Study Protocol

Warm Needle Acupuncture vs. Needle Acupuncture for Osteoarthritis of the Knee: A Pilot Study Protocol

Abstract

Introduction
Acupuncture has been shown to have clinically relevant benefits for chronic pain. However, interpretation of the results and whether they are due to the placebo effect remains contested. As a complex physical intervention acupuncture presents particular problems in clinical research that seeks to identify a specific effect. The existing evidence mosaic can be enhanced by randomised controlled trials that investigate the specific efficacy of different components of acupuncture. This study investigates the specific efficacy of the conducted heat in warm needle acupuncture.

Methods
The study is a randomised, controlled, parallel-group 2-armed clinical trial. It is designed so that the outcome administrator, participants and primary acupuncturist will be blinded to group allocation.

Analysis
The primary outcome measures WOMAC® NRS 3.1 score and SF 36 are both considered interval variables and provided the distribution of changes is normally distributed the change in score will be analysed using t-test. The information obtained from interviews with participants will be thematically analysed.

Discussion
Compromises from acupuncture in practice have been made in order to devise procedures that can investigate the specific efficacy of the conducted heat of warm needle acupuncture. The way in which these compromises may impact on interpretation of the results is discussed.

Keywords: acupuncture, moxibustion, moxa, warm needle, randomized controlled trial, protocol, complex intervention

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Introduction

Since the turn of the century a number of high-quality large-scale clinical trials have investigated acupuncture for chronic pain conditions. Consequently recent systematic reviews provide more reliable evidence when compared to reviews that were carried out in the late 1990s [1-4]. The current evidence indicates that acupuncture provides clinically relevant benefits when compared to usual care/ waiting list/ other physical interventions [4, 5].

The effects of acupuncture for chronic pain have also been shown to be superior to the so-called sham/placebo/ minimal acupuncture procedures - this difference is statistically significant[4]. Interpretation of the results, however, remains controversial which has led to the identification of paradoxes within acupuncture research [6].

To date none of the sham/ placebo procedures can be considered as inert controls from either a Chinese medicine or biomedical perspective [7]. In order to move the field of acupuncture research forward, without a true placebo, it will be necessary to develop an evidence mosaic that encompasses efficacy and pragmatic effectiveness clinical trials along with basic science research and qualitative investigations [6, 8, 9]. Within this mosaic clinical trials that compare different styles of acupuncture are now being conducted, for example Karner et al who compare *classical*, *modern*, and *sham* acupuncture [10].

This study protocol has been designed to compare acupuncture with and without the specific component of moxibustion: Warm needle acupuncture vs. needle acupuncture. It is an efficacy trial that investigates a specific component rather than acupuncture as a whole. Participants will be blinded, consequently, if there are differences between groups this will suggest that warm needle acupuncture has a physically mediated mechanism rather than psychologically mediated mechanism.

In the West, acupuncture has been defined purely as the insertion of needles [11]. However, the traditional practice of acupuncture is intimately related to the use of moxibustion. Moxibustion is the burning of an herb called moxa (Mugwort, *Artemisia vulgaris*) applied to

specific parts of the body, including acupuncture points. The Chinese word *zhenjiu* 针灸 that is translated as 'acupuncture' actually refers to both the use of needles *zhen* 针 and moxibustion *jiu* 灸.

Within the paradigm of traditional theories one of the purposes of using moxibustion is to *warm meridians and expel cold* [12]. Osteoarthritis will typically be diagnosed as *Cold Damp Bi syndrome* in Chinese medicine. The use of moxibustion is indicated in the treatment of *Cold Damp Bi syndrome* [12]. There are a variety of ways in which moxibustion is used, including warm needle, moxa box, moxa sticks and indirect moxa using ginger [12].

Warm needle acupuncture *wenzhen* 温针 is where moxa cones are placed on the handle of the needle, after the needle has been inserted. Once lit, heat transmits along the shaft of the needle to the acupuncture point. In Chinese literature, acupuncture without the use of moxibustion on the needle is referred to as *danchun zhenci* 单纯针刺，which could be translated as simple needle insertion or *changgui zhenfa* 常规针法 regular or conventional needle method. The procedure will be referred to here as 'needle acupuncture'.

Systematic reviews of acupuncture for osteoarthritis of the knee have concluded that acupuncture provides clinical benefits [3, 4, 13]. The clinical trials that form the evidence base of acupuncture for osteoarthritis of the knee did not use moxibustion as part of their acupuncture protocols [3, 4]. It was noted by some researchers that not using moxibustion was a potential weakness of the acupuncture intervention [14].

This pilot study investigates the difference between warm needle acupuncture and needle acupuncture with the ultimate objective to run a clinical trial that can test the hypothesis:

Greater clinical benefit will be obtained by using warm needle acupuncture when compared to needle acupuncture for osteoarthritis of the knee.

