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Adjunctive acupuncture for pain and symptom management in the inpatient setting: Protocol for a pilot hybrid effectiveness-implementation study

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Abstract

Background—Effective pain management among hospitalized patients is an important aspect of providing quality care and achieving optimal clinical outcomes and patient satisfaction. Common pharmacologic approaches for pain, though effective, have serious side effects and are not appropriate for all inpatients. Findings from randomized controlled trials (RCTs) support the efficacy of acupuncture for many symptoms relevant to inpatients including postoperative pain, cancer-related pain, nausea and vomiting, and withdrawal from narcotic use. However, the extent to which findings from RCTs translate to real-world implementation of acupuncture in typical hospital settings is unknown.

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Methods/Design—In partnership with the launch of a clinical program offering acupuncture services to inpatients at the University of California, San Francisco's Mount Zion Hospital, we are conducting a pilot study using a hybrid effectiveness-implementation design to: (1) assess the effectiveness of acupuncture to manage pain and other symptoms and improve patient satisfaction; and (2) evaluate the barriers and facilitators to implementing an on-going acupuncture service for inpatients. During a 2-month pre-randomization phase, we evaluated and adapted clinical scheduling and treatment protocols with acupuncturists and hospital providers and pretested study procedures including enrollment, consent, and data collection. During a 6-month randomization phase, we used a two-tiered consent process in which inpatients were first consented into a study of symptom management, randomized to be offered acupuncture, and consented for acupuncture if they accepted. We are also conducting in-depth interviews and focus groups to assess evidence, context, and facilitators of key provider and hospital administration stakeholders.

Discussion—Effectiveness research in 'real-world' practice settings is needed to inform clinical decision-making and guide implementation of evidence-based acupuncture practices. To successfully provide clinical acupuncture services and maintain a rigorous research design, practice-based trials of acupuncture require careful planning and attention to setting-specific, contextual factors.

Trial Registration—This trial has been registered in ClinicalTrials.gov. The identifier is NCT01988194, registered on November 5, 2013.

Keywords

acupuncture; integrative medicine; inpatients; effectiveness trial; hybrid trial; implementation research

Background

Pain is highly prevalent and difficult to manage among hospitalized patients: 80% of surgical patients and 53–60% of non-surgical, general medicine patients experience pain during their hospital stay; less than half report adequate pain relief[1–4]. Unrelieved pain can lead to a range of negative consequences including patient discomfort, greater morbidity, poor patient satisfaction, longer recovery times from surgery, and high risk of developing chronic pain[1]. Opioid medications are among the most effective and widely prescribed treatments for pain but associated side effects and complications are well known[5]. Pain management among general medicine patients presents unique clinical challenges because opioids and epidural analgesia used in surgical settings are often inappropriate for chronic pain or for complex patients[3]. Safe, effective pain management is needed to achieve optimal clinical care for hospitalized patients. Non-pharmacologic approaches, such as acupuncture, may alleviate pain with fewer side effects and adverse reactions than commonly used opioid analgesics.

Findings from randomized controlled trials (RCTs) indicate the efficacy of acupuncture for a range of pain conditions including chronic, surgical, and cancer-related pain[6–9]. A meta-analysis of 17,922 individuals from 29 RCTs found that patients receiving acupuncture had significantly less pain than patients receiving no acupuncture (effect sizes from 0.42 to 0.57) or sham acupuncture (effect sizes from 0.15 to 0.23) for back and neck pain, chronic

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headache, and osteoarthritis[10]. Acupuncture as an effective treatment for post-operative pain has been well established with multiple RCTs[11–14], including a 2008 systematic review indicating that acupuncture reduces pain intensity, opioid consumption and opioid-associated side effects[7]. Studies of post-operative pain in cancer patients also favor acupuncture[6, 15], although a recent Cochrane review was unable to draw conclusions based on the quality of evidence from prior trials[16]. Many RCTs also show strong evidence that acupuncture effectively treats chemotherapy-induced and postoperative nausea and vomiting[17–21].

