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Acupuncture for Cancer Related Pain: Protocol for a Pragmatic Randomised Wait-List Controlled Trial

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Abstract

Background: Acupuncture has been proved effective for cancer related pain (CRP) in China, America and some other countries. However, there is relative lack of evidence to support the use of acupuncture for CRP in Australia. **Objectives:** To assess the effectiveness and safety of acupuncture for management of CRP in a real-world setting and to understand cancer patients' experience of undergoing acupuncture for CRP. **Methods:** A pragmatic randomised controlled trial will be conducted in South Western Sydney Local Health District (SWSLHD) in NSW, Australia. Adults with cancer related pain (n = 106) will be randomised in a 1:1 ratio to receive the acupuncture intervention up front versus after a wait list period of 4 weeks. Pain level (by Numerical Rating Scale), analgesic use, auricular acupressure frequency and adverse events will be assessed at baseline, mid-treatment and post-treatment. Expectancy on trial outcome (by Credibility and Expectancy questionnaire) will be assessed at baseline. The perspective of the participants (by an interview) will be recorded after the last intervention. **Expected outcomes:** We hypothesise that acupuncture will relieve cancer related pain at mid-treatment and post-treatment. We also hypothesise that few adverse events will be provoked by acupuncture. **Trial registration:** Australia New-Zealand Clinical Trial Registry (ACTRN12620000325909).

Keywords

acupuncture, cancer related pain, pragmatic, clinical trial, complementary and alternative medicine

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Introduction

Cancer-related pain (CRP), pain due to cancer and/or cancer related treatment, is one of the most common and distressing symptoms of cancer. It can present at any stage, including during long-term survivorship.[1] It is experienced by 50.7% of cancer patients and by as much as 66.4% in advanced stage cancer patients.[2] CRP detrimentally impacts Quality of Life (QoL)[3] by causing emotional distress,[4] limiting mobility and increasing the risk of developing depression.[5] The combined effect of CRP and depression can further decrease QoL, as well as adversely impact cancer survivors' ability to return to work and engage in normal daily functioning.[6]

It was found that effective pain management might help improve the survival rate of cancer patients after oncologic surgery.[7] The 3-step ladder proposed by World Health Organisation (WHO) is the mainstay of CRP management.[8,9] Although it is effective in a large number of people with cancer pain, there still remains a group who either don't recieve ideal therapy or on ideal therapy have unrelieved

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pain.[10,11] It has been reported that treatment is insufficient in 42% of cases[12] and that up to 70% of cancer patients treated with analgesics still experience substantial levels of pain.[13] In addition, stronger analgesics are not without risk of side-effects,[14,15] and non-pharmacological mechanisms, including acupuncture, are increasingly being evaluated in cancer pain management to contribute to a multimodal pain management plan aiming to enhance overall pain control with optimal adverse event profile.[16]

Acupuncture is a Chinese Medicine therapy that involves the use of needles inserted into specific points on the skin.[17] There are several different forms of acupuncture, including traditional body acupuncture, electroacupuncture, microsystem acupuncture (such as auricular acupuncture and scalp acupuncture), acupressure and moxibustion.[18] Evidence supports the role of acupuncture within cancer care demonstrating effectiveness in controlling some cancer-related symptoms, good safety profile and its popularity amongst patients.[19-22] Acupuncture is recommended for cancer pain in the National Comprehensive Cancer Network (NCCN) guidelines[23] and the American Society of Clinical Oncology (ASCO) practice guidelines.[24] Implementation of acupuncture within hospitals as a prominent therapy offered as part of integrative oncology programs is an increasing trend in cancer care in developed Western countries worldwide.[25-27] In a 2013 European survey of integrative oncology, acupuncture (55%) was most commonly provided in integrative oncology centres in Europe for supportive care.[28] Despite having a foundation of scientific evidence from China, America and other countries, there is relative lack of evidence to support the use of acupuncture for CRP in Australia.

The primary objective of this study is to assess the effectiveness and safety of acupuncture for management of CRP in a real-world setting. The secondary objective of the study is to understand cancer patients' experience of undergoing acupuncture for CRP.

Methods

Study Setting and Design

The trial will be conducted at South Western Sydney Local Health District (SWSLHD) in NSW, Australia. Screening and recruitment will be conducted in English. Non-English-speaking eligible participants will be screened and recruited via a hospital-based translation service.

