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Acupuncture as analgesia for non-emergent acute non-specific neck pain, ankle sprain and primary headache in an emergency department setting: a protocol for a parallel group, randomised, controlled pilot trial

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ABSTRACT

Introduction: This study aims to assess the feasibility of acupuncture as an add-on intervention for patients with non-emergent acute musculoskeletal pain and primary headache in an emergency department (ED) setting.

Methods and analysis: A total of 40 patients who present to the ED and are diagnosed to have acute non-specific neck pain, ankle sprain or primary headache will be recruited by ED physicians. An intravenous or intramuscular injection of analgesics will be provided as the initial standard pain control intervention for all patients. Patients who still have moderate to severe pain after the 30 min of initial standard ED management will be considered eligible. These patients will be allocated in equal proportions to acupuncture plus standard ED management or to standard ED management alone based on computer-generated random numbers concealed in opaque, sealed, sequentially numbered envelopes. A 30 min session of acupuncture treatment with manual and/or electrical stimulation will be provided by qualified Korean medicine doctors. All patients will receive additional ED management at the ED physician's discretion and based on each patient's response to the allocated intervention. The primary outcome will be pain reduction measured at discharge from the ED by an unblinded assessor. Adverse events in both groups will be documented. Other outcomes will include the patient-reported overall improvement, disability due to neck pain (only for neck-pain patients), the treatment response rate, the use of other healthcare resources and the patients' perceived effectiveness of the acupuncture treatment. A follow-up telephone interview will be conducted by a blinded assessor 72±12 h after ED discharge.

Ethics and dissemination: Written informed consent will be obtained from all participants. The study has been approved by the Institutional Review Boards (IRBs). The results of this study will guide a full-scale randomised trial of acupuncture in an ED context.

Trial registration number: ClinicalTrials.gov: NCT02013908.

Strengths and limitations of this study

- This is the first randomised trial of acupuncture in an emergency department (ED) setting in South Korea.
- The study focuses on the role of acupuncture in patients with non-emergent musculoskeletal pain and primary headache who do not respond well to standard pain management in an ED.
- The study is a pilot study for testing the feasibility of acupuncture in an ED setting and is not intended to demonstrate the clinical differences between acupuncture and standard ED management groups for pain level.
- Individualised acupuncture point selection and a free practitioner–patient therapeutic relationship during the delivery of acupuncture treatment reflect the real clinical practice of acupuncture.
- The study aims to guide a future full-scale pragmatic randomised trial of assessing the overall effectiveness of acupuncture for pain management in the ED context and thus does not employ a placebo or sham acupuncture as a control group intervention.
- The fact that the outcome assessors were not blinded for the primary outcome assessment is a methodological caveat of this study.

INTRODUCTION

Acupuncture is being increasingly utilised worldwide, and limited evidence supports

the use of acupuncture for therapeutic intervention in certain conditions, such as low back pain,[1] tension-type headache,[2] migraine[3] and knee osteoarthritis.[4] Whereas chronic pain management has been the dominant area of acupuncture research, attracting the most interest, few studies have attempted to assess the role of acupuncture in treating acute pain conditions, such as low back pain,[5] ankle sprain[6] and sport-related injuries.[7] In the context of the emergency department (ED), patients often present with non-emergent acute musculoskeletal symptoms, resulting in ED crowding as well as delays in treatment from triage, which can ultimately lead to the poor care of patients and inefficiency in emergent management.[8 9] Previous studies have shown that insufficient pain relief at ED discharge was not uncommon. For instance, according to a multicentre study regarding the quality of pain management in ED settings, 27% of patients had pain at discharge.[10] Another audit of pain management in the ED also revealed that approximately two-thirds of patients with pain in the ED could not obtain pain relief when measured at discharge.[11] An integrated patient care approach to improve patient satisfaction and the efficient use of healthcare resources by non-emergent patients in the ED have been explored,[12 13] which implies the potential role of acupuncture in such contexts. In a systematic review, we found that current evidence is insufficient to make any recommendations concerning the use of acupuncture in the ED due to the high risk of bias and the scarcity of primary studies.[13] A multicentre study in Australia to assess the effectiveness and safety of acupuncture for acute pain management in patients with low back pain, ankle sprain or migraine in the ED setting is ongoing,[14] and the feasibility of acupuncture treatments in the ED has been suggested in a recent observational study.[15] These results need to be confirmed by replicate studies in different contexts. In South Korea, acupuncture is regularly practised to treat various conditions due to the pluralistic medical system incorporating Western medicine and Korean medicine.[16] Nevertheless, no study has assessed the role of acupuncture in treating non-emergent acute musculoskeletal conditions in the ED setting.

