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Original Article

Fidelity to the acupuncture intervention protocol in the ACUpuncture In The EmergencY department for pain management (ACUITY) trial: Expanding the gold standard of STRICTA and CONSORT guidelines

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ABSTRACT

Background: Acupuncture shows promise as an effective nonpharmacologic option for reduction of acute pain in the emergency department (ED). Following CONSORT and STRICTA guidelines, randomized controlled trials (RCTs) generally report intervention details and acupoint options, but fidelity to acupuncture interventions, critical to reliability in intervention research, is rarely reported.

Methods: ACUITY is an NCCIH-funded, multi-site feasibility RCT of acupuncture in 3 EDs (Cleveland, Nashville, and San Diego). ACUITY acupuncturists were trained in study design, responsive acupuncture manualization protocol, logistics and real-time recording of session details via REDCap forms created to track fidelity.

Results: Across 3 recruiting sites, 79 participants received acupuncture: 51 % women, 43 % Black/African American, with heterogeneous acute pain sites at baseline: 32 % low back, 22 % extremity, 20 % abdominal, 10 % head. Pragmatically, participants were treated in ED common areas (52 %), private rooms (39 %), and semi-private rooms (9 %). Objective tracking found 98 % adherence to the six components of the acupuncture manualization protocol: staging, number of insertion points (M = 13.2, range 2–22), needle retention time (M = 23.5 min, range 4–52), session length (M = 40.3 min, range 20–66), whether general recommendations were provided and completion of the session form.

Conclusion: To the best of our knowledge, this is the first RCT to assess and report fidelity to an acupuncture protocol. Fidelity monitoring will be fundamental for ACUITY2, which would be a future definitive, multi-site RCT. Furthermore, we recommend that fidelity to acupuncture interventions be added to CONSORT and STRICTA reporting guidelines in future RCTs.

Protocol registration: The protocol of this study is registered at clinicaltrials.gov: NCT04880733.

1. Introduction

Pain prompts the majority of visits to the Emergency Department (ED) but remains inefficiently treated[1] where commonly used medications have a high risk of adverse effects. Opioids are associated with respiratory depression, nausea, vomiting, dizziness, drowsiness, weakness, dry mouth, constipation and pruritis, even in the short term,[2] and can lead to long term use, misuse or death.[3] While programs to reduce opioid prescribing in the ED have had some success,[4–6] 8.1 % of all US ED visits resulted in an opioid prescription at discharge in 2019–2020.[3] Seven percent of opioid naïve patients prescribed an opioid for acute musculoskeletal (MSK) pain continued opioid use at 3–12 months after ED discharge.[7] Whereas acute MSK pain has been as successfully treated in the ED by non-steroidal anti-inflammatory drugs (NSAIDs).[3,7] NSAIDs carry risks of adverse effects such as gastrointestinal bleeding, acute stroke, myocardial infarction, congestive heart failure, cardiovascular death, hypertension, and acute renal failure, exacerbated in older patients.[3] To better manage acute pain in the ED, effective low risk options are needed.

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Acupuncture therapy shows promise as an effective pain-reducing, opioid-sparing option for acute pain. Evidence from systematic reviews and meta-analyses of randomized controlled trials (RCTs)[8–11] support the use of acupuncture in the ED for reducing acute pain.[12] Furthermore, evidence-based, nonpharmacologic options such as acupuncture therapy are supported or recommended as part of comprehensive pain care by U.S. Agency for Healthcare Research and Quality (AHRQ),[13,14] the Food and Drug Administration (FDA),[15] the Department of Health and Human Services (HHS),[16] the Joint Commission,[17] and the American College of Emergency Physicians (ACEP).[18,19] Further, acupuncture is recommended as a first-line treatment option for acute, subacute, and chronic low back pain by the American College of Physicians (ACP)[20] and the American Academy of Family Physicians (AAFP).[21]