This study is designed as a pragmatic randomised controlled trial that compares real acupuncture to a wait-list group with a 1:1 allocation ratio. Wait-list control design is a variation of crossover design, examining interventions that are much more attractive than a control such as a no-treatment and too complex or obvious to be blinded to participants.[29-35] It is often selected to measure effectiveness and safety, especially the benefit the intervention produces in routine clinical practice, to show the real-world practice.

In wait-list control acupuncture trials, a wait-list control is employed as the control instead of sham acupuncture because a "limbic touch" response caused by sham acupuncture results in emotional and hormonal reactions,[36] which may give rise to therapeutic effect and rendering the control invalid. Participants are assigned to either acupuncture intervention group or wait-list control group, where the observation period is employed as the control.

Wait-list control design is more ethical than no-treatment control and may recruit more eligible participants by reducing the number of those who declined participating because of a potentially unfair opportunity to benefit or to be exposed to risk.[37]

A well-designed pragmatic design is used in this trial because it will produce results that can be generalised and applied in routine practice settings,[38] we believe this is an appropriate design to best meet the objectives of this study.

Eligibility Criteria

Inclusion criteria

- Age 18 years old or older.
- A diagnosed CRP either due to cancer or cancer related treatment by a medical doctor, regardless of the cancer type, stage or the presence of metastasis. Included types of pain: somatic nociceptive pain, visceral nociceptive pain, neuropathic pain and mixed types of pain.
- Pain Numerical Rating Scale (NRS) score >3 on a 10 point scale.
- Estimated survival time>12 weeks.
- Cognitive ability to give written informed consent.

Exclusion criteria

- Presence of skin infection that potentially interferes with the needling (intervention) area.
- Presence of significant thrombocytopenia (platelet count $< 100 \times 10^9$/L),[39] fever[40] or active infection.[41]
- Inability to remain supine position and prone position for 20 minutes each continuously, given the nature of the acupuncture intervention.
- Pregnancy.[42]

Interventions

Participants in both groups will receive the acupuncture intervention but randomised to receive the intervention up front versus after a wait list period of 4 weeks. They are not permitted to receive any types of acupuncture treatment other than the study intervention during the trial period. The design of the acupuncture intervention is in compliance with the Standard for Reporting Interventions in Clinical

Trials of Acupuncture (STRICTA).[43] The acupuncturist is registered for acupuncture practice in Australia (AHPRA Registration).

Points selection. The points include body acupuncture points and auricular points. The body acupuncture points are the most commonly used for cancer pain,[44] that is, Zusanli (ST36)—bilaterally located on the lower limb, Hegu (LI4)—bilaterally located on the hand, Sanyinjiao (SP6)—bilaterally located on the lower leg, and Neiguan (P6)—bilaterally located on the forearm.

Bilateral back-shu points will be also used, which will be selected in correspondence with affected organ(s) if solid tumour is involved; otherwise, points will be determined based on Chinese medicine diagnosis.

The auricular points include Shenmen, the subcortical point, the sympathetic point. One side of the ear will be used alternately at each visit during the course of the intervention.

Procedure. The patient first assumes the supine position on a massage table with the needling area exposed and receives acupuncture on their limbs, with needle retention for 20 minutes. The acupuncture points (ST36, SP6, P6, and LI4) will be punctured with 0.25×40 mm stainless steel needles using the one-hand insertion method. The needle will be inserted into the skin surface with a depth of 5 to 20 mm depending on the acupoint. Lifting and twisting techniques will be used for these points until the participant can feel the needle sensation (ie, "Deqi," a sensation of soreness, numbness, distention or heaviness around the needle). After the needle is removed, the patient assumes the prone position, and receives acupuncture their back, with needle retention for 20 minutes. Back-shu points will be punctured with 0.25×25 mm stainless steel needles without performing any needling manipulations. After the body acupuncture, ear seeds manufactured by Earseed USA will be applied to the auricular points and pressed until the ear becomes red and hot. The pressure seeds sit on a sticky bandage and will remain on the ear for 3 days. The participant will be asked to press the seeds 3 times a day (ie, morning, noon, and evening) for 1 minute and every time CRP occurs until the pain is reduced. The pressure has to induce a degree of pain in the ear that is tolerable for the participant. The seeds will be removed at the following visit and be applied to the other ear.