We aim to conduct this pilot study to assess the feasibility of acupuncture research that evaluates the effectiveness and safety of acupuncture as an add-on intervention for patients with non-emergent acute musculoskeletal pain or primary headache in the context of the ED.

METHODS AND ANALYSIS

Study design

Randomisation and allocation concealment

A computer-generated block random sequence will be tabulated by an independent statistician. Sequentially numbered, opaque, sealed envelopes will be used to conceal the allocation sequence. These envelopes will be prepared by a hospital administrator who will not be associated with any stage of the study.

Study context

This study is a pilot randomised controlled trial that will be performed in the ED of Pusan National University Yangsan Hospital, Yangsan, South Korea. The hospital is located in the urban area of Yangsan, which had a population of approximately 280 000 people in 2014.[17] In total, 5 emergency medicine specialists, 3 residents, 21 specialised ED nurses and 5 paramedics are currently on service in the ED. Acupuncture will be provided in a separate room near the ED or at the bedside in the ED when a patient cannot self-ambulate.

Selection of target conditions

Three conditions (ie, acute non-specific neck pain, ankle sprain and primary headache) were chosen based on a review of existing evidence, our own clinical experience and a discussion among the study Korean medicine doctors (KMDs) and ED physicians. In our systematic review, we found that acupuncture may be a feasible analgesic intervention for acute musculoskeletal pain and acute non-bony injuries of the peripheral joints.[13] Cochrane and non-Cochrane reviews have also indicated the need for further research on the effectiveness and safety of acupuncture in various contexts in these conditions.[2 3 6 18] All study KMDs are acupuncture practitioners who are well experienced in treating such acute pain conditions, and they have treated musculoskeletal conditions in outpatient and inpatient settings.[19] Joint discussions among the study KMDs, ED physicians and investigators revealed that current ED management of such conditions seems to be suboptimal in terms of patient satisfaction, mainly based on the clinical experiences at the hospital. We reached the consensus that patients with acute non-specific neck pain, ankle sprain or primary headache may be eligible for participation in our research.

Pretreatment assessment and the participant recruitment process

The clinical trial information will be posted on the entrance wall of the ED. Complete physical, neurological and/or radiological examinations related to the patients' conditions will be performed by an ED physician to exclude any case that is inappropriate for study inclusion. Analgesics will be administered to a patient according to the standard ED pain management protocol. After 30 min of observation, a patient who still reports a moderate to severe pain level defined as a numerical rating scale (NRS) of at least four points will be regarded as a potential participant for the trial. The ED physician will provide initial verbal information about the recruitment to a potentially eligible patient at the patient's bedside in the ED. If the patient shows a willingness to participate in

the trial, a study KMD will be called and will arrive within 10±5 min in the ED. At the bedside, the study KMD will explain the objective and process of the trial and obtain a written informed consent from the patient. Patient enrolment will be conducted according to predefined eligibility criteria. For eligible participants who meet all required eligibility criteria and provide written informed consent, the study KMD will open an opaque, sealed envelope in front of the participant at his or her bedside in the ED to assign the patient either to acupuncture treatment or to standard ED management without acupuncture (allocation at a 1:1 ratio; figure 1).