While guidelines are slow to impact clinical practice in medicine,[22,23] ongoing research as well as dissemination of research evidence is crucial. Research into acupuncture effectiveness has moved from efficacy trials of very specific patient sets, using rote acupuncture prescriptions and non-inert sham acupuncture as a comparator[24–26] to more pragmatic trials: comparing acupuncture therapy to another therapy or usual care in a real-world settings with diverse real-world patients.[27–29] Acupuncture is now recognized as a complex intervention with interacting components. Researchers have adapted the Medical Research Council's guidance of 2000[30] and 2008[31] to develop and evaluate complex interventions like acupuncture therapy.[32] Modifying a Delphi process developed by the RAND Corporation for convergence of expert opinion within topic areas,[33] a consensus-based acupuncture intervention protocol can be created. Sometimes called 'manualization', this expert consensus process[34] seeks to strike a balance between standardization and flexibility in acupuncture research. Session parameters and acupoint options are standardized for replicability but are flexible enough to be responsive to diverse presentations and as they evolve through time.[35–40] This is especially important in pragmatic clinical trials (PCTs) where research seeks to evaluate responsive acupuncture care in real world clinical settings with generalizable populations to generate actionable clinical evidence at a fraction of the typical cost/time needed to conduct a traditional clinical trial.[28,41] PCTs are part of the U.S. National Institutes of Health (NIH) vision for bridging the gap between research and care.[29] PCTs are supported by the Center for Medicare & Medicaid (CMS), Patient Centered Outcomes Research Institute (PCORI), practice-based research networks (PBRNs) and community-based participatory research initiatives across the U.S. Federal government.[42]

The ACUITY team used a modified Delphi process in creating the responsive acupuncture protocol, detailed elsewhere.[40] Specifically, the process included creating an Acupuncture Advisory Panel (AAP) of nine acupuncture experts with 5–44 years of experience in acupuncture practice and 2–16 years of experience providing acupuncture in the acute pain care setting. Preliminary information from acupuncture trials for acute pain was assembled and disseminated to the AAP along with survey questions on session parameters and acupoints for specific acute pain conditions included in the trial. Responses were collated and intervention details were discussed, confirmed, and reconfirmed over three Zoom meetings.[40]

Consensus manualization of acupuncture therapy as a complex intervention in the ACUITY pragmatic trial resulted in a responsive acupuncture protocol: standardized acupuncture point options that are replicable while providing flexibility to respond to unique participant presentations.[34–40] While responsive manualizations allow acupuncture to be delivered in pragmatic trials and settings in a way that is akin to real-world clinical practice, adherence to protocol or 'fidelity' is not typically assessed or reported.[43] Treatment fidelity refers to the degree to which an intervention is implemented as intended.[44] In general, while intervention research is required to report trial design and protocol details,[45,46] there appears to have been an assumption by peer reviewers that the design and protocols have been followed. Whether in randomized trials with simple standardized protocols or in randomized trials of complex healthcare interventions, to date, fidelity has been poorly addressed.[47] Fidelity to the intervention is critical to the reliability, validity, replicability, and scale-up of the results of an intervention research study.[43] Indeed, fidelity has not yet been included in the CONSORT extension for acupuncture trials: STRICTA (STandards for Reporting Interventions in Clinical Trials of Acupuncture).[46]

Acupuncture in the Emergency Department for Pain Management (ACUITY) was funded by the National Center for Complementary and Integrative Health via an R01 grant (AT010598). The objectives were to: conduct a multi-center feasibility RCT, examine feasibility of data collection, develop/deploy an acupuncture intervention manualization, and assess feasibility/implementation (barriers/facilitators) in 3 EDs affiliated with the BraveNet Practice Based Research Network.

Here we report on the fidelity to the ACUITY acupuncture protocol in the treatment of acute non-emergent MSK, back, pelvic, noncardiac chest, abdominal, flank or head pain presenting in the ED.

2. Methods

ACUITY was a multi-site feasibility RCT comparing acupuncture to usual care for reduction of acute pain in the ED and is intended to serve as preparation for a future, definitive RCT. ACUITY focused on recruiting a diverse underserved population including Black/African Americans, Hispanics or Latinos, and those with less education attainment.[41] Another goal of ACUITY was to have the pragmatic delivery of acupuncture occur in various locations within the ED. Additional goals included assessing data quality completeness, evaluating participant recruitment and retention, developing an acupuncture intervention protocol and creating a system to track intervention details to assess fidelity to intervention. The ACUITY team used a modified Delphi process in creating the responsive acupuncture manualization protocol, detailed elsewhere.[40] The ACUITY protocol is registered at clinicaltrials.gov: NCT04880733.