Intervention course. The intervention will be conducted twice a week for 4 weeks, a total of 8 interventions. Should the pain symptoms completely resolve (Numerical Rating Scale (NRS) score = 0) and if the participant does not feel the need to continue the intervention, the intervention can be terminated prematurely. In the unlikely event of a serious adverse event (SAE) occurring,[45] the primary investigator will work with the participant's usual healthcare team to determine whether the SAE is the consequence of the treatment and stop the intervention when necessary.

Adherence. The eligible participants will receive a trial timetable. Text messages will be sent to the participants as a reminder of each upcoming session. The primary investigator will explain how to massage the ear seeds and the importance of ear massaging. If permission can be received from participants, text messages will be sent to them 3 times a day as a reminder about the ear seeds massage. The participants will be encouraged to contact the primary investigator or research assistant to ask any relevant questions about the trial.

Assessments

Primary outcome. Pain level measured with Numerical Rating Scale (NRS) will be used as the primary outcome for effectiveness. A 2-point or 30% reduction in NRS will be considered clinically significant.[46] NRS will be assessed during each session. Pain scale is considered as the most accurate and reliable measure of pain level and response to pain treatment.[47] NRS is a valid instrument to measure pain level with higher sensitivity and better applicability compared to other pain scales.[48-50]

Secondary outcomes

Analgesic use. The type, dose, and frequency of analgesic medications used recorded on a logbook will be recorded by the study team at every visit. No recommendations will be made regarding the participant's analgesic use. To determine whether analgesic use is responsible for the pain relief outcome, Linear Mixed-Effects Models will be used.[51] This statistical method will take account of the changes in analgesic use and its influence on the outcome by setting it as a covariate.

Safety. Each participant will receive an Adverse Events Log Book to record any perceived adverse events relating to the acupuncture and will be advised to bring the book to each visit. Any adverse events that are recorded in the book or that occur during the intervention will be recorded in the participant's Adverse Event Form by a research assistant. The severity, expectedness and causal relationship with the intervention will be assessed for every adverse event. The number and severity of adverse events, as recorded on an Adverse Events Form, will be reported in adherence to the requirements of the National Health and Medical Research Council for Clinical Trials Adverse Event Reporting.[52]

Other assessments

Credibility and Expectancy Questionnaire. Treatment outcome can be influenced by the degree to which participants

Table 1. Trial Procedures.

Time point	Week 1		Week 2			Week 3		Week 4		Week 8
Visit number	Vt 1 Bl	Vt 1 Al	Vt 2	Vt 3	Vt 4	Vt 5	Vt 6	Vt 7	Vt 8	Vt 9
Screening	X									
Informed consent	X									
Sociodemographics	X									
Assessment										
NRS	X	X	X	X	X	X	X	X	X	X
Analgesic use	X		X		X		X		X	X
Auricular acupressure frequency			X	X	X	X	X	X	X	
Adverse events		X	X	X	X	X	X	X	X	
CEQ	X									
Interview									X	
Intervention		X		X	X	X	X	X	X	

Abbreviations: Vt, visit; Bl, before intervention; Al, after intervention.

consider a treatment as credible, and to what extent patients expect favourable outcomes for themselves.[53] To eliminate the impact of expectancy on trial outcomes, the Credibility and Expectancy Questionnaire (CEQ) will be administered during the first visit of the trial. The CEQ was first developed in 1972 to assess the credibility of placebo behavioural interventions.[54] A revised version was developed to have acceptable psychometric properties[55,56] and has been widely used to assess expectancy in clinical trials.

Interview. Participants will be interviewed by the research assistant at visit 8 (Week 4) after the intervention has been provided in order to understand the perspective of the participants. Open-ended questions will be used to allow the participant to express his or her own views. The questions were designed on the basis of a previous study.[57] Participants have the right to decline to be interviewed. Table 1 sets out the trial procedures and outcome measurements as below.

Sample Size

The sample size calculation is based on a .9 probability to detect a difference and to reject the null hypothesis on a basis of $P < .05$. In order to achieve a 2-point reduction in NRS after 4 weeks of treatment, with a standard deviation of 2.5.[58] Based on this calculation, 76 participants completing the trial will be needed. Allowing for a 40% withdrawal and attrition rate, 106 participants will need to be recruited in order to assess the effectiveness of the intervention according to the primary outcome only.

Recruitment and Screening

The potential participants will be recruited by referrals from medical doctors, clinical trial nurses or by online and print advertisements. Medical professionals from Cancer Therapy Centre, Liverpool Hospital and Macarthur Cancer Therapy Centre, Campbelltown Hospital will undertake pre-screening of participants. The online and print advertisements include flyers, newspaper advertisements and online advertisements. Recruitment will be through posters in clinic rooms, community support groups, print and social media.