Eligibility criteria

Eligible

1. Age over 19 years and with acute pain, defined as pain occurring within 72 h of the ED presentation
2. Acute neck pain with no evidence of neurological abnormality (such as signs and/or symptoms of spinal cord lesion or nerve root compression including peripheral sensory dysfunction or weakness)
3. Acute headache that meets the classification criteria of primary headache, as described by the International Headache Society (codes 1–4)[20]
4. Acute ankle injury with no evidence of fracture or complete tearing of ligaments

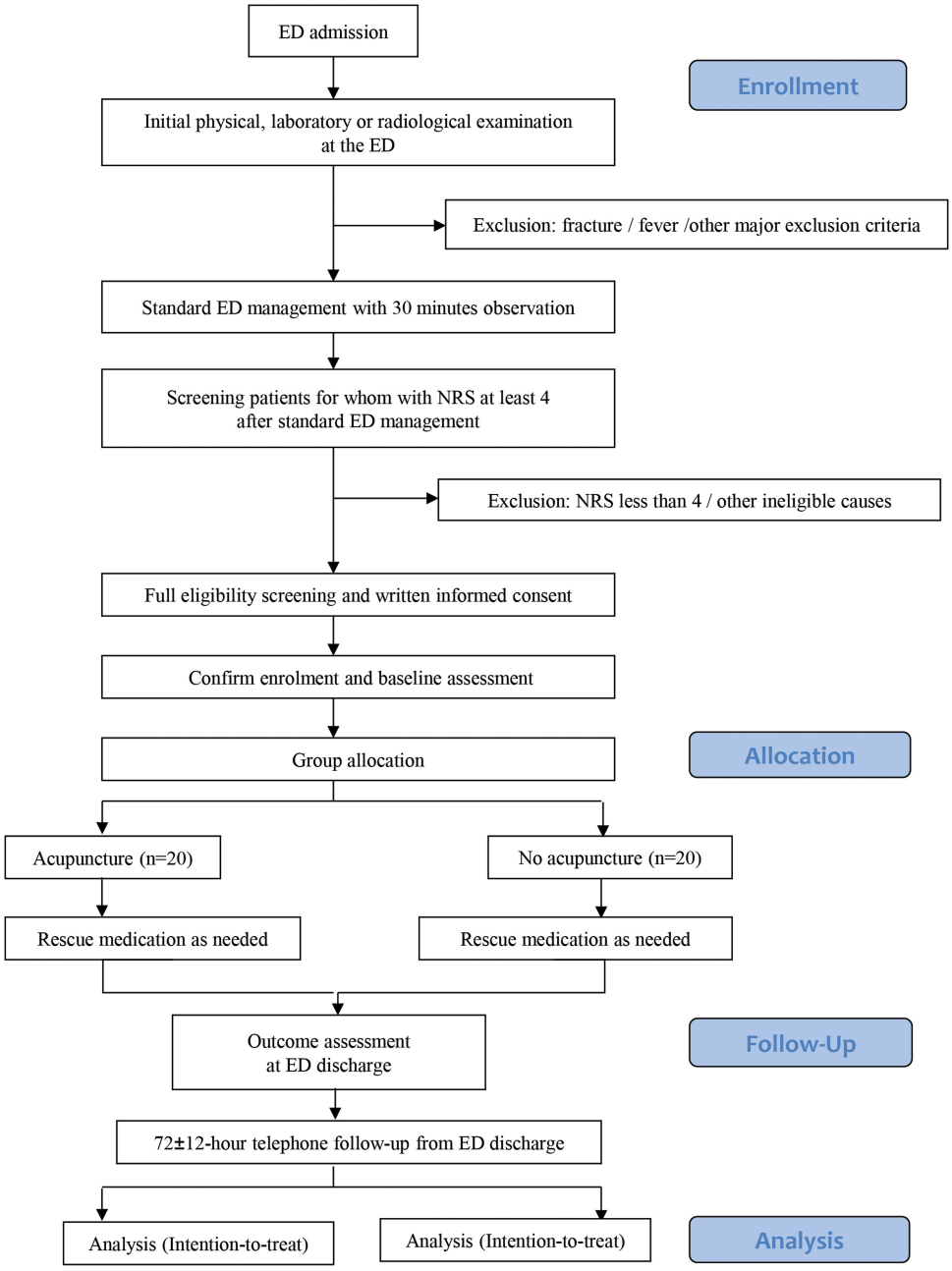

Figure 1 Trial flowchart.

