had some previous acupuncture experience. According to data from the National Health Interview Survey, the percentage of Americans of any age receiving acupuncture therapy increased from 1.1 % in 2002 to 1.5 % in 2012 to 2.2 % in 2022.[28,29] More recently, Candon et al. found that respondents to the Medical Expenditure Panel Survey with at least 1 acupuncture visit increased from 0.4 % in calendar year 2010 to 0.8 % in 2019 with a concurrent increase in insurance coverage of 9.1 %.[30] However, our study suggests that previous acupuncture utilization rates among older adults with cLBP willing to enroll in an acupuncture trial may be much higher, at least in urban areas similar to Oakland. It is also important to note that our estimate likely represents an underestimate of all those who have previously used acupuncture since the BackInAction study excluded participants who had received acupuncture within the prior 6 months. Thus, it may become increasingly difficult to recruit large numbers of completely acupuncture-naïve participants to enroll in future exploratory acupuncture trials in areas similar to Oakland, California (patients with no prior acupuncture exposure are often recruited for efficacy studies employing sham controls to enhance the credibility of the sham condition).[31–41]

Second, we found little difference between participants who were acupuncture-naïve and those with previous acupuncture experience with regards to their baseline characteristics, including age, sex, race, ethnicity, disability scores, income levels, and pain levels. The only difference noted was that acupuncture-naïve participants who desired acupuncture treatment had higher treatment effectiveness expectations, although those with previous acupuncture experience trended similarly, suggesting that generalizability will likely be good regardless of prior acupuncture exposure. Since the NIH Collaboratory is moving toward pragmatic trial designs in real-world clinical settings and real-world patient participants will vary as to their acupuncture experience, restrictions on the amount of acupuncture exposure may become less stringent. Our study suggests it may be possible for future pragmatic clinical trials to consider relaxing previous acupuncture-use considerations in their recruitment criteria.

Lastly, for future trials that do want to include only acupuncture-naïve participants, it may be more feasible to redefine what "acupuncture-naïve" means. Our data show that, among those who have had previous acupuncture experience, 63 % had fewer than 10 total lifetime treatments, a relatively low intensity of exposure. In addition, more than 80 % of those participants last had acupuncture more than 2 years prior, a relatively long time since exposure. Therefore, future studies might consider recruiting participants who have limited lifetime acupuncture visits and/or those who have had their last acupuncture visit 6–24 months prior. The BackInAction trial used a prior 6-month acupuncture abstinence period, which may be appropriate for pragmatic trials.

Limitations of our study include that participants were all from Northern California, predominantly Oakland and the surrounding area, and thus may not be representative of the general U.S. population, especially in more rural or suburban settings. In addition, since this is a cross-sectional retrospective study dependent on participants' recall, recollections of past experiences should be interpreted with caution since they are subject to recall bias. Patients with acupuncture treatment in the prior 6 months were excluded by protocol, and all KPNC participants were insured, further limiting generalizability. Finally, no corrections were made for multiple comparisons so statistically significant associations should be interpreted with caution.

In sum, we found that the majority of participants 65 years and older entering a clinical trial of acupuncture for cLBP in an urban area in California had some prior experience with acupuncture, though the cumulative frequency of prior acupuncture treatments was low and considerable time had passed since the last treatment for most participants. These findings have implications for the design of future studies of acupuncture among older adults, a population for whom safe and effective interventions, such as acupuncture therapy, are particularly compelling.

Author contributions

Conceptualization: PW, AA; Methodology: PW, AA, AP; Formal analysis: PW, AA; Investigation: GS, CA; Writing – Original Draft: PW, AA; Writing – Review & Editing: PW, AP, GS, CA, AN, AA; Project administration: GS.

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Ethical statement

This research was reviewed and approved by the Institutional Review Board of Kaiser Permanente Northern California (registration #1,474,280; Federalwide Assurance #00,002,344). Informed consent was obtained from all participants.

Data availability

Collaboration using the data that support the findings of this study will be considered by the corresponding author upon reasonable request.

Declaration of competing interest

All authors declare that they have no conflicts of interest.

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