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Original Article

Acupuncture in the emergency department (ACUITY): Results from a BraveNet multi-center feasibility randomized controlled trial

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ABSTRACT

Background: Pain plays a significant role in emergency department (ED) visits, however safe and effective non-pharmacologic options are needed. Prior studies of acupuncture in the ED reported pain reduction with minimal side effects, but most were small and single site.

Methods: We conducted ACUITY, a prospectively designed multi-center feasibility RCT. Our goal was to recruit 165 adults with acute non-emergent pain ≥4 on a 0–10-point scale at three EDs affiliated with BraveNet Practice Based Research Network. At baseline and 45–60 min later (post), participants self-assessed their pain and anxiety using a 0–10 rating scale. The primary feasibility outcome was recruitment of participants, whereas secondary outcomes were retention, and participant/provider acceptability.

Results: From May 3, 2021, to September 24, 2022, 632 eligible individuals were approached and 165 enrolled (165/632: 26.1 %), meeting our recruitment goal. Notably, 42.4 % of enrollees were Black/African American, 42.4 % were White/Caucasian, and 13.9 % were Hispanic/Latino. Participants were randomized to Acupuncture (n = 83) or Usual care (n = 82), of which 151 (91.5 %) and 128 (77.6 %) provided pain and anxiety scores at post-treatment and 1-week respectively. Acupuncture was rated acceptable to participants and providers. Mean pain ratings (pre-to-post) were 7.4 (2.2) to 4.8 (2.8) for acupuncture and 7.1 (2.3) to 6.4 (2.5) for usual care. Mean anxiety ratings (pre-to-post) were 4.5 (3.4) to 2.5 (2.6) for acupuncture and 4.1 (3.4) to 3.5 (3.2) for usual care.

Conclusion: Successful completion of ACUITY indicates we have the expertise and preliminary data to conduct a future definitive, multi-center RCT.

Trial registration: Clinical trials.gov: NCT04880733.

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1. Introduction

Pain accounts for the majority of emergency department (ED) visits (78 %),[1,2] and is often inadequately managed.[1,3] As of 2012, healthcare clinicians in the U.S. were already prescribing approximately 50 times more opioids than the rest of the world combined, a number that reflects the problem of over prescribing.[4] Opioids are associated with risks of respiratory depression, nausea, vomiting, dizziness, drowsiness, weakness, dry mouth, constipation and pruritis, even in the short term[5] and can lead to long term use, misuse or death.[6] The rate of drug overdose deaths increased in the U.S. from 13.8 per 100,000 in 2013 to 32.4 per 100,000 in 2021, where deaths of opioids continue to increase.[7] Other acute pain medications, such as nonsteroidal anti-inflammatory drugs (NSAIDs) are associated with numerous side effects increasing health risks.[8] A recent study reported that acute back pain patients using NSAIDS had a 1.76-fold increased risk of developing chronic pain in the future relative to patients not using NSAIDS.[9] Therefore, feasible and effective nonpharmacologic options are needed to treat acute pain for people unresponsive or intolerant to standard therapies and to reduce the national dependence on opioids and other pain medications.

Multiple organizations have called for the increased use of nonpharmacologic options for treating acute pain. For example, the Joint Commission has advocated for caution regarding use of opioids in hospitals, requiring accredited facilities to provide nonpharmacologic therapies for pain, such as acupuncture.[10,11] Acupuncture is also supported or recommended as part of comprehensive pain care by the U.S. Agency for Healthcare Research and Quality (AHRQ) ,[12] the U.S. Food and Drug Administration (FDA) ,[13] and the U.S. Department of Health and Human Services (HHS).[14] Furthermore, the American Academy of Family Physicians endorsed the American College of Physicians (ACP) Guidelines, which recommend acupuncture as a first option for acute, subacute, and chronic low back pain.[15,16] Lastly, the largest emergency medicine organization in the US, the American College of Emergency Physicians (ACEP) also recommends a multimodal approach to acute pain management including nonpharmacologic interventions.[17]

Acupuncture, in contrast to opioids, has a low risk of adverse events. The National Institutes of Health (NIH) Consensus Statement on Acupuncture published in 1998 stated that 'the incidence of adverse effects is substantially lower than that of many drugs or other accepted procedures for the same conditions.'[18] Systematic reviews and surveys report acupuncture to be a safe treatment when administered by properly trained practitioners[19–25] with only minor side effects, such as itchiness or varied sensations at the point of insertion, or feeling very relaxed or tired.[23] Rare serious complications such as infection or pneumothorax are directly related to insufficient training.[24,25]

Evidence from systematic reviews[26–29] supports the use of acupuncture in the ED for reducing acute pain.[30] However, there were many limitations across the prior trials that were reviewed, including, all but one were single-center trials, the majority had small sample sizes and insufficient statistical power, blinding of data assessors was rarely performed, neither race nor ethnicity of participants was reported, comparator groups were inappropriate, and only one study utilized a prescribed acupuncture intervention protocol.[31] Prior studies also did not include formal implementation strategies to understand and address potential challenges with integrating an acupuncture intervention within the ED setting.

Current research standards indicated the need to conduct a multicenter, feasibility randomized controlled trial (RCT) to prepare for a definitive, multi-center RCT that will address these shortcomings.[32]

We present the findings from ACUITY ("Acupuncture in the Emergency Department"), a BraveNet multi-center, feasibility RCT informing the development of a manualized acupuncture intervention, refining data collection procedures, and implementing a pilot RCT. The objective of ACUITY was to evaluate the feasibility of research procedures for a future, definitive RCT. We implemented a pilot RCT to assess participant recruitment and retention, along with data quality and completeness. ACUITY included a focus on inclusion of underserved populations (e.g., Black/African Americans, high school or less education levels, public insurance, and low household income) as well as delivery of acupuncture in various locations within ED environment (e.g., common areas and hallways, private and semi-private rooms). To assess feasibility, our primary outcome was recruitment of participants, and our secondary outcomes were participant retention, and acceptability, measured by participant and provider satisfaction.

2. Methods

2.1. Study design & overview

*Details of the ACUITY study design were published elsewhere.[33,34] Briefly, ACUITY included three EDs (University Hospitals Cleveland Medical Center (UH), the Vanderbilt University Medical Center (VUMC), and University of California-San Diego Hillcrest (UCSD)). The Data Coordinating Center (DCC) was at the Albert Einstein College of Medicine. The recruiting centers and the DCC are members of the BraveNet Practice Based Research Network (BraveNet),[35,36] which currently includes 32 integrative medicine clinic members in the U.S., Canada, Brazil, S. Korea and Australia (*https://ssihi.uci.edu/research/bravenet/*).*[35]

2.2. Participants and population

All recruiting centers included an urban tertiary care Level 1 trauma facility: annual ED volumes ranged from 45,000–71,000 visits per site. Adults presenting to the ED with acute non-emergent pain ≥4 on a 0–10-point numeric rating scale (NRS) were eligible. The Institutional Review Board (IRB) at University Hospitals Cleveland Medical Center (UH–CMC) 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).

2.3. Screening and eligibility

Eligibility criteria included the following: 18 years or older, able to communicate in English, a level 3, 4, or 5 score on the Emergency Severity Index (ESI) triage scale, a chief complaint of acute musculoskeletal, back, pelvic, non-cardiac chest, abdominal, or headache pain (≥4 on the NRS) due to a non-penetrating injury. Exclusion criteria included the following: fever exceeding 100°F, presenting with chief complaints of a psychological/psychiatric concern, migraine, current pregnancy, joint dislocation, bone fracture, self-reported or electronic health record (EHR) documented opioid medication taken orally within 4 h, or confirmed or suspected COVID-19 infection.