A literature review, which is being prepared for publication, has been conducted using Medline and the CNKI databases. All the relevant studies that were retrieved were conducted in China. The majority of these studies were non-blinded controlled trials that compared warm needle acupuncture to needle acupuncture. All the trials indicated a positive result in favour of warm needle acupuncture. Unfortunately the standard of

reporting was low and it is not possible to form any conclusions. None of the studies used a blinding procedure similar to the one employed in this protocol.

Aims

The aims of the study are to:

- Test the integrity of the study protocol. The study will enable the evaluation of the practicality of the procedures and identify any problems that may arise from: implementing the inclusion/exclusion criteria; patient information and consent procedures; staff training; administration of outcome assessments; randomization, allocation and blinding procedures.
- Assess the safety of warm needle acupuncture for osteoarthritis of the knee
- Assess the acceptability of warm needle acupuncture among UK patients
- Collect qualitative data from participants and staff to support the development of the protocol for an adequately powered RCT
- Provide an initial indication of the effectiveness of warm needle acupuncture compared to needle acupuncture to inform a sample size calculation for an adequately powered RCT

Study Design - Methods

The study is a randomised, controlled, parallel-group 2-armed clinical trial. It is designed so that the outcome administrator, participants and primary acupuncturist will be blinded to patient allocation.

The intention is to recruit 30 participants with osteoarthritis of the knee. Participants will be randomised into two groups; they will receive either warm needle acupuncture or needle acupuncture. The only difference in the procedures will be that lit cones are placed on the needles of the treatment group whilst unlit moxa cones will be placed on the needles of the control group.

Each patient will be offered up to 12 treatments over an 8 week period. The intention is to treat all participants and collect all data within a 12 month period. The treatments will be given at the Confucius Institute of Traditional Chinese Medicine teaching clinic based at London South Bank University.

Participants will be informed that study is 'a practice run' to support the development of a randomized controlled trial (RCT) and that the study is comparing two different kinds of acupuncture. The difference between warm needle acupuncture and needle acupuncture, the blinding procedures and that participants will be randomly assigned to one of the two groups will also be explained. Participants will be given the opportunity to ask any questions prior to enrolment.

Eligibility Criteria

The inclusion criteria incorporate the American College of Rheumatology clinical criteria for diagnosing idiopathic osteoarthritis of the knee [15]. Other elements of the inclusion criteria are designed to be broadly in line with previous high quality studies of acupuncture for osteoarthritis of the knee [14, 16]

Inclusion Criteria

Chronic pain in at least one knee joint during the last six months

At baseline the WOMAC® NRS 3.1 pain score must be ≥ 3 points (on a scale of 0–10)

In addition to the knee pain at least 3 of the following 6 must be present:

- Age > 50 years
- Stiffness < 30 minutes
- Crepitus
- Bony Tenderness
- Bony enlargement
- No palpable warmth

Ability to speak English
Signed consent form

Exclusion criteria

Standard exclusion criteria were applied [17]. In addition participants were excluded if they were considered to present with the Traditional Chinese Medicine (TCM) pattern differentiation of Heat Bi as this is not suitable for moxibustion.

Interventions

The acupuncture interventions were designed by an experienced TCM practitioner/ lecturer (Appleyard) and are based on standard texts used in the West and in China [18-20]; treatment protocols used in trials that have been included in systematic reviews [3, 4]; treatment protocols that have been used in trials investigating warm needle acupuncture for osteoarthritis of the knee published in Chinese.

Acu-point selection protocol

The same semi-flexible point selection protocol will be used in both groups. Only points local to the knee will be chosen. The practitioner will be instructed to select acu-points according to the location of the pain. There will be 4-6 points used per knee, therefore 8-12 needles per treatment. Two points will be used as the core treatment ST 35 dubi, Ex-LE 5 xiyan. These points will be omitted only if needling is not tolerated or inflammation/skin injury covers the acupuncture point. Four other acu-points can also be used from the following: Ahshi painful points local to the knee (locus dolendi), ST 36 zusanli, GB 34

yanglingquan, Sp 9 yinlingquan, ST34 liangqiu, Sp 10 xuehai, GB 33 yangxiguan, LR 7 xiguan, LR 8 ququan, heding Ex-LE 2

Warm needle acupuncture

In addition to the acupuncture needles the warm needle acupuncture group will receive moxibustion. Smokeless moxa will be used. Up to 4 points will be selected to apply moxibustion to the needles per knee. Typically moxibustion will be applied to ST 35 dubi, Ex-LE 5 xiyan and two other points. Two cones will be sequentially applied to each needle.