Nearly 400 hospitals in the United States offer complementary and integrative health approaches, including 42 programs of acupuncture for inpatient services[22]. Rigorous evaluations of the effectiveness of such programs are sparse and inconclusive[23, 24]. An observational study of 1837 hospitalized patients receiving integrative medicine (e.g., acupuncture, acupressure, massage therapy, or reflexology) found an overall 56% reduction in pain (average decrease of 1.9 points on an 11-point scale)[23], but did not include a comparison group. Similarly, a large scale retrospective study of nearly 11,000 oncology-related hospital admissions found that cancer inpatients receiving integrative medicine had a 47% reduction in pain and a 56% reduction in anxiety, and acupuncture was one of the most effective therapies[25]. In an RCT of inpatients receiving usual care with and without acupuncture, Painovich et al. found high acceptability of acupuncture but no significant difference in length of stay[24]. Despite strong evidence of acupuncture's efficacy for pain management[7, 10], and high acceptability of acupuncture among inpatients[24], the therapeutic advantage of adding acupuncture to routine care for hospitalized patients is unclear.

Explanatory RCTs are designed to estimate efficacy of an intervention under highly controlled conditions. While useful for addressing cause and effect under ideal circumstances, findings from these studies are often not broadly applicable because of relatively homogenous study participants, highly standardized interventions, and comparator conditions that may not be meaningful in clinical practice. To inform clinical decision making about acupuncture, rigorously conducted trials that are representative of actual routine clinical care are needed[26]. In addition, to bolster the clinical value of research, hybrid designs that combine effectiveness and implementation research are recommended.

To address this gap in the literature, we are conducting a pilot study to prepare for a large-scale practical clinical trial to test the effectiveness of acupuncture among inpatients. Our primary objective is to assess the effectiveness of adjunctive acupuncture for pain and symptom management compared with usual care. Our secondary objective is to identify potential barriers and facilitators to implementing a sustainable acupuncture service in the context of inpatient care.

Methods/Design

Overall Study Design

In conjunction with the launch of clinical acupuncture services for inpatients at a university hospital, we sought to rigorously evaluate the effectiveness and implementation of

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acupuncture in a high volume clinical setting. We therefore chose a Hybrid Type 1 design, defined as "testing a clinical intervention while gathering information on its delivery during the effectiveness trial and/or on its potential for implementation in a real-world situation"[27]. A Hybrid Type 1 design is indicated when the clinical intervention is safe, has strong face validity and a strong evidence base that support applications in the populations of focus, and minimal associated risks[27]. Given the growth of hospital-based acupuncture services[22, 28], the inclusion of acupuncture in clinical guidelines for pain management[29–31], and the low risks associated with acupuncture[32–34], the evidence base and safety profile of acupuncture support the use of a Hybrid Type 1 design.

To assess whether providing acupuncture along with routine inpatient care improves pain and symptom management compared with routine care alone, we are conducting an exploratory, randomized controlled trial of acupuncture services among inpatients using a parallel group design with participants randomized to usual care alone or usual care with adjunctive acupuncture. We conducted (1) a pre-trial phase to refine implementation of clinical acupuncture services and to pilot and finalize study procedures with minimal impact on clinic flow and (2) a pilot effectiveness RCT.

To assess barriers and facilitators of providing a sustainable acupuncture service, we are collecting qualitative data through one-on-one interviews and focus groups of providers and hospital leadership. The University of California San Francisco, Committee on Human Research (institutional review board) reviewed and approved all study procedures and modifications. The study is registered in ClinicalTrials.gov with the identifier NCT01988194.

Objective #1: Assess the effectiveness of adjunctive acupuncture for pain and symptom management compared with usual care

Study setting: We are conducting a pilot effectiveness study for objective 1 at the University of California, San Francisco's Mount Zion Hospital, an urban academic hospital in the United States with 90-beds and specialty care including internal medicine; gastrointestinal; gyno-, ortho- and uro-oncology; headache; orthopedics; pain; radiation; tracheostomy. Inpatient wards at Mount Zion Hospital are usually at 75–80% capacity, with approximately 70 patients on any given day and an average length of stay of nine days. For logistical feasibility, we launched our study focusing primarily on the surgical oncology ward and expanded to include the medicine and breast cancer wards as capacity allowed.