2.4. Study flow and consent

Further details of the study flow and consent have been published elsewhere.[34] Potential subjects were identified by a member of the ACUITY staff or an ED staff member. If the individual was willing to participate, ACUITY staff obtained written informed consent for all study subjects.

Remuneration for participating in the ED portion of the study was a $25 gift card. An additional $25 was provided for participants completing the 1-week follow-up as well as the exploratory 4-week follow-up assessment.

2.5. Randomization

Administrative personnel from the DCC (RK) used the secure software Research Electronic Data Capture (REDCap) to perform the randomization. The patient was randomized by REDCap after they consented and took the baseline assessment and before the pain and anxiety

NRS.[37] Block randomization with unequal block sizes were performed within each center,[38] as designed by the study statistician. The sizes of sequential blocks varied randomly between two and four to minimize the predictability of treatment assignments and preserve balance between groups.

2.6. Intervention arms

The ED clinician retained the ability to prescribe any medications or interventions at their discretion regardless of the study arm. For those in the acupuncture group, pain medications were delayed until after completion of the acupuncture intervention and collection of post-treatment scores.

2.6.1. Acupuncture intervention

Further details of the acupuncture intervention are published elsewhere.[33] Briefly, a consensus-based responsive protocol was developed to promote standardization of the acupuncture intervention while retaining flexibility based on the acupuncturist's assessment of the participant as well as their specific pain presentation(s).[33] At each ED center, the intervention was provided by a nationally licensed, board-certified acupuncturist[39] who held valid and current state acupuncture licensure and was credentialed within the center's health system. Pre-sterilized, single-use uncoated acupuncture needles were used for the acupuncture intervention. Additionally, extended auricular therapy acupressure was recommended for all participants, using ear seeds retained on auricular acupuncture points with non-latex tape to extend the treatment benefits after ED care.[40] Participants were directed to leave them on until one week after their ED visit unless the seeds fell off or became uncomfortable. Session forms recorded intervention steps, interview, palpation, length of session, length of needle retention time as well as acupuncture points selected from a consensus of common points utilized for each acute pain condition.[33] Fidelity to the acupuncture protocol was tracked using REDCap session forms by the expert acupuncturist and co-author (AN). AN used a checklist to conduct post hoc fidelity at all 3 sites. There were no issues with lack of compliance with the manualized acupuncture protocol. Because the fidelity check was conducted after the study was complete there was no opportunity for retraining. However, author AN did meet with all study acupuncturists to share her findings to prepare for a future trial.

2.6.2. Usual care

Participants assigned to the usual care arm received care and treatment for pain and any other symptoms or conditions as would usually be provided, in accordance with the relevant pain management and care policy at each participating ED.

2.7. Data collection

Any shared data, forms, reports, and other records were identified by a participant identification number to maintain confidentiality. All information was locked and exported for analysis. Both the electronic data collection data and exported databases were stored in compliance with respective rules and regulations.

2.7.1. Patient reported outcomes

ACUITY included patient reported outcome (PRO) ratings of pain intensity and anxiety on a 0–10 NRS. All baseline and post-treatment PROs (pain intensity and anxiety) were entered directly by the participant on a tablet computer via REDCap. All patient answers were masked; therefore, all research staff were blinded to patient scores. Patient satisfaction data were collected as part of post-treatment, at ED discharge, and at 1-week follow-up and exploratory 4-week follow-up assessment.

For those in the intervention group, the post-treatment pain and anxiety assessments were collected within several minutes after acupuncture was complete. Based on feedback during the pilot launch, the expected session duration for the acupuncture arm was reduced to 45 min (± 15 min).[33] For the usual care group, post-treatment pain assessments were collected 60 min (± 15 min) after collection of the pre-treatment score to allow for usual care to be delivered.[34] For participants in both groups, the ED discharge assessments were intended to be obtained within 15 min of participants' discharge from the ED. However, to limit patient burden, discharge scores were not attempted to be collected if the participant was discharged within 15 min of post-treatment score collection. Such cases were not considered missing data.

One-week and 4-week follow-up assessments were collected directly from the participant through REDCap (via text message prompt) or on a paper survey and entered by the research team if completed over the phone. To reduce bias, phone contacts at 1-week (± 4 days) and 4-week (± 4 days) follow-ups were conducted by an ACUITY staff member who had not interacted with the participant during their ED participation.

2.8. Data analysis

2.8.1. Primary outcome

2.8.1.1. Recruitment. The number of eligible patients presenting to the ED during enrolling sessions and the proportion who agreed to participate were tracked. Recruitment rates (# enrolled / # eligible), pace of accrual were assessed at each data collection point, overall and across centers. We assessed variables across different patient groups (including age, race, sex), and across the study arms.

2.8.2. Secondary outcomes

2.8.2.2. Retention. The rates of lost to follow up were assessed at all data collection points across different patient groups (including age, race, sex), across study arms, overall, and by centers. Retention and data completeness were assessed at each data collection point, overall and across centers. We assessed variables across different patient groups (including age, race, sex), and across the study arms.

2.8.2.3. Acceptability. After the completion of study recruitment at their site, ED staff were asked to complete a brief survey (via REDCap) to assess ED clinician acceptability. Questions assessed general satisfaction with acupuncture as a treatment in the ED ("Do you view acupuncture in general as an appropriate intervention for the ED setting?" (Likert scale 0-Very inappropriate—4-Very appropriate) and "Do you view acupuncture in general as helpful in managing patient pain in the ED?" (Likert scale 0-Not at all helpful—4-Very helpful)).

If ED staff had contact with ACUITY in action, two additional questions were asked: To assess general satisfaction with how ACUITY was delivered in the ED, we asked ED physicians, residents, nurses, and other ED staff "Were you satisfied with how the ACUITY acupuncture intervention was delivered in your setting?" (Likert scale 0-Very dissatisfied—4-Very satisfied) and "Did the ACUITY project impose a burden on ED staff in your setting?" (Likert Scale 0- Not a burden—4-Extreme burden).

To assess patient acceptability, at post-treatment and at the1-week follow-up survey, all participants were asked: "How satisfied are you with how your pain was managed during your ED visit?" and "Overall, how satisfied are you with your treatment during your ED visit?" each on a 5-point Likert Scale from 0-Very dissatisfied—4-Very satisfied. Data were exported from Microsoft Excel and analyzed as frequencies and proportions using IBM's SPSS version 22.0.

2.8.3. Other outcomes

2.8.3.4. Data completeness. Data collected via REDCap at each time point was evaluated for quality and completeness using Microsoft Excel. We compared proportions of missing data overall, across centers, and by demographics.

2.8.3.5. Acupuncture intervention fidelity. Although it was not an original goal of ACUITY, during the study our team recognized that formal fidelity checks of the acupuncture treatment would enhance the study.

Accordingly, acupuncture treatment fidelity tracking followed STRICTA guideline elements (see Supplement) and included: steps/staging of care, dose (minimum/maximum of the number of needles, points treated, duration of needle retention time and session time), general recommendations given and completion of session forms. Fidelity assessment provided the proportion of participants who were treated in a manner consistent with the acupuncture intervention manualization, and whether the intervention was delivered as planned or cut short due to ED flow or medical care requirements. The full detail of the ACUITY fidelity results are published elsewhere.[41]

2.8.3.6. Pain and anxiety. Since feasibility studies are not appropriate for detection of a treatment effect between groups due to limited sample size and statistical power,[42–44] we include descriptive data on pain and anxiety outcomes (means [M] and standard deviation [SD]) for interest.