All potential participants will be pre-screened by a medical doctor and then screened by a coordinating nurse according to the eligibility criteria. All participants deemed eligible will receive a Patient Information Sheet and a Consent Form and be given time (at least 1 week) to consider their participation. If they subsequently decide to participate in this trial, an appointment will be made with the primary investigator at which time formal written consent will be obtained. Participants may receive the information of this study through advertisements or word of mouth, the Primary Investigator (PI) is likely to be contacted in this instance, through a trial coordinating nurse organised by the PI, a further medical screen will be arranged. The CONSORT flow diagram is as follows (Figure 1).

Randomization Method

A random sequence is generated by an online computerized randomization system using a random code generator. Participants will be randomly assigned to intervention group or wait list group at a 1:1 ratio. Randomization is conducted by an independent researcher, sealed envelope is adopted for concealment of the allocation sequence till assignment occurs so to prevent investigator/principal practitioner from influencing which participants are assigned to the intervention or control group. Blinding is not applicable in this wait-list controlled trial.

Data Collection, Management, and Analysis

Data collection and management. After signing informed consent at the first visit (Week 1), each participant will

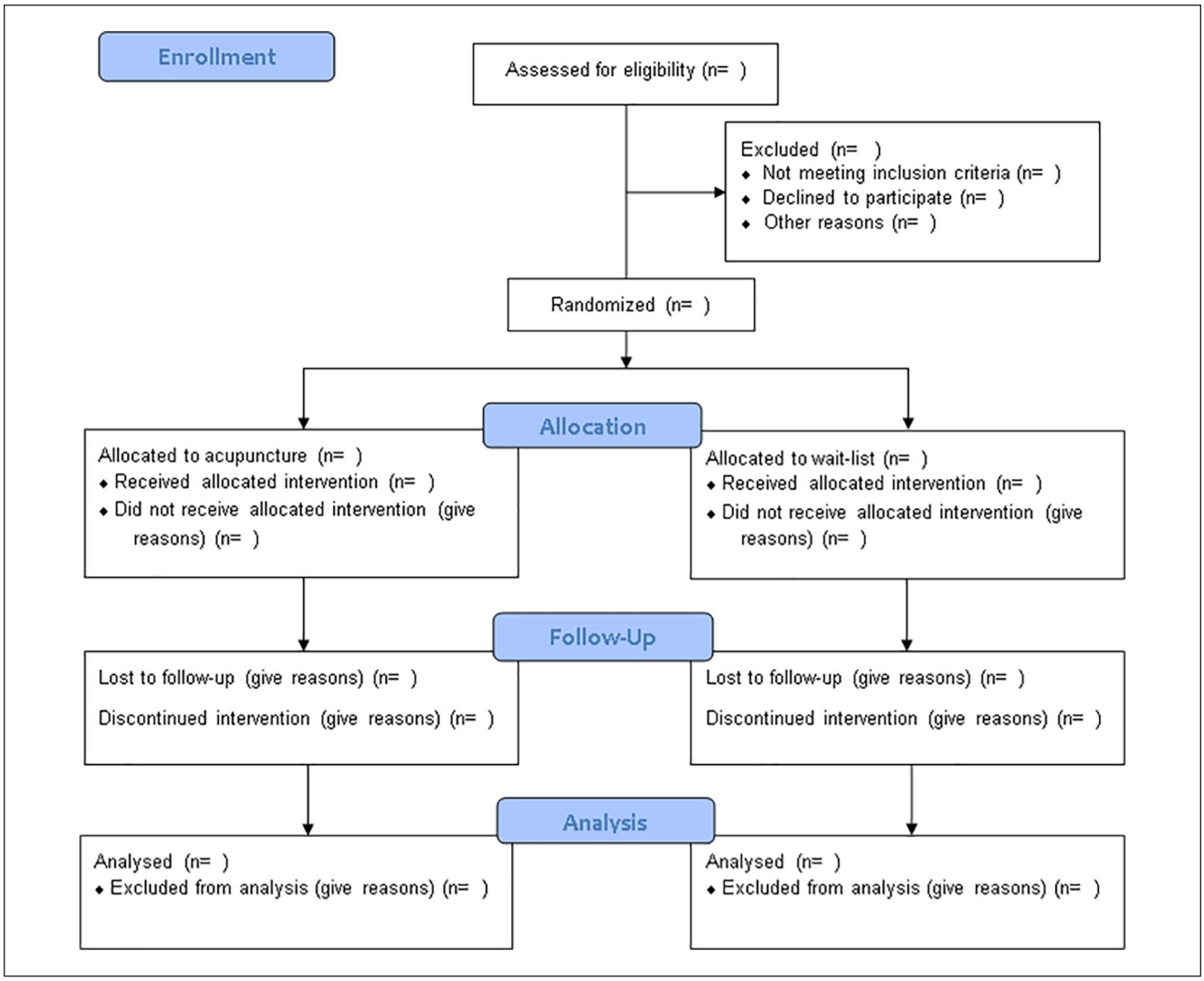

Figure 1. CONSORT flow diagram of the study.

receive their study allocation number. De-identified sociodemographic information (Age, gender, ethnicity, education level, and income) and medical history will be collected at the first visit (Week 1) by the primary investigator. A Credibility and Expectancy Questionnaire will be provided to the participant by the research assistant at the first visit (Week 1) before intervention is provided. NRS and Adverse Events will be collected by the research assistant directly from the participant during each visit. Analgesic Use will be collected by the research assistant at visit 1, 2, 4, 6, and 8 before the intervention is provided.

For the participants in the intervention group, Auricular Acupuncture Frequency will be collected by the research assistant from visit 2 to visit 8 before the intervention is provided. For the wait-list control group, Auricular Acupuncture Frequency will not be collected until participants start receiving the intervention. Participants will be interviewed by the research assistant after the final intervention has been provided at visit 8 (Week 4). The interviews, which collect participants' feedback to this study will be recorded with an audio recorder subject to participant consent. In the scheduled 4-week follow-up NRS, Analgesic Use, and Adverse Events will be collected. The timetable for the 4-week follow-up is the same as that used during the 4-week intervention procedure.