ACUITY was launched at each trial site sequentially, hence trial acupuncturists were trained sequentially in all aspects of ACUITY including the study design, acupuncture intervention protocols, study logistics, and REDCap electronic data capture forms for charting of session details.[48,49] The ACUITY team intentionally created a means to track fidelity where session details were recorded using REDCap session forms and acupoint option grids (Supplement 1 and 2).[40] Details of the intervention recorded by the acupuncturists included: steps or staging of care including evaluation, palpation and history of the condition and site, number of acupoints used, specific acupoints needled (whether local and distal were included; whether auricular points were used), needle retention time, whether general recommendations were given, and length of the session. Exporting the REDCap data to Excel allowed an accurate assessment of each acupuncturists' adherence to protocol for each of the intervention details, as well as an overall fidelity assessment for the trial. Tracking of the STRICTA items to assess fidelity to the responsive acupuncture manualization protocol was done by objective review (author AN) of all acupuncture sessions. Fidelity assessment was made by 3 authors (AN, NLD, JAD).

3. Results

Across 3 recruiting sites, 83 participants were randomized to acupuncture (3 withdrew consent, 1 was unable to receive acupuncture due to a need for clinical imaging). Of the 79 participants who received acupuncture, characteristics were as follows: average age 45.1 years (16.0 SD), 51.9 % women, 43 % Black/African American, 13.9 % Hispanic, 31.7 % with a college degree or more education, 53.2 % with either Medicare or Medicaid. All participant demographics and characteristics are reported in Table 1. The primary acute pain site at baseline was varied with 32 % low back, 22 % extremity, 20 % abdominal, 10 % head, 8 % multiple primary sites of pain and less than 5 % each for flank, neck, and chest. Nearly one third of the participants had acute

Table 1
Participant demographics and characteristics including primary pain location, prior acupuncture use, pain intensity and anxiety collected at baseline.

Variable	Acupuncture (n = 79)
Sex (%)	
Female	51.9 %
Male	48.1 %
Age, M (SD)	45.1 (16.0)
Race (%)	
American Indian/Native American	0.0 %
Asian	1.3 %
Black/African American	43.0 %
Native Hawaiian/Pacific Islander	0.0 %
White	46.8 %
Other	8.9 %
Declined to answer	3.8 %
Ethnicity (%)	
Hispanic/Latino	13.9 %
Education (%)	
No high school diploma	1.3 %
High school or equivalent	32.9 %
Some college	32.9 %
College degree	24.1 %
Graduate or professional degree	7.6 %
Decline to answer	1.3 %
Insurance (%)	
Medicare	32.9 %
Medicaid	20.3 %
Private insurance	43.0 %
No insurance	2.5 %
Decline to answer	1.3 %
Primary body site of pain at baseline (%)	
Back	31.6 %
Extremity	21.5 %
Abdomen	20.3 %
Head	10.1 %
Multiple	7.6 %
Flank	3.8 %
Neck	2.5 %
Chest	2.5 %
Prior Acupuncture (%)	24.1 %
Pain intensity at baseline M (SD) (n = 76)	7.4 (2.2)
Anxiety at baseline M (SD) (n = 76)	4.5 (3.4)

M, Mean; SD, Standard Deviation.

back pain as a primary pain site at baseline. Baseline pain and anxiety data (on the 0–10 Numeric Rating Scale) are also reported in Table 1.

Approximately 71 % of participants were treated in either a seated or seated and reclining position; 28.2 % were able to be in a prone, supine, or lateral recumbent position. Compared to acupuncture delivered in private-practice clinical settings, conditions were different in the ED environment wherein the position of the participant limited the delivery of the intervention in 40 % of the sessions (see Table 2). Pragmatically, participants were treated in various ED locations including common areas (52 %), private rooms (39 %), and semi-private rooms (9 %).

Table 3 illustrates the six components which were used to assess fidelity to the protocol. The components are equally weighed and include 1) staging of care; 2) needling sites (number); 3) needle retention time; 4) acupuncture session length; 5) whether general recommendations were provided to participants at the session end and 6) completion of the acupuncture session form. First, the steps/staging of care included talking with the participant about the presenting problem(s), including location and nature of pain, range of motion (ROM) observation, palpation of regions and 'channels', selection of acupoints, and so on.[40] Second, the expected number of needling sites ranged from 1 to 18, ACUITY fidelity allowed for up to 2 additional sites, for a potential total of 20 sites. Two sessions reported 21 and 22 sites respectively resulting in 97.4 % (77/79) adherence to protocol. Third, the expected needle retention time was 15–30 min with the fidelity definition (+/−5 min) allowing for a range of 10–35 min. Three sessions did not report needle retention time. The resulting fidelity to protocol for needle retention time was 96.2 % (76/79). Fourth, the expected session length was 30–60 min with a fidelity definition (+/- 10 min) allowing for session to be from 20 to 70 min. One session did not report session length and one session included an ultrasound deviating from the session length expectation resulting in 97.4 % (77/79) fidelity. Fifth, general recommendations of basic self-care relative to traditional East Asian Medicine and acute pain included general moderation of food and diet, water and remaining hydrated as well as general movement, activity or exercise precautions and general breathing awareness. These recommendations were given in 97.4 % (77/79) of sessions. Sixth, completion of the acupuncture session form and points grid is necessary for fidelity tracking, and we set a 95 % completion rate as the threshold for adherence to form completion allowing for a few minor details to be missing.[50] With that threshold, ACUITY had 100 % form completion adherence to the protocol. Finally, averaging the six components resulted in an overall rate of 98.1 % adherence to the responsive acupuncture manualization protocol (See Table 3).