Study population: Consistent with the design of an effectiveness trial, inclusion criteria were intentionally broad to reflect the heterogeneity of clinical practice. Eligible participants were: admitted to Mount Zion Hospital for an anticipated length of stay of at least 48 hours, 18 years of age or older, English-speaking, and under the care of a surgical or medical team that had given prior approval for their patients to receive acupuncture treatments. Exclusion criteria included: contraindication to acupuncture (e.g., sepsis or endocarditis); inability to consent (e.g., cognitive or communication impairment); knowledge of the study (e.g., hospital readmission with prior study participation); or unstable medical condition (e.g.,

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myocardial infarction, patients in the intensive care unit, severe depression, severe pulmonary disease).

Study procedures: Phase I of our study included a pre-randomization run-in period over two months to finalize study procedures. The run-in phase allowed us to introduce acupuncture services to the hospital staff; develop our systems for identifying new admissions, screening for eligibility, establishing work flow for acupuncturists; and establish rapport with patient care managers, nurses, and hospitalists. This phase also allowed us to accurately estimate how many inpatients at Mount Zion Hospital would be interested in acupuncture, to identify reasons for lack of interest, and to improve our approach to offering and explaining acupuncture. We also consented a small subsample of patients to pilot study instruments, assess administration time, and identify data collection challenges.

After the two-month run-in phase, Phase II of the study was a pilot effectiveness RCT with the following procedures.

1. *Identification, Recruitment, and Consent of Participants*. To determine initial eligibility, research staff reviewed the electronic medical records of newly admitted patients and conferred with the ward's charge nurse regarding the inclusion/exclusion criteria described above. All patients who met initial eligibility criteria were asked if they were interested in participating in a study of symptom management with a stated purpose of learning more about the management of pain and other symptoms in the hospital and patient satisfaction with care. Participants were consented and enrolled in the study on postoperative day 1 for surgical patients or on hospital day 2 for non-surgical patients. As an incentive, study participants were entered into a raffle to win one of three Amazon.com gift certificates for $75. A research coordinator trained in human subjects protection obtained informed consent from interested patients to participate in data collection for the study and to grant permission to access their records. A total of 237 participants were recruited from the inpatient wards at Mount Zion Hospital at the UCSF Medical Center in San Francisco from December 2013 to August 2014. Wards of primary focus included surgical oncology, medicine, and breast cancer.

2. *Randomization and Blinding.* We used Zelen's design, a two-tiered consent process in which only study participants randomized to the experimental condition are asked to consent to treatment[35]. This allowed us to maintain some level of blinding and to minimize disappointment bias among patients in the treatment as usual group. Participants who consented to the study of symptom management responded to a series of questions about their level of interest in different types of complementary and integrative health therapies, such as massage, guided imagery, acupuncture, and nutritional counseling if available during their hospital stay[36]. Those that indicated at least a minimal interest in receiving

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acupuncture were randomized either to usual care or to be offered acupuncture treatments in a 1:1 ratio.

A randomization table with random block sizes of two or four were constructed using a Python script. The data manager for the study (JC) programmed the study's database system to assign condition sequentially through the randomization table records using Microsoft Access 2010 (Microsoft Corporation, Redmond, WA, USA). Research coordinators consenting participants were blind to the randomization sequence. Participants randomized to treatment as usual were blinded to the existence of acupuncture in the study. Those who were offered acupuncture and accepted were then voluntarily consented to receive acupuncture treatments. Participants who were offered acupuncture but declined received usual care (*see* Figure 1).

3. *Data collection*. Consented participants completed surveys about their symptoms during their hospital stay at baseline, four daily follow-ups, and an exit interview on the day of hospital discharge or over the telephone within two weeks of discharge. Participants in the acupuncture group completed additional questionnaires specific to their experience with acupuncture (see Table 1). Trained study staff administered surveys using a tablet computer. Study data were collected and managed using Research Electronic Data Capture (REDCap) [37], hosted at the University of California, San Francisco. REDCap is a secure, web-based application designed to support quality data collection for research studies, providing validated data entry, audit trails for tracking data changes, and automated export procedures to common statistical packages[37]. Since inpatient schedules are unpredictable, we offered participants three options for data collection: (1) via iPad with the research coordinator, (2) via a self-administered paper-based survey, or (3) via a link sent to their smartphone.