During the study, all data collected will be recorded in participant source document files in paper format (sociodemographic data, clinical data, paper questionnaires) and will be transferred to electronic format for storage and analysis. De-identified electronic data will be stored on a password-protected computer which is part of the secure system of Western Sydney University. Files will be accessible for review only to the research team. Specific requests for approval from the supervisory panel

is required for any access by any other person. All completed questionnaires and study information will be de-identified and stored in a locked filing cabinet together with consent forms at the Wellness Centre, Liverpool Hospital.

After participants have completed the trial, his/her paper documents will be transferred by a password protected box to a locked filing cabinet at Chinese Medicine Centre in Western Sydney University. The participants' data will be retained for at least 15 years from the publication of results.

Data analysis

Quantitative data. At the conclusion of the study, quantitative data will be analysed by SPSS 25. For the continuous data, a Linear Mixed effects Model (LMM) analysis will be conducted in order to determine the influence of time on the effectiveness outcomes. For the type of analgesic used, a Chi-square analysis will be conducted to determine the difference between pre- and post-intervention. The continuous data will be reported in terms of mean, standard deviation and statistical significance level. The categorical data will be reported in terms of the number of each analgesic type used. A P level of .05 will be considered as statistically significant. Data analysis will be based on an intention-to-treat approach.

Qualitative data. The answers of the interviews will be entered manually into word files and imported to NVivo 11 by the research assistant. The data will be analysed by the research assistant using a thematic analysis with a data-driven approach. The analysis will follow a 6-step process: familiarization with the data; generating initial codes; searching for themes; reviewing themes; defining and naming themes; producing the report.[59]

Trial Monitoring

This trial will be monitored by the core study team with monthly meetings. All adverse events will be bought to the immediate attention of the investigators. Participants who develop any adverse events will be managed according to the severity of their symptoms. The relevant ethics committee will be notified of any adverse events those that meet serious AE criteria. Regular meetings will be scheduled by the primary investigator to discuss the adverse events with hospital clinicians. Participants will be provided a 24-hour contact number for any urgent matters or concerns.

Ethics and Dissemination

Ethics. The protocol of the trial has been approved by Ethics committee of South Western Sydney Local Health District with the identifier of 2019_ETH13683.