2.8.3.7. Pain medications. We assessed pain medications used during the ED visit and prescriptions for pain medications provided at discharge.

2.8.3.8. Adverse events. All adverse events (AEs) and serious adverse events (SAEs) were collected for all participants via EHR review as well as those who completed the 1- and 4-week follow-up surveys.

3. Results

3.1. Primary outcome

3.1.1. Recruitment

We report the results of this multi-center, feasibility RCT based on the framework for developing and evaluating complex interventions.[32] Our goal was to recruit 165 adults presenting to a participating ED. Specifically, recruitment was from May 3, 2021, to September 24, 2022, during which time 632 eligible patients were approached for participation. Of 632 individuals approached, 165 enrolled (26.1 % recruitment rate) and were assigned to acupuncture (n = 83) or usual care (n = 82). Of note, the two most common reasons individuals declined to participate was lack of interest (n = 282) and acupuncture or needle fear (n = 79). The participant CONSORT diagram[45] is shown in Fig. 1. The first 5 participants enrolled per site were designated as pilot participants to ensure that study procedures were understood and followed. As there were no substantive issues, these pilot participants' data were included in the analyzed sample.

To maximize the knowledge gained in this multi-center study, recruitment was phased with the UH, UCSD and VUMC launching recruitment in this sequenced order. Specifically, UH started recruitment on May 3, 2021, and completed recruitment on November 15, 2021. UCSD started recruitment on September 13, 2021, and completed recruitment on March 2, 2022. Both centers had three, 6-hour recruitment sessions per week, held on weekday afternoons and early evenings. VUMC began recruitment on January 11, 2022, and completed recruitment on September 24, 2022. VUMC had an average of two, 4-hour recruitment sessions per week on weekday mornings or afternoons with one 4-hour recruitment session on one Saturday per month. Due to COVID-19 related recruitment delays at VUMC, UH relaunched recruitment on August 22, 2022, and UH's overall recruitment was completed September 21, 2022, thus meeting our goal. ACUITY was conducted during the COVID-19 pandemic, which increased the ED census of our sites and led to crowding.[46,47]

3.1.1.9. Demographics and baseline data. Among the 165 enrollees, 57 % (n = 94) were female, and the mean age was 44.6 (SD = 17.0) years. Participants were racially and ethnically diverse: 42.4 % were Black/African American, 42.4 % were White/Caucasian, and 13.9 % were Hispanic/Latino. The most common pain presentations were back (32.1 %), abdominal (20 %) and extremity pain (18.2 %). Pain intensity and anxiety at baseline averaged 7.2 (2.2 SD) and 4.4 (3.4 SD) respectively. Across all centers, 35.8 % had private insurance, 30.9 % had Medicare and 24.2 % had Medicaid insurance. A summary of the demographics and initial condition of participants for each center and across all centers is displayed in Table 2.

3.2. Secondary outcomes

3.2.1. Retention

Of those randomized, 156 (acupuncture n = 79, usual care n = 77) and 151 (acupuncture n = 76, usual care n = 75) completed the pain and anxiety baseline and post-treatment measures respectively (151/165 = 91.5 % retention) and were included in the analysis. The demographics and initial condition of 151 participants, who provided both pre-treatment and post-treatment scores, are displayed by treatment group in Table 3. There were no major demographic differences between the acupuncture and usual care groups.

3.2.2. Acceptability

3.2.2.10. ED staff perspectives on appropriateness and helpfulness of acupuncture. The mean age of ED respondents (n = 125) was 37.6 years (SD = 9.35); 52.0 % were female (n = 65); and 38.4 % were nurses, 26.4 % were attending physicians, 10.4 % were residents, 9.6 % were nurse practitioners, and 15.2 % were other healthcare staff (e.g., paramedic). Overall, across all respondents, 42.4 % reported acupuncture to be an 'appropriate' or 'very appropriate' intervention for the ED setting (range across sites: 37.8 % - 46.5 %) whereas 24.0 % reported acupuncture to be an 'inappropriate' or 'very inappropriate' intervention for the ED setting (range: 18.9 % - 28.9 %). Most respondents, 55.2 % (range: 52.3 % - 62.2 %), reported acupuncture as being 'somewhat helpful' or 'very helpful' in managing patient pain in the ED whereas 13.7 % (range: 11.4 % - 18.9 %) reported acupuncture as being 'somewhat unhelpful' or 'not at all helpful' in managing participants with pain in the ED.

For ED respondents with direct contact with the ACUITY study (n = 32), the intervention was found to be acceptable, with 75.0 % of respondents 'satisfied' or 'very satisfied' with the delivery of the intervention (range: 66.7 % - 100 %) and 6.3 % of respondents 'dissatisfied' or 'very dissatisfied' with the delivery of the intervention (range: 0 % - 8.3 %). They also rated ACUITY as imposing minimal burden on the ED staff, with 71.9 % rating the intervention as 'not a burden' (range: 40.0 % - 80.0 %). Fig. 2A and 2B display the number of respondents for each question.

3.2.2.11. Patient acceptability. Satisfaction with Pain Management: Overall, the intervention was acceptable to participants, with 88.4 % of acupuncture participants (n = 69) 'satisfied' or 'very satisfied' with how their pain was managed during their ED visit at post-treatment, compared to 49.3 % of usual care participants (n = 72). At 1-week, 79.7 % (n = 69) of acupuncture participants and 62.5 % of usual care participants (n = 64) were 'satisfied' or 'very satisfied' with how their pain was managed during their ED visit.

Satisfaction with Treatment: Further, 92.6 % of acupuncture patient participants (n = 68) were 'satisfied' or 'very satisfied' with their treatment during their ED visit at post-treatment, compared to 59.2 % of usual care participants (n = 72). At the 1-week follow-up, 77.1 % of acupuncture patient participants (n = 70) were 'satisfied' or 'very satisfied' with their treatment during their ED visit and 62.5 % (n = 64) of usual care participants were 'satisfied' or 'very satisfied' with their treatment during their ED visit. Fig. 3A displays the responses for each question by group at post-treatment and Fig. 3B displays the responses by group at the 1-week follow-up.