In addition to calculating the adherence to the protocol, we report averages by each recruiting site (University Hospital [UH], Vanderbilt University Medical Center [VUMC], University of California San Diego [UCSD]). In terms of acupuncture needling details, we report the number of acupoint sites that were needled (see Table 4). The overall mean number of sites was 13.2 (range of 2–22) and minimal differences across centers. The overall average needle retention time was 23.5 min (range 4–52 min) with UCSD having the longest average needle retention duration. The overall mean session length was 40.3 min (range 20–66) with UH having the shortest average session duration. Finally, auricular acupuncture was recommended for each participant within the session, with the option for needling and/or to use ear seeds (extended auricular acupressure) as a means of extending the session. More than half (55.7 %) of participants received some form of auricular therapy with either needles, ear seeds, or both. However, while ACUITY session forms tracked which ear points were used, they did not require the acupuncturists to distinguish between needles or seeds within a session. These details will be charted in the acupuncture documentation for the larger trial. VUMC charted the least use and UCSD had the highest use of auricular therapy.

Traditional acupuncture therapy emphasizes use of both local and distal points relative to the site of pain. However, the location of some sessions in the ED and limitations to accessing acupoints due to participants' physical position meant some sessions were not 'ideal' in terms of local and distal point access. Sessions accessing only distal points were at 41.8 %; with 58.2 % using local and distal points (see Table 5). Private room locations for sessions facilitated use of both local and distal points.

The charting by acupuncturists in REDCap (Supplements 1 and 2) created a record of session details that informed tracking of fidelity to the manualization parameters.[40] Supplement 3 provides the frequency of 'recommended lead points'[40] for all acute pain conditions for participants who received acupuncture (n = 79). Frequency (% of participants) of acupoints recommended specifically for acute low back pain (n = 30), in addition to the recommended lead points, is also reported in Supplement 3. The level of detail provided in Supplements 1, 2, 3 and 4 supports the reliability of the acupuncture manualization protocol, the ability of the acupuncturist to chart session details, and compliance with STRICTA guidelines. The STRICTA table including fidelity to protocol items is detailed in Supplement 4.

4.1. Discussion

ACUITY was a multi-site, feasibility RCT conducted to prepare for a future, definitive RCT of acupuncture for pain relief in the ED. As fidelity of acupuncture interventions is not routinely assessed or reported in RCTs,[46] two innovations of ACUITY were to (1) develop a responsive manualization of acupuncture therapy protocol for treatment of

Table 2
Treatment location, environmental conditions, other treatment limitations and participant position characteristics of the acupuncture treatment charted by the acupuncturists in REDCap.

Variable	Low Back $N = 30$	Other pain $N = 49$	Total $N = 79$
Location (% of participants)			
Private room	36.7	40.8	39.2
Semi-private room	6.7	10.2	8.9
Common room, waiting area or hallway	56.7	49.0	51.9
*Environmental conditions (yes, %)**	53.3	32.1	39.8
Noisy	33.3	24.5	27.7
Crowded/busy	40.0	22.6	28.9
Participant seated	33.3	22.6	26.5
Participant confined to single position	26.7	11.3	16.9
Too cold	3.3	1.9	2.4
Too bright	36.7	18.9	25.3
Other	6.7	0	6.0
*Other treatment limitations (yes, %)**	66.7	32.1	44.6
Participant position	56.7	15.1	30.1
Time too short	0	3.8	2.4
Participant on the phone	0	3.8	2.4
Limited access to points	56.7	26.4	37.3
Other interruptions	3.3	0	1.2
Patient 1st position within the session (participants, %)			
Seated	24.1	26.4	26.9
Seated and reclining	31.0	49.1	44.9
Supine on table	17.2	0	6.4
Prone on table	13.8	3.8	**7.7**
Lateral recumbent	13.8	13.2	14.1

* Note: Environmental conditions and treatment limitations exceed 100 % reflecting multiple limitations or impact on treatment.