Intervention

Acupuncture treatment: As this study is 'piggybacking' on a clinical program, we used protocol guidelines consistent with a pragmatic study design [38]. The study team opted not to use standardized acupuncture protocols with prescribed point selection. Rather, acupuncturists had flexibility in determining treatment plans and provided care typical of clinical practice. Two licensed acupuncturists (JA, MT) from the UCSF Osher Center for Integrative Medicine provided acupuncture services to inpatients. Each acupuncturist has more than 20 years of experience as a traditional Chinese medicine (TCM) practitioner and has worked in an integrative medicine setting for over 10 years. Practitioners diagnosed participants according to principles of TCM, including a physical examination with tongue and pulse diagnosis. Acupuncture treatments were individualized to the participants. Treatments were performed with sterile, disposable acupuncture needles (0.16 × 30 mm, 0.18 × 30 mm, and 0.20 × 40 mm, Seirin, Shizuoka, Japan) after the acupuncture points were sterilized with a disposable 70% isopropyl alcohol pad. Acupuncturists inserted needles at a depth of approximately 1–2 mm and manually manipulated needles with a

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twisting motion to achieve a propagating sensation along the channel (referred to in TCM as *de qi* sensation). Needles were left in place for approximately 30 minutes. During the treatments, participants were encouraged to lie on their hospital beds in a comfortable position, and practitioners remained at the participant's bedside throughout the treatment. Practitioners reviewed the participants' electronic medical records before each treatment for information about type of surgery, reason for hospitalization, and relevant updates. Details of acupuncture treatments (e.g., frequency and duration, TCM diagnosis, needles and points used) were documented in standard charting used by the Osher Center for Integrative Medicine.

Scheduling of acupuncture treatments: Day-to-day management of the acupuncture schedule was based on priorities of ensuring that participants in the research study received treatments, providing the maximum amount of clinical care available through the acupuncturists, and accommodating clinical referrals from providers. Acupuncture treatments were offered to participants in the following order: (1) participants newly randomized to the acupuncture group, (2) participants who had been randomized to the acupuncture group, declined treatments, and then changed their minds, (3) on-going participants in the acupuncture group receiving a follow-up treatment, and (4) patients receiving acupuncture as a clinical service not part of the study. Acupuncture treatments were provided four afternoons per week. New study participants were allotted one hour per treatment, while on-going study participants and patients receiving acupuncture off-study were allotted 45 minutes per treatment. Study participants received a maximum of four acupuncture treatments, after which point they were only offered additional treatments if there was room on the schedule. Patients receiving acupuncture off-study included those who were ineligible for the study based on the inclusion/exclusion criteria, those who had requested to leave the study but still wanted acupuncture treatments, or those referred by their providers in other wards. Patients could refuse acupuncture treatment at any point.

Treatment as usual: All study participants who did not receive acupuncture received the usual care under the guidance of their surgical or medical teams. The research coordinators did not give educational materials or symptom management advice to the participants. All patients in the usual care group did not receive any additional treatments beyond routine care. No changes were made to the participants' medication regimens.

We chose usual care as our control group to address our primary question of whether adding adjunctive acupuncture to routine pain management would improve pain and symptom management. However, changes in usual care during the course of the study are important to consider [39]. For instance, during our study, certain surgical teams implemented a "fast track" protocol [40] for their patients, a quality improvement initiative which encouraged rapid recovery and early discharge from the hospital using a multimodal care plan that included physical activity and pain control. We considered whether we should exclude 'fast track' patients from our study because of potential bias from co-interventions. We decided not exclude these patients based on the rationale that 'fast track' was part of usual care at the time and because using randomization procedures would help balance 'fast track' patients between groups.

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Co-interventions: Participants in all of the groups were allowed to use any modalities or medications for the treatment of pain and other symptoms as prescribed by their surgical or medical teams, such as intravenous opioids and anti-emetics or epidural opioids. We did not impose any co-interventions in the study.