5. A pain level of at least four points of pain intensity on NRS (ranging from 0 to 10) at the completion of 30 min observation after standard ED management

Ineligible

1. Any suspected non-musculoskeletal cause (neoplasm or neurological complications) of the neck or ankle pain
2. Any suspected secondary headache classified by codes 5–12 in the International Classification of Headache Disorders[20]
3. Pain due to bone fracture or joint dislocation
4. Pain with fever (defined as a temperature above 37.5°C)
5. Deemed inappropriate at the ED physician's discretion
6. A pain level of less than four points of pain intensity on NRS (ranging from 0 to 10) at the completion of 30 min observation after standard ED management
7. Pregnancy

Blinding of participants, practitioners, other relevant healthcare staff, outcome assessors and data analysers

This is an open-label study comparing acupuncture combined with standard ED management with standard ED management alone. Thus, the blinding of the participants, acupuncture practitioners and other ED staff will not be possible. Blinding of the participants to the study hypothesis (ie, acupuncture plus standard ED management is potentially more effective than standard ED management alone) will be attempted by avoiding descriptions of the direction and magnitude of the effectiveness of the allocated treatments on the information sheet included in the informed consent form. However, we cannot guarantee that such blinding will be helpful in reducing performance bias among the South Korean participants, who are likely to already have cultural familiarity with acupuncture. Owing to the lack of independent outcome assessors for primary outcome measurement due to limited research resources, blinding of the outcome assessors to the primary outcomes will not be possible. However, the outcome assessors who will measure the outcomes will not be involved in the treatment allocation process to reduce any potential performance bias among the patients and outcome assessors.[21] Regarding the 72±12 h telephone follow-up assessments, an independent outcome assessor who will be blinded to the groups will conduct the outcome measurements. Statistical data will be analysed by an independent biostatistician who will also be blinded to the group allocation results.

Acupuncture treatment protocol

Manual stimulation via a penetrating needle acupuncture using a semi-standardised regimen (ie, a set of mandatory acupuncture points plus optional points according to the patient's conditions) will be employed. Electrical stimulation of the acupuncture needles will be added using the electrical needle stimulator (ES-160, Ito, Tokyo, Japan) with a biphasic square wave, alternating low and high frequencies between 2 and 100 Hz and a strong but tolerable intensity at the treating KMD's discretion. The regimen was developed based on a previous literature review[22–24] and the consensus of three experts in Korean medicine and the ED physicians. More detailed components of the acupuncture treatment, in accordance with the revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) recommendation,[25] are described in online supplementary appendix 1.

Standard ED management protocol

A routine protocol for acute pain management was developed by the study ED physicians (table 1). For initial pain management, a non-steroidal anti-inflammatory drug (NSAID) will be injected intravenously (ketorolac tromethamine 30 mg/1 mL) or intramuscularly (diclofenac 90 mg/2 mL) after initial plain radiographs for the confirmation of acute non-specific neck pain, ankle sprain without fracture or non-eligible conditions in patients presenting with moderate to severe pain measuring at least four points on the Wong-Baker pain scale (0–10).[26] In the case of patients with acute headache, the same NSAID injection will be administered as the first-line treatment. If the patient does not achieve adequate pain relief (defined as a remaining pain intensity scoring greater than or equal to four points after the administration of the NSAID injection), an opioid analgesic (pethidine HCl 25 mg/0.5 mL diluted with normal saline 10 mL) will be injected intravenously. If the patient presents with a new onset of severe headache or continues to experience severe headache, brain CT will be performed to exclude the possibility of stroke or other serious neurological conditions such as brain tumour or other pathological brain lesions before the administration of the NSAID injection. A 30 min observation in the ED will be performed unless there is an obvious need for additional rescue medication at the ED physician's discretion.