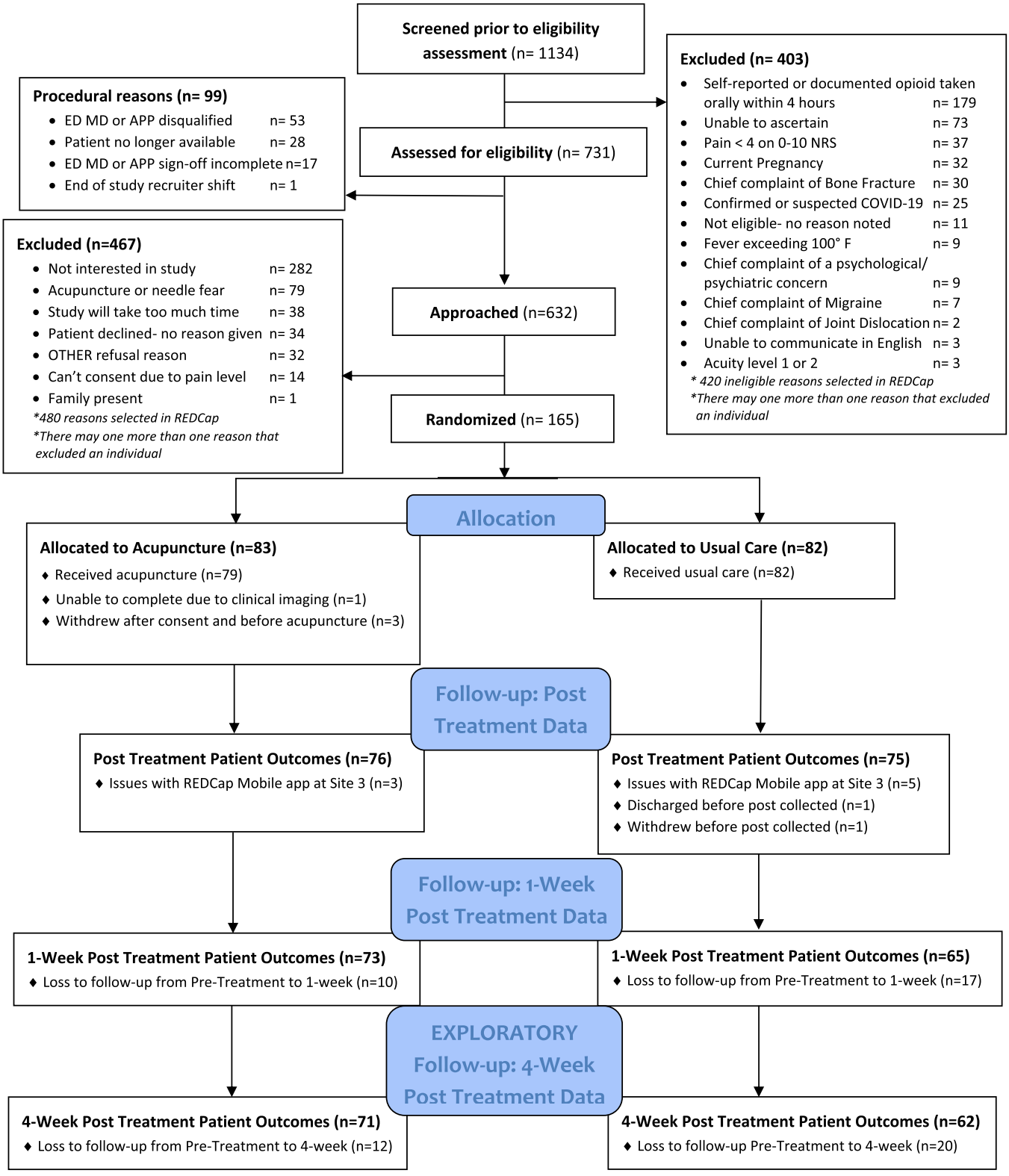

Fig. 1. CONSORT Diagram
The figure depicts the flow of the ACUITY trial using the CONSORT reporting recommendations. Abbrevitaions: ED, Emergency Department; MD,Medical Doctor; APP,Advanced Practice Provider; NRS,Numeric Rating Scale.

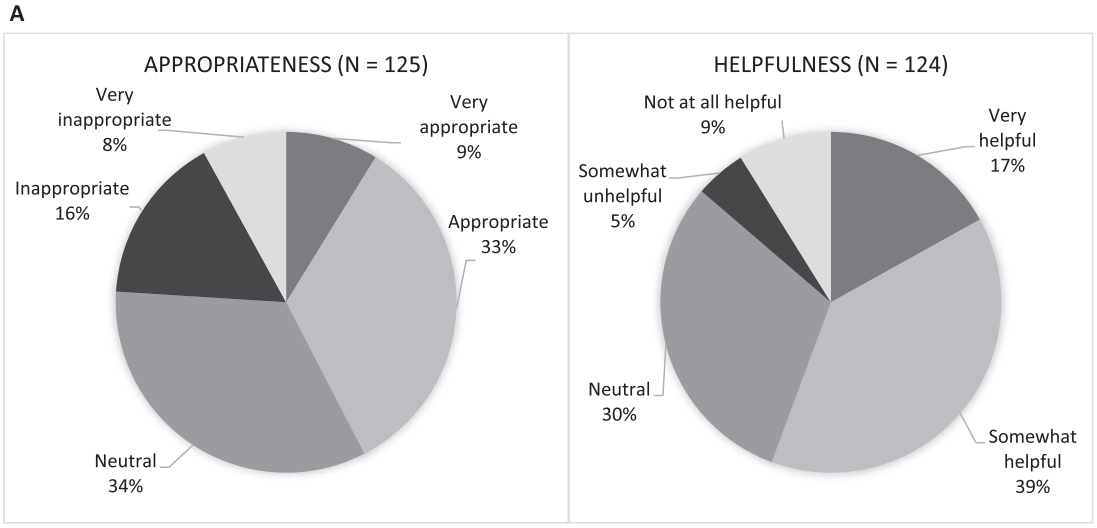

Fig. 2A. ED Staff Perspectives on Appropriateness and Helpfulness of Acupuncture
The left panel depicts ED staff perpectives on the apppropriateness of acupuncture in the ED on a 5 point Liekert scale. The right panel depicts ED staff perpectives on the helpfullness of acupuncture in the ED on a 5 point Liekert scale.

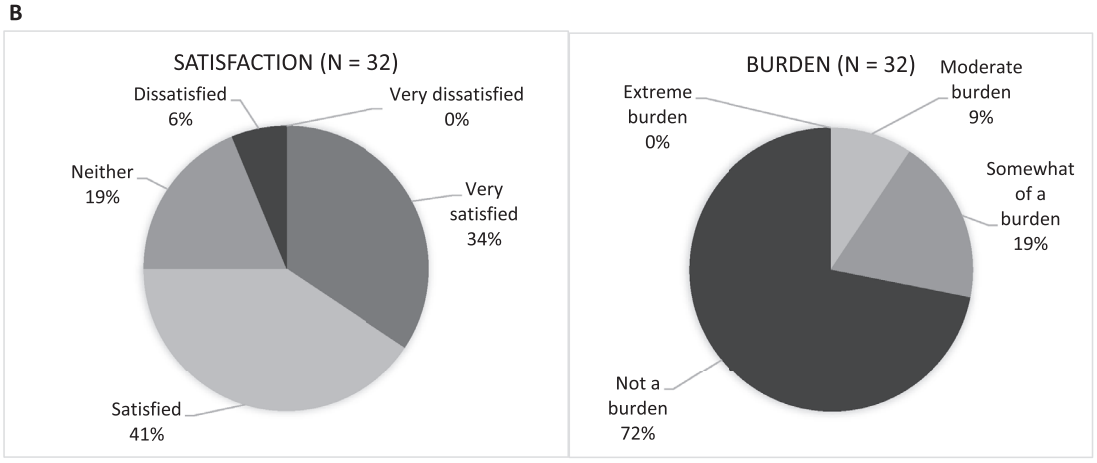

Fig. 2B. Perspectives of ED Staff that interacted with ACUITY on Satisfaction and Burden of ACUITY
The left panel depicts the perspectives of ED staff who interacted with the ACUITY study on their satisfaction of ACUITY on the ED flow on a 5 point Liekert scale. The right panel depicts the perspectives of ED staff who interacted with the ACUITY study on the buren caused by ACUITY on the ED flow on a 5 point Liekert scale.