Outcome Measures: To test the hypotheses that compared to usual care, adjunctive acupuncture improves pain managment and other symptoms among hospitalized patients, we assessed core outcome domains recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)[41, 42] delineated below.

Participants' worst, least, and average daily pain intensity scores were measured on a numeric rating scale ranging from 0 to 10 assessed in the late morning for up to five days during the participants' hospital stay (baseline and four follow up days). As recommended by Shi et al.[43], our primary outcome is *worst* pain over the past 24 hours. For a comprehensive assessment of patients' pain, we administered the revised American Pain Society's Patient Outcome Questionnaire[44], which measures pain severity and relief; impact of pain on activity, sleep, and negative emotions; side effects of treatment; helpfulness of information about pain treatment; and ability to participate in pain treatment decisions. We used the single item Patient Global Impression of Change scale on the last hospital day to assess minimal clinically important difference in changes in participants' pain[45].

- The following secondary outcome measures were also collected: functionality and health-related quality of life through the EQ-5D[46]; a brief nausea and vomiting impact scale[47]; most bothersome symptoms using the Measure Yourself Medical Outcome Profile[48]; sleep quality[49]; and the Profile of Moods State short form[50].
- Clinical data, such as primary and secondary diagnoses, use of medications, and length of stay, will be obtained from participants' medical record.
- Socio-demographic variables (age, gender, race/ethnicity, place of birth, level of education, household income, marital status, employment status, and health insurance status) were collected at baseline.
- Patients' satisfaction was assessed during the final survey using an adapted version of Pain Treatment Satisfaction Scale[51], which includes subscales of satisfaction with pain treatment in terms of information, medical care, effectiveness, and side effects. Experiences with study participation and satisfaction with acupuncture treatments were also collected in the final survey.

Statistical Analyses

Sample size—With 80 in each group, our sample size is sufficient for analysis of change in pain scores with a mean difference of 1.0 (SD = 2.2) between groups at alpha = 0.05 and 81.5% power. Although our total sample size is larger than typical pilots, an important

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purpose of this study is to demonstrate recruitment feasibility for a future pragmatic study requiring a large n to account for patient heterogeneity.

Baseline characteristics of participants, including sociodemographics and health condition variables, in each arm will be compared to assess group equivalency and sample generalizability. We will also assess the number of study participants in the 'fast track' quality improvement initiative and the distribution of these patients between groups. Descriptive means will be calculated for continuous variables such as age. For categorical measures, proportion of each category will be calculated and assessed by exact statistical methods.

The primary outcome of interest, change in daily worst pain intensity, will be analyzed for participants with at least one follow-up assessment. Repeated measures for daily pain will be assessed using mixed-effects regression analyses controlling for significant baseline characteristics. As a practical clinical trial, our primary analysis of interest is based on patients' as-treated status, comparing randomized participants who received at least one acupuncture treatment with those who did not receive any acupuncture treatments. Outcomes analysis based on intent-to-treat will also be conducted comparing participants randomized to treatment as usual with those randomized to acupuncture regardless of actual number of treatments received. Subgroup analyses will be performed for surgical vs. non-surgical patients and condition-specific comparisons. Secondary pain and quality of life outcomes will be analyzed similarly to the primary outcome.

Objective #2: Understand Barriers and Facilitators of Acupuncture Implementation

Study design: We are conducting a qualitative study using face-to-face structured interviews and focus groups to examine stakeholder perspectives on the barriers and facilitators to acupuncture implementation into routine inpatient clinical care. This methodology was utilized because the incorporation of integrated care into routine clinical practice has received little attention and has not been explored fully.

Study setting and participants: The qualitative component of the study is taking place across the University of California San Francisco (UCSF), an urban academic quaternary care health system. UCSF has three main hospital facilities with almost 900-beds and 38,000 admission annually. Through nominated expert sampling[52], we are identifying key informants that represent different roles in our organization (e.g. administrative leadership, clinical leadership, attending MD, nursing and non-physician staff). We chose this sampling strategy to capture a diverse range of views and to ensure all stakeholders involved in the delivery of inpatient care are represented. Once potential participants are identified, we will recruit them to take part in an interview or focus groups via email. Focus groups will include the recommended number of 8–10 participants each[53]. We anticipate a sample size of up to 18 participants to achieve data saturation[54].