Use of rescue medication after group allocation

Rescue medication will be selected among two types of opioid analgesics (pethidine HCl 25 mg/0.5 mL diluted with normal saline 10 mL or morphine 3 mg intravenous boluses). Patients with pain that is equal to or more than four points on the Wong-Baker scale after group allocation and after receiving the allocated treatments (ie, acupuncture in the acupuncture group and observation in the standard ED management group) will be considered as a possible case for rescue medication administration. The final decision of administering rescue medicine will be at the discretion of the ED physician.

Table 1 Measurements of patient characteristics and outcomes

	−T1 ED admission	T0 inclusion	T1 treatment/ observation	T2 ED discharge	F1 72 h
Demographic characteristics		X			
Initial physical, laboratory or radiological examination at the ED	X			X	
Wong-Baker pain scale	X				
Standard ED management with 30 min of observation					
NSAID injection (as a first-line treatment for all three conditions)	X				
Ketorolac tromethamine 30 mg/1 ml IV or diclofenac 90 mg/2 mL IM					
Opioid injection (optional for severe headache)	X				
Pethidine HCl 25 mg/0.5 mL diluted with normal saline 10 mL					
Other rescue medication (as needed)	X				
Pethidine HCl 25 mg/0.5 mL diluted with normal saline 10 mL or morphine 3 mg IV boluses			X		
Discharge medication (optional; oral administration)				X	
NSAID (acetaminophen 650 mg, tramadol HCL 37.5 mg/acetaminophen 325 mg or talniflumate 370 mg three times daily for 3 days)					
Muscle relaxants (tisanidine HCL 1 mg three times daily for 3 days)					
Pain NRS		X		X	X
Relative instrument (NDI for neck pain)		X			X
Expectation to the acupuncture treatment		X			
Harms/adverse events			X	X	X
Perceived effectiveness of acupuncture					X
Use of additional healthcare resources					X

ED, emergency department; NSAID; non-steroidal anti-inflammatory drug, IV; intravenous injection, IM; intramuscular injection, NRS; numerical rating scale, NDI; Neck Disability Index.

The rationale of the comparison and the lack of a placebo/sham intervention group

The primary aim of this study is to explore whether acupuncture treatment combined with standard ED management can provide benefits to patients with non-emergent acute musculoskeletal pain and primary headache who do not respond to the standard pain management in an ED setting. Currently, sham or placebo acupuncture is used to assess the net efficacy of the hypothesised specific component of the acupuncture treatment while reducing any possible influence from clinical contexts and other treatment-related processes.[27] With the pragmatic purpose of this study, we decided not to employ a placebo/sham acupuncture as a control group intervention.

OUTCOMES

Primary outcomes

The pain intensity NRS score (ranging from 0, referring to no pain at all, to 10, indicating intolerable and extreme pain) will be measured to assess pain reduction measured at ED discharge in all three conditions.

Secondary outcomes

Subjective pain

The pain intensity NRS score at 72±12 h after ED discharge will be assessed via a phone call as one of the secondary outcomes. The treatment responders will be defined as patients who have experienced at least a 50% reduction in pain intensity from baseline values; these values will be calculated using the pain intensity NRS scores. Differences in the proportion of participants who are classified as treated responders at ED discharge and 72±12 h after ED discharge will be compared between treatment groups.

Pain-related disability (for neck pain)

The participant-perceived reduction in disability due to neck pain will be measured using the Neck Disability Index (NDI) in patients with acute non-specific neck pain. The NDI is a validated 10-item scale for patients with neck pain and disability.[28] Each item is scored between 0 and 5 points, with higher scores indicating worse clinical outcomes, and the summation of the 10-item scores is transformed into percentage scores (ranging from 0 to 100). A validated Korean version of the NDI[28] will be used at 72±12 h after discharge via a phone call.