Discussion

This trial is the first collaborative acupuncture study to be implemented in a public hospital in Australia. It is a joint international effort across different disciplines and institutes, involving BUCM (Beijing University of Chinese Medicine) and WSU (Western Sydney University) and Cancer Services, South Western Sydney Local Health District. BUCM and WSU are distinguished as universities with the longest history in traditional Chinese medicine education and research in China and Australia respectively. Liverpool Hospital, home of the Cancer Services of District, is the largest public hospital in New South Wales, Australia with a history of more than 200 years. In 2018, the 3 institutes entered a partnership with an establishment of the Sino-Australian Cancer Research Alliance, a clinical research cooperation platform. This trial represents an important collaboration investigating the feasibility of acupuncture-related scientific research in the Australian public health system as well as its effectiveness and safety for cancer related pain.

Implementation of an acupuncture clinical trial is associated with a number of challenges. This includes a relatively lack of cultural acceptance in an Australian public hospital healthcare environment.

Hence, a number of strategies were put in place during the design period.

Defining a Research Topic

This was carefully and thoroughly investigated. This was done in consideration of future recruitment and other relevant factors. In Australia, about 145 000 new cases of cancer will be diagnosed in 2020.[60] Together with the high incidence rate of cancer-related pain, we also sought to focus on disease condition that is currently sub-optimally managed in clinical care or are associated with known adverse effects. Cancer pain is treated by a range of analgesic medications, which in turn can be associated with a range of toxicities including, constipation, nausea, drowsiness, confusion and/or hallucinations. By contrast, the use of acupuncture for analgesic purposes is associated is overall well tolerated by patients and typically associated with only minor adverse effects.

We sought to build on and add to the existing body of scientific literature relating to acupuncture-treated analgesia, and in doing so, expect that this will lead to a greater acceptance from the health professional workforce for this intervention. There has been a large amount of evidence on acupuncture-related analgesia. The National Institute of Health (NIH) held a hearing on acupuncture therapy in 1997, and in its outcome, acupuncture was accepted as effective for analgesia and for management of vomiting in cancer patients. NIH also recommends acupuncture for cancer

symptom management and a majority of NIH designated centres (73%) provide acupuncture as part of integrative oncology programs to treat a variety of symptoms and conditions associated with cancer and the side effects of cancer treatments.

Designing a Research Protocol

Several factors were taken into consideration in line with the features of acupuncture in practice and the clinical research requirements.

1) Ethical considerations: All participants will be encouraged to maintain and continue as relevant their analgesic medications, however a logbook is required to monitor the use of these medications which will be incorporated in the study analysis and for determining the impact of the acupuncture intervention.
2) Reflecting a real-world environment without compromising the scientific credibility: A wait-list control design has been selected here in response to the consideration that applying sham acupuncture as a control in acupuncture trials is controversial and potentially non-credible design. Furthermore, accounting for the complexity of acupuncture clinical practice, a pragmatic design instead of exploratory design is used in this trial to produce results that can be generalised and applied in routine practice settings. By combining the 2 designs, the effectiveness of acupuncture for cancer-related pain will be assessed in a scientific way.
3) Assessing pain as primary outcome: the most commonly used pain assessment tools to be used in this trial including NRS. In future, some additional biological assessments assessing neurotransmitters such as 5-hydroxytryptamine concentration may be considered.
4) Design of the acupuncture research protocol: The design of this trial is in compliance with the Standard for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) which is an official extension of CONSORT. The details of needling and the intervention doses have been thoroughly explored and considered. The practitioner background is also an important contributing factor in the design. In this case, the chief investigator has 18 years of clinical experience in acupuncture practice. The use of the revised STRICTA, in conjunction with the CONSORT methodology, will improve both the quality of implementation and the reporting of results related to this clinical acupuncture trial.
5) Rationale of the acupoint selection: The section of acupuncture points has been based on an intensive literature research and clinical experience. The top 4 of the most frequently used acupoints for cancer related pain located on the 4 limbs over the recent 5 years have been selected for the trial. Acupoints on the back (Back-Shu points) are traditionally used for managing pathological conditions associated with internal organs; Back-Shu points are selected in correspondence to where the original (primary) solid tumour is, for instance, Lung-Shu is used for a participant who suffers from pain in relation to lung cancer., either primary or secondary
6) Mixed methods adapted in the trial: To better determine the value of providing acupuncture in the Australian public health system for cancer-related pain, it is necessary to investigate the experience and extent of satisfaction for participants who are involved in this acupuncture clinical trial. Hence, an interview with open-ended questions is designed to better understand the perspective of the participants. It is expected that the findings of these interviews may help improve both the experience and acceptance of acupuncture by Australian patients who suffer from cancer pain.
7) This study has potential limitations. The 8-week intervention period design is based on previous clinical studies of acupuncture for pain. A longer intervention period may provide more insight into the effectiveness of the intervention, and its lasting power. However, a longer intervention period may contribute to greater participant withdrawal over time. The study outcomes did not include analysis of biomarkers in the blood correlated with pain, that is, via blood tests conducted at baseline, end of intervention period, and at end of follow-up period. Diagnostic biomarkers would provide a more objective measure of any changes that take place, to provide more compelling results. However, the requirement for participants to undergo several blood tests may contribute to a greater participant withdrawal rate. A perceived limitation is the absence of a true placebo as a control intervention. This limits our understanding of the characteristic effect of the intervention. However, in complex non-pharmaceutical interventions such as acupuncture, incidental effects are often emergent and interwoven with characteristic effects. It is therefore impossible to eliminate the incidental (placebo) effects completely. The use of sham interventions in acupuncture RCTs is a controversial subject. The use of a wait-list control allows to control for the effect of time, other treatments, etc., while allowing all the aspects of the intervention (therapeutic relationship, etc.) to take part in the effect.