Data collection: The Promotion Action on Research Implementation in Health Services framework[55, 56] will guide interviews and focus groups. Our interview guide explores three primary domains of barriers and facilitators of acupuncture implementation evidence,

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context, and facilitation (see supplementary materials). Questions related to evidence refer to both formal and informal types of knowledge such as research, clinical experience, preferences and personal experiences. Questions related to context explore the quality of the environment, or setting, for implementation including organizational culture, leadership, and feedback mechanisms. Facilitation questions focus on mechanisms that can promote or hinder successful implementation. For each domain, participants will be asked a series of questions. Further probes will be used to draw out greater detail depending on responses. All focus groups and interviews will be audiotaped and professionally transcribed.

Data analysis: Prior to analysis, the transcripts of focus groups and interviews will be de-identified for confidentiality and to limit analytical bias among researchers[57]. We will then conduct content analysis to systematically examine the data in order to obtain a condensed description of content[58, 59]. Two reviewers independently will complete open coding using a data-driven (inductive) approach to identify initial coding categories. A data-driven coding approach will guide analysis to identify new categories from the transcripts[58] related to the implementation of inpatient acupuncture. Reviewers will meet regularly to discuss coding with disparities resolved by negotiated consensus[60]. Categories will then be grouped under high order headings (themes) if appropriate[58, 59].

Trial status

Patient recruitment for the pilot effectiveness trial is complete. Data extraction from electronic medical records is in process; except for interim analysis, data cleaning and analysis have not yet begun. Qualitative interviews of providers are in process.

Discussion

The use of acupuncture is rising in the United States and is increasingly offered in conventional healthcare settings. Our study approach evaluates acupuncture clinical practice using a pragmatic effectiveness framework[61–64] and has the potential to contribute to implementation and dissemination of evidence-based acupuncture practices. Research of acupuncture in an actual inpatient setting allows us to prioritize generating evidence for clinical decision-making. However, conducting a practice-based trial involves challenges with implementing a new clinical service, balancing clinical and research priorities, and adapting to a complex setting not designed for research. Here we highlight key approaches to implementing clinical acupuncture services and issues with maintaining a rigorous research design.

Educating hospital staff about acupuncture

Educating staff about acupuncture was important for successful integration into inpatient care. We reviewed indications for acupuncture patient referrals (e.g., pain, anxiety, insomnia, and challenging overall symptom management) to foster appreciation of acupuncturists as part of the care team and to prepare for inpatient services beyond the study. We also provided staff and patients with an informational sheet that described acupuncture and a typical treatment, summarized current evidence with literature references, and included contact and pager information for the service.

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To streamline delivery of acupuncture without interrupting standard care, we consulted with nursing staff to learn about existing hospital workflows. Our team worked with nursing staff to determine optimal timing of acupuncture sessions and learned in the pre-randomization phase how to adapt to interruptions, which are common during hospital care. Acupuncture scheduling was conducted in the afternoon hours to avoid most routine and scheduled procedures. However family visitors in addition to social worker and chaplain services are more erratic in nature thus causing unintended interruptions.

Training acupuncturists about hospital culture and inpatient care

As unfamiliar as the inpatient staff was with acupuncture, we found that our acupuncturists were similarly unfamiliar with the hospital and inpatient culture. Training of acupuncturists included discussions of hospital inter-team dynamics, hospital schedules, and workflow, like peak hours of nursing demand. Acupuncturists reviewed standard hospital room equipment, indications to contact nursing staff for assistance, standard alarms, and standard inpatient hand hygiene and universal precautions, including safety protocols for researchers and acupuncturists. As TCM terminology differs significantly from standard hospital documentation, we focused on best practices for inpatient charting with acupuncturists to ensure optimal communication with the primary team.