Patient-reported overall improvement

Patient global assessment is a widely used scale for measuring subjective pain. Patient global assessments of overall treatment outcomes will be measured by a single

item consisting of a five-point Likert-scale question (much improved, somewhat improved, the same as baseline, somewhat worsened or much worsened) to assess the immediate and short-term treatment outcomes in all three conditions. The answers 'much improved' and 'somewhat improved' will be dichotomised as 'improved', and the rest of the answers will be categorised as 'not improved' for the statistical analysis.

Use of healthcare resources

The use of additional rescue medication to relieve pain during the ED stay and the length of stay in the ED (from group allocation to ED discharge) will be measured based on electronic medical charts. The use of additional medication or healthcare resources (such as hospital admissions and outpatient clinic visits) will be measured based on the patients' self-reports via telephone interviews 72±12 h after ED discharge via a phone call.

Adverse events

All expected and unexpected adverse events in both groups will be measured during the allocated intervention process and during the entire study period. The types and frequencies of adverse events will be measured. The adverse events of acupuncture may include bleeding, needling pain, and other discomforts and complications that have been deemed to be related to acupuncture treatments by patients, the study KMDs and the ED staff. Open-ended questions and a checklist of possible adverse events, which were compiled based on literature reviews and our own clinical observations and which have been routinely used in the outpatient acupuncture clinics at our hospital, will be used for the collection of information. The items of a checklist include the following: symptoms aggravated; pain at the needled sites; feel exhausted; dizziness; nausea; bruising (more than 20 mm in diameter); itching; local redness; feeling or generalised hot sensation all over the body and generalised discomfort (other than hot sensation). In addition, whether any procedure-related event (such as needles forgotten on the patient's body and broken needles) occurs in the busy context of the ED will be closely monitored by the study investigators.

Patients' perceived effectiveness of acupuncture treatment

Patients' perceived effectiveness of acupuncture will be measured via telephone follow-up 72±12 h after ED discharge. Perceived effectiveness will be defined as the patients' response to the question 'How much do you agree that the acupuncture treatment that you have received was helpful for your condition?' (very helpful, somewhat helpful, do not know, somewhat unhelpful or very unhelpful). The answers 'very helpful' and 'somewhat helpful' will be dichotomised as 'effective', and the rest of the answers will be categorised as 'not effective' for statistical analysis.

Data management

Research assistants will complete the Case Report Forms (CRFs) with the information required by the protocol. An independent research assistant who remains blinded to the group allocation will enter the data into the Excel spreadsheet after the completion of the trial. Another independent research assistant will enter the data separately. An independent researcher will compare the two data sets to check whether they are entered correctly. When different data entry is identified, data entry will be compared with the original CRF to resolve the inconsistency. All changes to the entered data set will be recorded on the data entry log. Access to the data set file during data entry will be allowed only for specific research assistants and members of a data monitoring committee (DMC). The DMC will consist of two independent researchers (one in research methodology and the other a clinical expert on Korean medicine) who will not be involved in the trial and will regularly monitor patient safety, investigate adverse events and perform quality control assessments of the data. Errors or omissions in the CRFs will be addressed on the data query forms that will be used to request resolution from the researchers. If there is any serious concern with regard to the patient safety, the DMC will terminate the trial. The investigators will convene to discuss practical issues such as protocol revision and any clinical events that may need discussion. There is no plan for regular interim or prespecified interim analysis because we expect this small pilot trial to be of short duration and anticipate a minimal risk of harm to be associated with acupuncture and standard ED management. However, interim analysis will be performed at the request of the committee regarding safety or other important issues raised by the DMC.

Sample size calculation

This is a pilot trial whose exploratory nature does not necessarily require a formal sample size calculation. Thus, the sample size was determined as the minimum number required to achieve the pragmatic purpose of the trial (ie, the collection of information such as aggregate values of the outcome results and their variation, safety data and feasibility-related information necessary for designing a future, full-scale clinical trial).