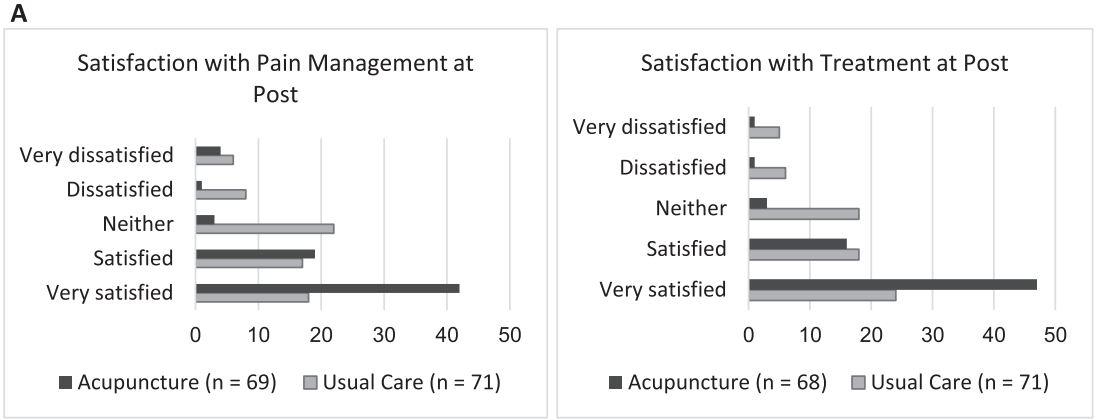

Fig. 3A. Patient Satisfaction with Pain Management and Treatment at Post-treatment timeframe
The left panel displays the responses for satisfaction with pain management at post-treatment and the right panel illustrates the satifaction with treatment at post-treatment.

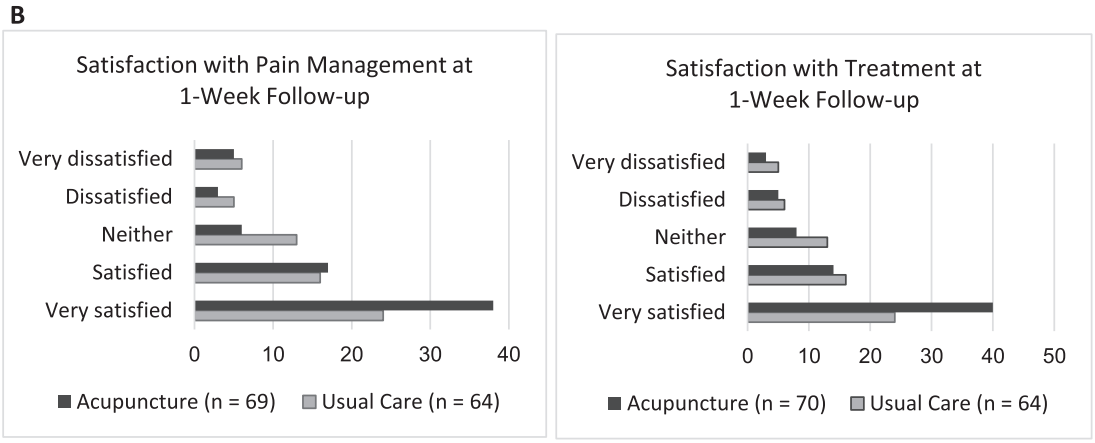

Fig. 3B. Patient Satisfaction with Pain Management and Treatment at 1-week Followup timeframe
The left panel displays the responses for satisfaction with pain management at 1-week followup and the right panel illustrates the satifaction with treatment at 1-week followup.

Table 1
Recruitment and retention for each center and across all centers.

Variable	UH	VUMC	UCSD	Total
Recruitment and Retention (n, *%)*				
Screened	473	373	288	1134
Assessed for eligibility	276	314	141	731
Approached	220	300	112	632
Enrolled	61 (27.7 %)	49 (16.3 %)	55 (49.1 %)	165 (26.1 %)
Received assigned intervention	60	48	53	161
Pain and anxiety scores obtained (n, %)				
Pre-Assessment	61 (100 %)	48 (98.0 %)	47 (85.5 %)	156 (94.5 %)
Post-Assessment	60 (98.4 %)	47 (95.9 %)	44 (80.0 %)	151 (91.5 %)
Discharge[#]	16 (26.2 %)	46 (93.9 %)	12 (21.8 %)	74 (44.8 %)
1-week Follow-up	50 (82.0 %)	40 (81.6 %)	38 (69.1 %)	128 (77.6 %)
4-week Follow-up	46 (75.4 %)	39 (79.6 %)	37 (67.3 %)	122 (73.9 %)
Rate of Recruitment (M)				
Patients screened/month	72.9	57.4	44.3	174.6
Patients enrolled/month	8.1	6.1[*]	8.5	22.7
Hours to enroll 1 patient	6.6	6.9	5.6	6.4

[*] VUMC had fewer recruitment sessions than the UH and UCSD. [#] For all 3 sites, if a given patient's discharge time was <15 min from their Post-treatment assessment, then the discharge score for that patient were not collected.

[#] For all 3 sites, if a given patient's discharge time was <15 min from their Post-treatment assessment, then the discharge score for that patient were not collected.

3.3. Other outcomes

3.3.1. Data completeness

We found acceptable levels of data completion. At baseline, 94.5 % of participants completed the NRS pain and anxiety measures, with 91.5 %, 44.8 %, 77.6 %, and 73.9 % of baseline participants completing measures at the post-treatment, ED discharge, 1-week follow-up and exploratory 4-week follow-up respectively. Details of retention for each center and across all centers are displayed in Table 1. Note that if a participant's discharge time was <15 min from the post-treatment assessment then the discharge scores were not collected per the study protocol.[34]

3.3.2. Acupuncture intervention fidelity

Specifics of fidelity to the acupuncture manualization protocol have been published separately.[41] Briefly, fidelity assessment showed 98.1 % of patient participants were treated in a manner consistent with the responsive acupuncture manualization protocol and treatment fidelity parameters.[41] Further, the mean number of needle insertion sites was 13.2 with a range expected of 1–18 (±2) needle sites. Needle retention time mean was 23.5 min, with expected range of 15–30 (± 5) minutes. Total session time mean was 40.3 min, expected range 30–60 (± 10) minutes and varied depending on the acupuncturists' assessment of the participant, the location of the session in the ED and or workflow considerations of the ED.[41] Participants in the acupuncture group received one treatment during their ED visit and the acupuncture was performed immediately after study enrollment. High fidelity to the acupuncture intervention was supported by the acupuncturists experience in treating acute pain, pretrial training of acupuncturists in the responsive acupuncture manualization and orientation to the REDCap session forms and acupoint grid that included STRICTA specific items (see Supplement).

3.3.3. Pain and anxiety

As a feasibility RCT, it was beyond our scope to perform statistical analysis on change scores between or within groups. For interest, we present pre- and post-treatment scores of pain intensity and anxiety for the acupuncture and usual care groups by recruiting center in Table 4a, 4b. For interest, we also report at post-treatment, on the 0–10 NRS the overall mean pain intensity was 4.8 units (SD 2.8) for acupuncture and 6.4 units (SD 2.5) for usual care and mean anxiety was 2.5 units (SD 2.6) for acupuncture and 3.5 units (SD 3.2) for usual care.

For the 1-week follow up, on the 0–10 NRS the overall mean pain intensity was 4.0 units (SD 3.1) for acupuncture and 4.5 units (SD 3.2) for usual care, and mean anxiety was 2.8 units (SD 2.9) for acupuncture

Table 2
Demographics and initial condition of participants for each center and across all centers.