Beyond the logistics of creating a new service for this study, providing acupuncturists with context and setting appropriate expectations about the patient population was important. The high mortality, surgical site exposure, and severity of disease index among hospitalized patients were a contrast from general outpatient acupuncture practices. We regularly held sessions for the acupuncture team to debrief about patients who died or were expected to die during the study and to create an open forum to discuss challenges with inpatient care.

Implementing randomization and blinding

During our outreach to physicians, nurses and other staff to facilitate garner support for the study, we used enthusiasm for non-pharmacologic interventions coupled with success in challenging patients with unmet needs to ensure continued provider support. Nursing staff came to know our study staff as the acupuncture team. At times, staff interest in acupuncture as a modality to help their patients would inadvertently ‘unblind’ patients and make them ineligible for the study. We continued education efforts with staff to keep their support and interest, without compromising the study design.

Data collection challenges

To minimize participant burden and to reduce the impact of survey administration amidst clinical procedures, we planned to extract as much data as possible from existing sources such as the electronic medical records (EMR). However EMR data are not collected with the same consistency or quality as data collected for research purposes. For instance, level of pain intensity is routinely collected using a 11-point numeric rating scale as the fifth vital sign. However, if a data time point is missed, pain intensity may be recorded in the EMR as zero, without clarity about whether this is missing data or if the patient had no pain. Other EMR data on patient symptoms and medication use can be inaccurate or difficult to extract in an analytically useful form. We used anticipated length of stay to pre-screen potentially

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eligible patients but found that this information was often missing or would vary considerably from actual length of stay. We also planned to use the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAPHS) as a widely accepted measure of patient satisfaction. HCAPHS surveys are routinely mailed to all inpatients after discharge and collect data on patient perspectives on communication with providers, pain management, and the hospital environment. However, using HCAPHS data for research purposes is not permissible. We collected our own data specific to study needs for daily pain, patient satisfaction, and other measures to ensure that we obtained quality data.

In addition to structural challenges to data collection, day-to-day technical obstacles arose. Researcher coordinators experienced numerous interruptions during the enrollment, consent, and daily data collection processes. These included patients' unpredictable sleep schedules, varying symptom severity, and visitors affecting patients' availability for research procedures.

Extrinsic factors pertinent to the conduct of a practice-based trial

Perhaps more so than in traditional RCTs, many factors independent of the study affected patients' participation in and behaviors during our practical clinical trial. For instance, we found that family members and visitors are actively involved with patient decision-making and often want to be consulted. Having materials and contact information for patients' caregivers helped assuage concerns and facilitated understanding about acupuncture research. Once enrolled, participants' assessments sometimes happened with family members present. While this usually did not pose any impediments, feedback from research assistants suggested that patients were at times not as forthcoming, were somewhat distracted by presence of family and visitors, or tried to hurry through the assessment so that their visitors were not kept waiting. During the recruitment process, we also found that a broad range of care providers regularly interact with patients and that provider validation greatly influenced patient buy-in. Prior to the study we had ensured that all attending MDs and nursing staff were aware of our study and had sought approval to include their patients. We found that establishing relationships and outreach to social workers, physical therapists, chaplains, patient care assistants, among others, was also critical to the success of our study.

Conclusion

Effectiveness research in 'real-world' practice settings is needed to inform clinical decision-making and guide implementation of evidence-based acupuncture practices. To successfully provide clinical acupuncture services and maintain a rigorous research design, practice-based trials of acupuncture require careful planning and attention to setting-specific, contextual factors.