Statistical data analysis

Statistical analyses of the obtained data will be conducted for two populations: (1) an intention-to-treat population, defined as all randomised participants with a primary outcome assessment at baseline, and (2) a per-protocol population, defined as participants who will complete the final post-treatment primary outcome assessment without major protocol deviations (eg, changing the allocation group). The primary analysis will be an intention-to-treat analysis, whereas a per-protocol assessment will be conducted as a sensitivity analysis. For continuous outcomes, the data will be presented as the

mean and SD (or the median and IQR) according to the normality of the distribution. For dichotomous outcomes, the data will be presented as the frequency. An independent experienced biostatistician who will be blinded to the allocation of the groups will perform the data analysis using the SAS 9.3 software package (SAS Inc, Cary, North Carolina, USA), and the two-sided $p<0.05$ will be regarded as the level of significance with 90% power. Analysis of covariance will be performed using the mean reductions in the pain NRS and the NDI scores (only for patients with neck pain) at ED discharge as the dependent variable, the baseline pain NRS and the baseline NDI scores (only for patients with neck pain) as the covariate and the allocated group as the fixed factor. To investigate the trend of changes in pain and neck function scores within each group, repeated-measure analysis of variance using the pain NRS and the NDI scores as the repeated measures will be performed.

Categorical outcome variables (ie, the perceived effectiveness of acupuncture treatments, patients' expectations of acupuncture treatments and patient global assessment) will be dichotomised according to the predefined criteria and analysed along with other dichotomous variables. These dichotomous variables will be analysed using a χ^2 test or Fisher's exact test. Within-group differences from baseline to ED discharge and 72±12 h follow-up will be analysed by a paired t test or Wilcoxon signed rank test.

Ethics and dissemination

Written informed consent and study approval

Written informed consent will be obtained from each study participant. The participants will be notified at ED discharge that a financial reimbursement of 30 000 Korean won (approximately US $30) for the participants' time will be given to the enrolled participants, regardless of the group allocation results, at the 72±12 h follow-up after ED discharge.

DISCUSSION

This study will be the first randomised controlled trial on the use of acupuncture for acute pain management in the ED setting in South Korea. South Korea is characterised by a dual healthcare system in which the state recognises two legitimate mainstream types of medicine: Western and Eastern (which is also called 'Korean').[16] Whether the two healthcare systems can be integrated in a particular clinical or research context to improve patients' health and improve current medicine has been of great concern in South Korea.[16 29] This study is expected to address the current necessity of collaborative practice between Korean and Western medicine to achieve optimal care in the particular context of the ED. This study also aims to replicate the Australian multicentre study on acupuncture in the ED setting[14] and thus seeks to investigate whether acupuncture is effective, safe and feasible in the context of different ED settings and countries.

Trial status

The trial is currently in the recruitment phase. The first patient was randomised on 8 January 2014. Currently, five patients have been completely enrolled and underwent the trial. We are currently discussing how to overcome the unexpected low recruitment rate. A hand-size card with a call number of the trial coordinator has also been distributed to each ED physician for the purpose of easy trial contact. The expected due date of trial completion is 4 November 2014.

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Contributors KHK, GYY and JHR conceived of the study. KHK, SHN, JHR, GYY, JKK, BRL, YIK, MRP, MKM, YMP and JYC initiated the study design and YRK, YIK, MRP, MKM and YMP helped with its implementation. MJK and YJK served as clinical research assistants and KHK drafted the study protocol manuscript. All authors contributed to the refinement of the study protocol and approved the final manuscript.

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Competing interests None.

Patient consent Obtained.

Ethics approval The study was approved by the Institutional Review Boards (IRBs) of both Pusan National University Korean Medicine Hospital (IRB approval number 2013019) and Pusan National University Yangsan Hospital (IRB approval number 03-2013-012).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement We will share the data after the trial is finished. Raw data will be available by an author contact after the completion of the trial.

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