Table 3
Summary of fidelity to the acupuncture intervention protocol.

Intervention detail	Total: $n = 79$
Steps/Staging of care	79 (100 %)
Needle sites	77 (97.4 %)
Expected range 1-18	
(Fidelity definition: up to 20 sites)	
Needle retention time	76 (96.2 %)
Expected range 15-30 mins	
(Fidelity definition: +/- 5 min	
Session length	77 (97.4 %)
Expected range 30–60 mins	
(*Fidelity definition: +/- 10* min)	
General recommendations given	77 (97.4 %)
Completion of session forms	79 (100 %)
(*Fidelity definition: ≥95 % complete*)	
TOTAL Fidelity	98.1 %

Table 5
The number and percentage of participants who had distal only or both local and distal acupoints used overall, by recruiting site, pain location, location of treatment, and treatment limitation.

Category	Distal only N (%)	Both local and distal N (%)
Overall (n = 79)	33 (41.8)	46 (58.2)
Recruiting Site		
UH ($n = 30$)	16 (53.3)	14 (46.7)
VUMC ($n = 24$)	2 (8.3)	22 (91.7)
UCSD ($n = 25$)	15 (60.0)	10 (40.0)
Pain location		
Low back ($n = 30$)	19 (63.3)	11 (36.7)
Abdomen ($n = 18$)	5 (27.8)	13 (72.2)
Leg ($n = 11$)	6 (54.5)	5 (45.5)
Head ($n = 10$)	4 (40.0)	6 (60.0)
Location of treatment		
Private room ($n = 31$)	6 (19.4)	25 (80.6)
Semi-private room ($n = 7$)	3 (42.9)	4 (57.1)
Common room, waiting area or hallway ($n = 41$)	24 (58.5)	17 (41.5)
Treatment limitations (n = 37 yes)	22 (59.5)	15 (40.5)
Participant position ($n = 25$)	17 (68.0)	8 (32.0)
Time too short ($n = 2$)	1 (50.0)	1 (50.0)
Participant on the phone ($n = 2$)	0 (0)	2 (100)
Limited access to points ($n = 31$)	18 (58.1)	13 (41.9)
Other interruptions ($n = 1$)	1 (100)	0 (0)

various pain conditions and (2) reliably track the study acupuncturists' adherence, or fidelity to the manualization protocol. Strictly speaking, we define fidelity to an acupuncture intervention according to the existing STRICTA guideline checklist items used to report details of the intervention design (see Supplement 4). Importantly, objective review found ACUITY acupuncturists had a 98 % adherence to the responsive acupuncture manualization. What is considered adequate, high, or low fidelity to an acupuncture intervention in an acupuncture trial has not been established, or even discussed in the literature. One interpretation in 'health behavior change' trials is that fidelity > 80 % reflects 'high fidelity' whereas < 50 % signals 'low fidelity'.[51] ACUITY reports high fidelity to specific treatment parameters of steps and staging of care including evaluation, palpation and history of the condition and pain site(s), completing session forms: number of acupoints used, specific acupoints needled, (whether local and distal included, whether auricular

Table 4
Details of the acupuncture intervention by ED site with totals.

Variable	UH	VUMC	UCSD	Total
Needle sites used: average (*SD*)	12.5 (2.5)	14.8 (3.1)	12.6 (4.0)	13.2 (3.3)
Needle retention time (minutes): average (*SD*)	21.0 (3.9)	20.8 (1.9)	29.2 (10.1)	23.5 (7.3)
Session length (minutes): average (*SD*)	36.0 (5.9)	42.8 (5.1)	43.4 (15.3)	40.4 (10.2)

SD- Standard Deviation.

points used), needle retention time, whether general recommendations were given and length of the session. Despite environmental (such as the space being too loud) and treatment limitations (such as the patient seated in a chair or wheelchair), ACUITY acupuncturists were successfully able to adhere to the acupuncture protocol in the session.