Variable	UH (n = 61)	VUMC (n = 49)	UCSD (n = 55)	Total (n = 165)
Sex (%)				
Female	59.00 %	61.20 %	50.90 %	57.00 %
Male	41.00 %	36.70 %	49.10 %	42.40 %
Missing		2.10 %		0.60 %
Age M (SD), n = 164	42.0 (16.1)	48.0 (15.7)	46.5 (16.8)	45.3 (16.3)
Race (%)				
American Indian/Native	1.60 %	0.00 %	1.80 %	1.20 %
Asian	1.60 %	2.00 %	3.60 %	2.40 %
Black/African American	80.30 %	24.50 %	16.40 %	42.40 %
Native Hawaiian/Pacific Islander	0.00 %	0.00 %	1.80 %	0.60 %
White	8.20 %	69.40 %	56.40 %	42.40 %
Other	9.80 %	2.00 %	16.40 %	9.70 %
Declined to answer	3.30 %	0.00 %	7.30 %	3.60 %
Missing		2.00 %		0.60 %
Ethnicity (%)				
Hispanic/Latino	1.60 %	4.10 %	36.40 %	13.90 %
Not Hispanic/Latino	83.60 %	91.80 %	56.40 %	77.00 %
Declined to answer	14.80 %	2.00 %	7.30 %	8.50 %
Missing		2.00 %		0.60 %
Education (%)				
No high school diploma	3.30 %	2.00 %	7.30 %	4.20 %
High school or equivalent	45.90 %	18.40 %	30.90 %	32.70 %
Some college	32.80 %	40.80 %	27.30 %	33.30 %
College degree	18.00 %	22.40 %	29.10 %	23.00 %
Graduate or professional degree	0.00 %	12.20 %	5.50 %	5.50 %
Declined to answer	0.00 %	2.00 %	0.00 %	0.60 %
Missing		2.00 %		0.60 %
Income (%)				
Less than $20,000	52.50 %	8.20 %	32.70 %	32.70 %
$20,000 – $50,000	32.80 %	26.50 %	29.10 %	29.70 %
$50,001 to $100,000	3.30 %	16.30 %	10.90 %	9.70 %
$100,001 to $150,000	3.30 %	4.10 %	9.10 %	5.50 %
More than $150,000	0.00 %	6.10 %	7.30 %	4.20 %
Declined to answer	8.20 %	36.70 %	10.90 %	17.60 %
Missing		2.00 %		0.60 %
Insurance (%)				
Medicare	23.00 %	28.60 %	41.80 %	30.90 %
Medicaid	52.50 %	4.10 %	10.90 %	24.20 %
Private insurance	18.00 %	55.10 %	38.20 %	35.80 %
No insurance	1.60 %	10.20 %	5.50 %	5.50 %
Declined to answer	4.90 %	0.00 %	3.60 %	3.00 %
Missing		2.00 %		0.60 %
Primary body site of pain at baseline (%)				
Back	45.90 %	24.50 %	23.60 %	32.10 %
Extremity	36.10 %	8.20 %	27.30 %	24.20 %
Abdomen	1.60 %	49.00 %	14.50 %	20.00 %
Head	6.60 %	10.20 %	9.10 %	8.50 %
Multiple	4.90 %	2.00 %	9.10 %	6.70 %
Flank	1.60 %	4.10 %	5.50 %	3.60 %
Chest	1.60 %	2.00 %	3.60 %	2.40 %
Neck	0.00 %	0.00 %	3.60 %	0.60 %
Other	1.60 %	0.00 %	3.60 %	1.80 %
Prior Acupuncture (%)	*13.10 %*	*22.40 %*	*38.20 %*	*24.20 %*
Pain intensity at baseline M (SD), n = 156	*8.0 (2.3)*	*6.5 (2.1)*	*7.0 (2.0)*	*7.2 (2.2)*
Anxiety at baseline M (SD), n = 156	*5.9 (3.1)*	*2.0 (3.0)*	*4.9 (2.9)*	*4.4 (3.4)*

M- mean; SD - standard deviation, UH- University Hospitals; VUMC- Vanderbilt University Medical Center; UCSD- University of California, San Diego.

and 3.4 units (SD 3.1) for usual care. Not included in the Table 4 are the discharge scores (due to low percentage completion based on discharge within 15 min of the post-treatment assessment) or 4-week outcomes (due to exploratory nature of this measure).

3.3.4. Pain medications

Use of any pain reliever (opioid, acetaminophen or NSAID) was similar across groups during the ED visit (61 in usual care and 56 in acupuncture arm) as was presence of a prescription at discharge (19 vs 19). Opioid pain relievers were similarly administered during the ED visit to 15 usual care participants and 20 acupuncture participants. Opioid prescriptions at discharge were infrequent and similar across arms (0 instances in usual care and 2 prescriptions in the acupuncture arm).

3.3.5. Adverse events

There were 61 AEs and 2 SAEs that occurred across centers in the RCT: 34 in the acupuncture arm, and 29 in the usual care arm. The rate of AE/SAE events were 41.0 % vs. 35.4 % for acupuncture and usual care respectively (p = 0.459 by Chi-squared test). For all centers, 100 % of the AEs reported by participants in the ED or during their 1-week and/or 4-week follow-up survey (n = 60) were not related to the interventions received during their ED visit in either study arm. The study PI, center

Table 3
Demographics and initial condition of participants providing pre- and post-treatment pain scores.

Variable	Total (n = 151)	Acupuncture (n = 76)	Usual Care (n = 75)	*P values*
Sex (%)				*0.159*
Female	57.00 %	51.30 %	62.70 %	
Male	43.00 %	48.70 %	37.30 %	
Age M (SD), n = 151	45.1 (16.3)	45.6 (16.1)	44.5 (16.7)	*0.703*
Race (%)				
American Indian/Native	0.70 %	0.00 %	1.30 %	0.4967
Asian	2.00 %	1.30 %	2.70 %	0.62
Black/African American	44.40 %	44.70 %	44.00 %	0.9274
Native Hawaiian/Pacific Islander	0.70 %	0.00 %	1.30 %	0.4967
White	43.00 %	48.70 %	37.30 %	0.159
Other	9.30 %	6.60 %	12.00 %	0.2508
Declined to answer	3.30 %	2.60 %	4.00 %	0.6812
Race (%)				0.4238
White	41.70 %	46.10 %	37.30 %	
Black/African American	43.10 %	43.40 %	42.70 %	
Other	13.20 %	9.20 %	17.30 %	
Decline to answer	2.00 %	1.30 %	2.70 %	
Ethnicity (%)				*0.5513*
Hispanic/Latino	13.20 %	11.80 %	14.70 %	
Education (%)				*0.6905*
No high school diploma	3.30 %	1.30 %	5.30 %	
High school or equivalent	32.50 %	34.20 %	30.70 %	
Some college	35.80 %	34.20 %	37.30 %	
College degree	22.50 %	22.40 %	22.70 %	
Graduate or professional degree	5.30 %	6.60 %	4.00 %	
Decline to answer	0.70 %	1.30 %	0.00 %	
Income (%)				*0.7624*
Less than $20,000	32.50 %	28.90 %	36.00 %	
$20,000 – $50,000	29.10 %	27.60 %	30.70 %	
$50,001 to $100,000	9.90 %	11.80 %	8.00 %	
$100,001 to $150,000	5.30 %	5.30 %	5.30 %	
More than $150,000	4.60 %	3.90 %	5.30 %	
Decline to answer	18.50 %	22.40 %	14.70 %	
Insurance (%)				*0.1282*
Medicare	29.10 %	32.90 %	25.30 %	
Medicaid	25.80 %	21.10 %	30.70 %	
Private insurance	36.40 %	42.10 %	30.70 %	
No insurance	5.30 %	2.60 %	8.00 %	
Decline to answer	3.30 %	1.30 %	5.30 %	
Location of pain (%)				*0.6427*
Back	34.40 %	32.90 %	36.00 %	
Extremity	25.20 %	21.10 %	29.30 %	
Abdomen	18.50 %	18.40 %	18.70 %	
Head	8.60 %	9.20 %	8.00 %	
Flank	3.30 %	3.90 %	2.70 %	
Chest	2.60 %	2.60 %	2.70 %	
Neck	0.70 %	1.30 %	0.00 %	
Multiple	4.60 %	7.90 %	1.30 %	
Other	2.00 %	2.60 %	1.30 %	
Prior Acupuncture (%)	23.80 %	25.00 %	22.70 %	*0.7365*
Pain intensity at baseline M (SD, n = 151	7.3 (2.2)	7.4 (2.2)	7.1 (2.3)	*0.4237*
Anxiety at baseline M (SD), n = 151	4.3 (3.4)	4.5 (3.4)	4.1 (3.4)	*0.5238*

M, mean; SD, Standard deviation.