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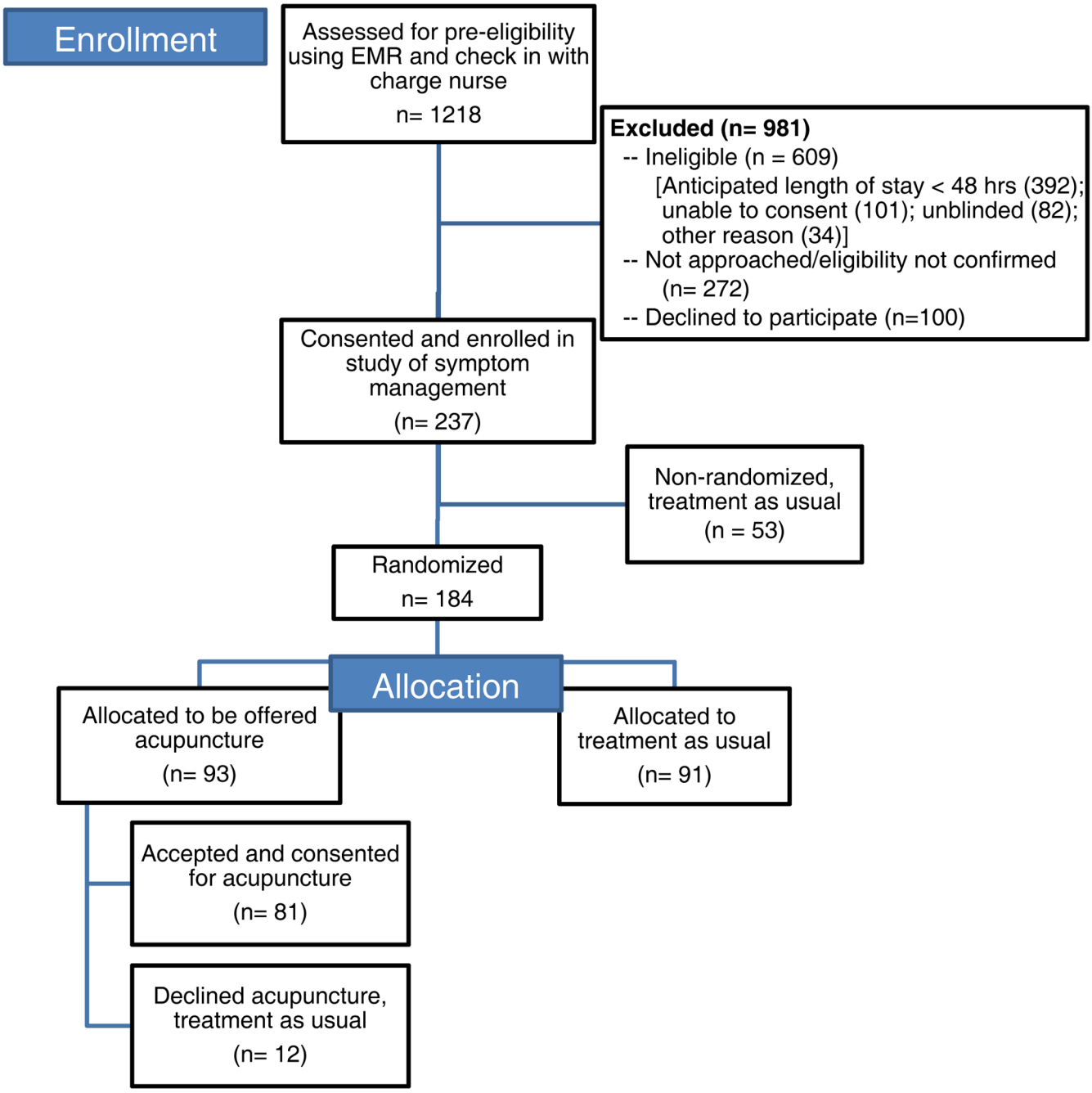

Figure 1.
Participant flow chart

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Table 1

Schedule of study procedures and data collection

Day in hospital	**1**	**2**	**3**	**4**	**5+**
Study procedures					
Inclusion/exclusion criteria	●				
Informed consent	●				
Random allocation	●				
Acupuncture treatment	○	○	○	○	
Data collection measures					
Demographic characteristics	●				
Complementary and integrative health survey	●				
Pain intensity	●	●	●	●	
Impact of pain	●	●	●	●	
Nausea and vomiting	●	●	●	●	
Patient-reported symptoms	●	●	●	●	
Sleep disturbance	●	●	●	●	
Profile of moods	●	●	●	●	
Health-related quality of life	●	●	●	●	
Global impression of change					●
Pain treatment satisfaction					●
Exit interview					●

● All participants, ○ Acupuncture group only