This is the first rigorously designed acupuncture trial in Australia as a joint effort between medical professionals

and allied health researchers and clinicians. It reflects the efforts of an international research collaboration. We hope that this trial will serve not only as a reference for other acupuncture researchers, but also build on the existing scientific evidence base for acupuncture as a more accepted and mainstream treatment for cancer-related pain within the Australian healthcare system.

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Author contributions

Qi Zhao and Suyang Zheng drafted the present manuscript, Geoff P Delaney, Eugene Moylan, Meera Agar, Eng-Siew Koh, Hezheng Lai, Yoann Birling, George Zhang, Kang Wang, Yong Ma, Xiaoshu Zhu reviewed and edited the manuscript.

Conceptualization: Qi Zhao, Suyang Zheng

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Writing – original draft: Qi Zhao and Suyang Zheng

Writing – review & editing: Qi Zhao, Suyang Zheng, Geoff P Delaney, Eugene Moylan, Meera Agar, Eng-Siew Koh, Hezheng Lai, Yoann Birling, George Zhang, Kang Wang, Yong Ma, Xiaoshu Zhu.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Trial Registration Data

Category	Information
Primary registry	Australia New Zealand Clinical Trial Registry
Trial identifying number	ACTRN12620000325909
Protocol number	2019/ETH13683
Primary sponsor	Western Sydney University and South Western Sydney Local Health District
Sponsor contact	Associate Professor Xiaoshu Zhu Locked Bag 1797, Penrith NSW 2751 Email: x.zhu@westernsydney.edu.au
Contact for public queries	Dr Qi Zhao Tel: +61 0480176491 Email: q.zhao2@westernsydney.edu.au
Contact for scientific queries	Dr Qi Zhao Tel: +61 0480176491 Email: q.zhao2@westernsydney.edu.au
Public title	Acupuncture for Cancer Related Pain (CRP)
Scientific title	Acupuncture for Cancer Related Pain: A pragmatic randomised-controlled trial
Countries of recruitment	Australia
Problem studied	Cancer Related Pain
Interventions	Acupuncture
Key eligibility criteria	Age 18 years old or older A diagnosis of cancer related pain (CRP) made by a medical doctor, regardless of the cancer type, stage or the presence of metastasis. Included types of pain: somatic nociceptive pain, visceral nociceptive pain, neuropathic pain and mixed types of pain Numerical Rating Scale (NRS) score >3 Estimated survival time>12 weeks Cognitive ability to provide consent
Study type	Interventional Wait-list control Randomized
Expected first enrolment	September 2020
Target sample size	106
Recruitment status	Not recruiting
Primary outcome	Pain level measured by Numerical Rating Scale (NRS)
Key secondary outcomes	Analgesic medications used—type, dose, and frequency recorded on a logbook Safety—assessing the severity of the adverse events by both the research team and hospital clinicians
Ethics review	Approved on 4th February 2020 by South Western Sydney Local Health District Human Research Ethics Committee
Expected completion date	31st December 2024
IPD sharing	Individual participant data underlying published results only will be shared immediately following publication, no end date. The data will be available for IPD meta-analyses case-by-case basis at the discretion of Primary Sponsor

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