Table 4A
Pre- and Post-treatment pain intensity and anxiety scores for Acupuncture and Usual care groups.

Variable	UH (n = 60)				VUMC (n = 47)				UCSD (n = 44)				Total (n = 151)			
	Acupuncture		Usual care		Acupuncture		Usual care		Acupuncture		Usual care		Acupuncture		Usual care	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Pain intensity	8.0	4.6	8.1	7.0	6.4	4.6	6.4	6.0	7.7	5.3	6.5	6.0	7.4	4.8	7.1	6.4
M (SD)	(2.1)	(2.7)	(2.3)	(2.9)	(2.1)	(2.6)	(2.0)	(2.1)	(2.0)	(3.1)	(2.0)	(2.4)	(2.2)	(2.8)	(2.3)	(2.5)
Anxiety	5.4	2.7	6.1	4.9	2.5	1.9	1.3	1.0	5.3	2.9	4.4	4.1	4.5	2.5	4.1	3.5
M (SD)	(3.3)	(2.7)	(2.9)	(3.1)	(3.1)	(2.7)	(2.7)	(2.1)	(3.3)	(2.6)	(2.4)	(2.8)	(3.4)	(2.6)	(3.4)	(3.2)

M, Mean; SD, standard deviation, UH, University Hospitals; VUMC, Vanderbilt University Medical Center; UCSD, University of California, San Diego.

Table 4B
Baseline and One-Week Follow-up pain intensity and anxiety scores for Acupuncture and Usual care groups.

Variable	UH (n = 50)				VUMC (n = 40)				UCSD (n = 38)				Total (n = 128)			
	Acupuncture		Usual care		Acupuncture		Usual care		Acupuncture		Usual care		Acupuncture		Usual care	
	Pre	1-wk	Pre	1-wk	Pre	1-wk	Pre	1-wk	Pre	1-wk	Pre	1-wk	Pre	1-wk	Pre	1-wk
Pain intensity	8.0	4.9	7.7	5.6	6.5	3.1	6.1	4.4	7.7	3.8	6.1	3.4	7.4	4.0	6.7	4.5
M (SD)	(2.1)	(3.2)	(2.4)	(3.3)	(2.1)	(2.8)	(1.9)	(2.9)	(2.1)	(3.1)	(2.0)	(3.0)	(2.2)	(3.1)	(2.2)	(3.2)
Anxiety	5.5	3.0	5.7	4.0	2.4	2.2	1.5	2.8	4.9	3.1	4.2	3.2	4.4	2.8	4.0	3.4
M (SD)	(3.2)	(3.0)	(2.8)	(3.4)	(3.2)	(2.8)	(3.0)	(3.1)	(3.4)	(2.8)	(2.5)	(2.9)	(3.5)	(2.9)	(3.2)	(3.1)

M, Mean; SD, standard deviation, UH, University Hospitals; VUMC, Vanderbilt University Medical Center; UCSD, University of California, San Diego.

PIs and study physicians determined that these AEs were unrelated to the participant's respective assigned intervention.

Unanticipated SAEs (n = 2) were documented in participants' EHR. The first SAE was the inpatient death of a patient (acupuncture arm) at Center 2 about seven days after their ED discharge and subsequent inpatient admission. The second SAE was the hospitalization of a participant (usual care arm) for a suspected stroke on the day of their ED visit at Center 1. Both unanticipated SAEs were determined to be unrelated to the respective interventions by the study physician at the recruiting center.

4. Discussion

Successful completion of this multi-center, feasibility RCT provides the necessary framework for conducting a future, multi-center, superiority RCT of acupuncture therapy compared with usual care in patients with pain in EDs across the BraveNet PBRN. In the current feasibility RCT, 55.7 % of screened patients met all eligibility criteria and were approached for participation; 26.1 % of eligible and approached patients consented to participate in the study (recruitment rate); and 92.1 % of those consenting participants completed post-treatment measures of pain and anxiety (retention rate). These data provide a reasonable estimate of the recruitment and retention rates for designing the future definitive RCT.

Recruitment rate across centers ranged from 16.3 % to 49.1 %, center variability in recruitment rates will be an important consideration for future research. Furthermore, this rate is lower than seen in other RCTs (range of 29.1 % to 69.5 %)[31,48-51] and observational trials (54 % to 89 %) of acupuncture.[52-54] It is possible that ACUITY's lower enrollment rates are attributable to the fact that the study was conducted during the COVID-19 pandemic where crowding in the ED was common.[46,47] Due to this ED crowding, the delivery of the acupuncture intervention in ACUITY differed from prior RCTs[31,48-51,55-58] in that acupuncture was successfully and safely delivered to participants in hallways, waiting rooms, on gurneys and in wheelchairs as well as in private curtained areas and private rooms in the ED.

Alternatively, the reduced recruitment rate may have been affected by the distinct demographic characteristics of participants receiving care at our enrolling centers. Uniquely, our study had a significant inclusion of Black/African American (42 %) participants, Hispanic (14 %) participants and those with Medicare or Medicaid insurance (55 %). To the best of our knowledge, there is only one published acupuncture in the ED RCT[54] to report racial and ethnic demographics of participants. Reasons for this are unknown, but it could be that other study samples were homogenous (e.g., non-Hispanic Whites). Further efforts to improve recruitment will be employed in our future definitive trial, such as addressing needle fear and adjusting the timing of involvement of ED physicians and advanced practice clinicians to improve recruiting while not interfering with patient care flow.

Our retention rate of 92.1 % would have been higher at post-treatment, were it not for an issue of technology in REDCap data collection at the UCSD site. Because all study staff were blind to study participants' pain and anxiety scores (participants directly entered into REDCap on a tablet computer), the error was not noted immediately. Staff blinding was important to ensure participants were free to answer honestly and without potential influence of their responses by study staff. Finally, since data quality checks were routinely performed by the clinical coordinating center, the issue was detected and resolved quickly and will be closely monitored in our future research.

Pain is the most common reason patients visit the ED for care.[1,2] The current study included participants with a wide variety of pain conditions, with the most common being acute back (32 %), abdominal (20 %), and extremity pain (18 %). The various pain conditions included in this study reflects the heterogeneity of ED pain presentations. However, these percentages differed between centers, with back pain being most common at UH (46 %) and UCSD (32.1 %), and abdominal pain being most common at VUMC (49 %), but uncommon at UH (1.6 %). Further, baseline pain intensity also varied across centers, ranging from 6.5 at VUMC to 8.0 at UH. Likewise, baseline anxiety varied from 2.0 at VUMC to 5.9 at UH. It is unclear why pain intensity presentation and baseline pain and anxiety levels differed across centers, but these findings reinforce the value of conducting multi-center studies with larger study populations.