Fidelity to an intervention is critical to the reliability, validity, replicability, and scale-up of the results of an intervention research study.[43] While not yet required in the STRICTA guidelines,[46] fidelity reporting was added to the updated CONSORT (Consolidated Standards of Reporting Trials) Statement extension (2017) for 'Nonpharmacologic Treatments': 'whether and how' fidelity or adherence to interventions is assessed or enhanced.[52] There has been movement to assess and report intervention fidelity in some complex interventions that also use manualizations such as behavioral research,[53,54] surgery,[55] quality improvement,[56] manual therapies[57,58] and mind-body[59] therapies. We propose that assessment of fidelity be added as a STRICTA extension in acupuncture trial reporting.

Our detailed responsive acupuncture manualization protocol and REDCap session forms facilitated tracking and reporting the high degree of fidelity to intervention, including reporting of the frequency of use of acupoints. The authors make no conclusions about acupoint selection except to report high fidelity to the acupuncture protocol even if a session intervention was not 'ideal' due to the limitations of a session location (such as being in a common area) and/or access to participants' acupoints (such as the participant being seated). While it is theoretically ideal to utilize both local and distal points in private practice or clinical ambulatory settings, we found that use of both was reported in 58.2 % of the sessions due to limitations noted above. We found that regardless of the body site of reported pain, the most common points utilized for all pain locations were LI 4 right (67 %) and LI 4 left (53 %). Bilateral LI 4 and LV 3, known as 'four gates' (in the web of the hand between the thumb and first finger, similarly at the web of the foot) are often used together and were among the recommended 'lead' points for all acute pain conditions. LI 4 was used more on the right and LV 3 was used less than LI 4; this may have been due to acupoint access limitations. BL 62 is commonly used and a recommended aLBP lead point, and GB 34 was an optional point. Yet, GB 34 was used roughly 1/3 of the time and BL 62 slightly less often. Tracking fidelity and reporting high fidelity to intervention not only supports the feasibility determination for this multi-site pilot study,[60] but the methods of fidelity assessment can be used to support future research including a large multi-site RCT of acupuncture for acute pain in the ED.

4.2. Limitations

As discussed above, two main challenges for ACUITY acupuncturists were the (1) location within the ED for delivering acupuncture (52 % of sessions were in common areas) and (2) limitations to accessing specific acupoints due to participants' physical position (such as treatment in a chair). In the purest sense, some acupuncture sessions were not 'ideal' due to these limitations even though a high fidelity to ACUITY acupuncture protocol was maintained. Because ACUITY was launched at each trial site sequentially with site-specific training, orientation and ramp up, there was not the opportunity to engage the acupuncture teams in cross-site meetings during study recruitment. Such meetings would enable the individual assessing fidelity (author AN) to uncover issues as they may occur during the RCT. In the future RCT, the fidelity assessor will regularly meet with the acupuncture teams to encourage certain treatment options, assess adherence to the protocol and to maintain consistency of optimal care across multiple settings and groups of providers for a longer period of time and for a larger recruited sample.

4.3. Conclusion

To the best of our knowledge, ACUITY is the first RCT to report fidelity to an acupuncture protocol. Reporting 98 % adherence to intervention supports the feasibility of this multi-site study. Assessing and reporting fidelity will be fundamental for ACUITY2, a future definitive multi-site RCT of acupuncture in the ED for acute pain. Fidelity to the intervention is critical to the reliability, validity, replicability, and scale-up of any intervention research results. Fidelity assessment and reporting is a suggested addition to CONSORT and STRICTA research guidelines for acupuncture trials.

Conflict of Interest Disclosure

AN, JAD, CL, ND, MDM report no conflict of interest.

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Einstein Data Coordinating Center: Qi Gao PhD, Ryung Kim PhD.

CRediT authorship contribution statement

Arya Nielsen: Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing, Project administration. **Natalie L. Dyer:** Methodology, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing. Claudia Lechuga: Methodology, Data curation, Writing – review & editing. **M. Diane McKee:** Investigation, Writing – review & editing, Project administration, Funding acquisition. **Jeffery A. Dusek:** Conceptualization, Methodology, Investigation, Data curation, Writing – review & editing, Project administration, Funding acquisition.

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Ethical statement

This research was reviewed and approved by the institutional review board of (IRB) at University Hospitals Cleveland Medical Center (UH-CMC) which served as the single IRB for ACUITY with the other centers using the IRB Reliance protocol per NIH standards. The protocol and all amendments were approved by the UH-CMC Institutional Review Board (STUDY20200618). Informed consent was obtained from all participants.

Data availability

The data that support the findings of this study are available within the article [and/or its supplementary materials].

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imr.2024.101048.

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