The current study demonstrated high fidelity, with 95.2 % of acupuncture sessions completed, and 98.1 % of acupuncture sessions adhering to the manualized acupuncture protocol.[41] In review of the ACUITY acupuncturist's documentation (by author AN), we noted interventions did not routinely use auricular points,[40] with either ear needles, ear seeds or both used in about 56 % of the sessions.[41] Recommendation for use of auricular therapy and additional training will be included in our future definitive trial. Steps and staging of the acupuncture session as well as traditional acupuncture point options are included in the manualization to provide a balance between standardization and flexibility, allowing for responsive individualization of the session across various presentations of acute pain.[33] Development and use of the responsive acupuncture intervention manualization in the current study has provided the appropriate framework for conducting a future, multi-center, definitive RCT of acupuncture in the ED.[33] Tracking and reporting fidelity to the acupuncture intervention also supports the reliability of the acupuncture manualization protocol,[41] allowing other researchers to replicate this standardized yet flexible intervention in the ED setting. Due to the COVID-19 pandemic and ED crowding,[46,47] the delivery of the acupuncture intervention in ACUITY differed from prior RCTs[31,48–51,55–58] in that acupuncture was successfully and safely delivered to participants in hallways, waiting rooms, on gurneys and in wheelchairs as well as in private curtained areas and rooms.

Subsequent completion of a future, definitive RCT will provide critical evidence to evaluate inclusion of acupuncture therapy as a readily available treatment in EDs across the United States. Such an expansion would provide ED patients and ED physicians, residents, and advanced practice providers with an additional, effective treatment option for acute pain as part of a comprehensive pain care strategy that can reduce reliance on opioid prescribing and risks associated with ongoing opioid use.

The current study was the first study to include implementation outcomes[59] in the context of acupuncture in the ED. We found that 42 % of

ED respondents considered acupuncture “very appropriate” or ”appropriate” for pain relief in the ED, relative to 24 % who indicated it was very “inappropriate” or ”inappropriate”. When asked about the helpful aspect of acupuncture, 55 % of ED respondents considered acupuncture very helpful/helpful, relative to 13 % who indicated it was very unhelpful/unhelpful. While in the ED, 88.4 % and 92.6 % of acupuncture participants were very satisfied/satisfied with pain management and satisfaction of acupuncture care respectively. Also, while in the ED, 49.3 % and 59.2 % of usual care participants were very satisfied/satisfied with pain management and satisfaction of usual care respectively. While these results are generally supportive of acupuncture, our team conducted formal qualitative interviews of ED respondents and ED participants. A future article of these qualitative results will provide a more in-depth assessment of their perceptions.

All outcomes regarding pain medication, that is, use of any pain reliever (opioid, acetaminophen or NSAID), use of opioids specifically, the presence of any prescription, and opioid prescriptions at discharge, were similar in the acupuncture and usual care groups. However, we did not perform statistical tests as we were not powered to do so, and prescriptions were low overall. A future fully powered trial will be designed to provide the appropriate sample size to statistically assess any differences in pain medication use and prescriptions.

4.1. Limitations

There are several limitations of the current feasibility trial. First, implementing an RCT in the ED during the COVID-19 pandemic held unique challenges. Specifically, due to delays in hospital admission processes, our participating EDs had record censuses[46,47] resulting in limited space within EDs high turnover areas, (e.g., super track, fast track, and urgent care). This fact complicated screening and recruitment for ACUITY and also reduced capacity to offer a dedicated space for acupuncture treatment. Yet even considering these limitations, our teams were able to reach our recruitment and retention goals near our projected timeline. Fostering a collaborative, working relationship with the ED medical leadership helped to keep communication channels open in the event of rising COVID-19 numbers, or if changes needed to be made to accommodate rising ED utilization.

The criteria for feasibility of our primary outcome, recruitment, was the successful recruitment of participants into the study, which was achieved. However, we did not set specific a priori threshold criteria for meeting fidelity in terms of % retention or acceptability, which could be seen as a limitation. Generally other feasibility studies of acupuncture in the ED have not reported feasibility criteria, yet authors reported their studies as feasible.[48,49,52,53] As the conduct of feasibility studies become more common, clear benchmarks for meeting feasibility should be clarified a priori.

A third limitation was our use of self-reported ratings to assess participants’ pain intensity and anxiety. However, as self-report of pain is standard clinical practice[13,14] and a reliable physiological measure to quantify acute pain in the ED has not been identified,[60] we contend that our approach was appropriate. Third, the expected time from pre-to post-treatment in the acupuncture group was 45 min (± 15 min),[33] whereas in the usual care group the expected time from pre-to post-treatment remained at 60 min (± 15 min). This difference makes the comparison between the two groups potentially difficult. In future research, post-treatment scores will be obtained at 45 min (± 15 min) for participants in both the acupuncture and usual care groups. In our future definitive trial, pre to post treatment times will be consistent for both arms. Fourth, we encountered a challenge in the collection of pain and anxiety scores for the first few subjects at the UCSD site. In our desire to blind study staff to the participants’ post-treatment pain scores, an error in REDCap programming meant that it was impossible for study staff to observe the occurrence of missing data in real time. Planned data checks as part of quality assurance meant that the error was discovered rather quickly and resolved. Future research will allow research staff to observe that a valid score of 0 to 10 was entered, but the exact score will remain masked. Fifth, to ensure that opioid use would not influence subsequent pain assessment and confound the study, we excluded patients who had in the 4 h prior to screening reported having taken opioids themselves or received opioids as part of their care in the ED. As a result of this exclusion, it is possible that our study sample, in both the acupuncture as well as the usual care arm, was skewed toward enrolling individuals who may have rejected opioid use, and this may have impacted the clinician’s use of opioids in the ED or opioid prescriptions at discharge. Future research would reduce the exclusion of opioid use to two hours prior to screening. Sixth, we aimed for inclusion of underserved populations and had a diverse sample, however, we only included participants who spoke English, which could have excluded a proportion of patients from underserved populations. Future research could explore whether expanding language eligibility would be worthwhile. Finally, some may consider it a weakness that our acupuncture intervention manualization model allowed for flexibility with point selection and needle retention time. Rather than a weakness, we consider the reliable use of a manualized acupuncture protocol and our assessment of fidelity or adherence to that protocol to be a strength of our study. Specifically, it facilitated a reasonably consistent delivery of the acupuncture intervention and will allow for replication in diverse ED settings in future studies.

4.2. Conclusion

Our results suggest acupuncture therapy is a feasible intervention for adults presenting to the ED with heterogeneous acute, non-emergent pain. We were able to recruit the necessary number of participants in the allotted time frame, retain them for the duration of their study participation and report a high level of data collection. The acupuncturists demonstrated high fidelity to the acupuncture manualization protocol. Preliminary outcome measures of pain and anxiety showed sensitivity to change following the intervention. Successful conduct of this multicenter, feasibility RCT provides the necessary materials and knowledge for the ACUITY team to propose a future multi-center, definitive, superiority RCT of acupuncture versus usual care for acute pain relief in the ED. Refinements will include providing more information at screening to address participants’ concerns of needle phobia, enlisting more coordinated efforts with the ED team to improve the recruitment rate, additional training of acupuncturists for use auricular therapy, and refinement of acupuncture documentation processes in REDCap. Successful conduct of a future, definitive, multi-center RCT could provide critical evidence to support inclusion of acupuncture in EDs across the US. If successful, this could provide Americans with additional nonpharmacologic methods for robust pain management and ideally reduce patients’ opioid use.

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Conceptualization: JD.

Declaration of competing interest

The author(s) report no conflicts of interest in this work.

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Ethical statement

The Institutional Review Board (IRB) at University Hospitals Cleveland Medical Center (UH–CMC) 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).

Data availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imr.2024.101095.

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