Number of treatments

Participants will receive up to 12 treatments, 8 treatments in the first 4 weeks (twice a week), then 4 treatments in 4 weeks (once a week). Needles will be retained for approximately 25 minutes

Medication

Participants will be able to continue to take any medications, although they will be asked to keep a record of medication use. They will also be able to continue with any exercises, physiotherapy, massage treatment or osteopathy that they were undertaking prior to enrolment. However, participants will be asked to refrain from starting other therapeutic interventions during the course of the trial, such as physiotherapy, massage and steroid injections. Should they start to use one of these therapies they will be withdrawn from the study.

Randomisation

Participants will be randomised to receive either warm needle acupuncture or needle acupuncture. An independent statistician based at LSBU will generate the randomisation sequence using a computer randomisation package. As this is a pilot study with low numbers, participants will be randomised in blocks of 10 to ensure periodic balance between the two groups.

Blinding

Acupuncturist

A key innovation of this study is the blinding of both patient and practitioner. The blinding process requires two practitioners; the acupuncturist and an assistant.

The acupuncturist selects the points and inserts the needles. Blinding of the acupuncturist is important to ensure that no bias is created through additional care and attention to those in the warm needle group. An assistant lights the moxa and is the only person who should be aware of group allocation. A sealed envelope containing group allocation will be opened at each treatment. See Flowchart 1: Preparation of sealed envelopes

Patient

The only difference in the procedures will be that lit cones are placed on the needles of the treatment group whilst unlit moxa cones will be placed on the needles of the control group. All patients will see the needles being inserted and the moxa cones placed on the needles by the acupuncturist. Skin guards will be placed at the base of the needle to reduce the immediate sense of heat on the surface of the skin. These skin guards have been specifically designed for this study and are made of a heat resistant and washable material.

The acupuncturist will carry out a consultation at each session as per normal practice. Participants are treated in an upright sitting position. Once the needles, skin guards and moxa are in place a small table and screen are placed in front of the patient to prevent them from seeing their knees. The acupuncturist leaves the room and the assistant acupuncturist enters. In the treatment group the assistant acupuncturist will then remove one cone at a time and light it. In the control group this action is mimicked to try and ensure the participants experience the same sensations, i.e. all patients will hear the moxa being 'lit' and feel the cones being removed and replaced. Although smokeless moxa will be used there is still a faint smell that all patients may be able to detect. Therefore in the control group moxa will be lit and allowed to burn in a small dish out of sight at the participant's feet. If the participant feels that the moxa is too hot they can ask the assistant to remove the moxa, however, the assistance will not confirm whether or not the moxa was actually lit. See Flowchart 2: Blinding procedure

Flowchart 1: Preparation of sealed envelopes

Flow chart 2: Blinding procedure

Data collection

The primary outcome measure of the knee pain and stiffness is the WOMAC® NRS 3.1 English for UK Osteoarthritis Index [21]. The secondary outcome measure assessing the health related quality of life (HRQL) is the SF 36 [22]. Questions will also be asked regarding patient expectation [23], medication, safety and the quality of blinding (See below). This data will be collected at baseline, midpoint (4 weeks), end of treatment (8 weeks) and follow up (16 weeks).

Qualitative semi-structured interviews will be conducted to gather information on the participants' experiences and perceptions of four areas; the trial process; needling sensations; the treatment process within the context of a trial; wider benefits or harms. These will be done at the end of treatment (week 8).

Expectation questions

The following questions are asked at baseline

1. How effective do you consider acupuncture to be in general? very effective/ effective/ slightly effective/ not effective/ don't know

2. What do you personally expect from the acupuncture treatment you will receive? cure/ clear improvement/ slight improvement/ no improvement/ don't know

3. Do you think the warm needle acupuncture will be more effective that needle acupuncture for your knees? much more effective/ more effective/ slightly more effective/ not more effective/ don't know

This question is asked at the fourth treatment

4. How confident do you feel that this treatment can alleviate your knee pain? very confident/ confident/ slightly confident/ not confident/ don't know

Quality of blinding question

This question is asked at the midpoint and end of treatment.

Do you think you are receiving warm needle acupuncture or needle acupuncture? warm needle/ needle acupuncture/ don't know

If participants choose either warm needle or needle acupuncture they are also asked why.

Ethics

Ethical approval of this research has been obtained from London South Bank University's Ethics Committee (UREC 1562). The World Medical Association Declaration of Helsinki and Social Research Association: Ethical Guidelines [24]; and London South Bank University Research Ethics Committee Code of Practice for Research Involving Human Participants [25] have been used for guidance. This study was designed with reference to British Acupuncture Council Codes of Practice [26].

Analysis

The primary outcome measures are WOMAC® NRS 3.1 score and SF 36 at the beginning and end of the pilot study. These are both considered interval variables and provided the distribution of changes is normally distributed the change in score will be analysed using t-test. As a pilot study it will be underpowered for detailed investigation of change over multiple time points or for investigation of possible explanatory variables, however, in order to inform the planning of future studies repeated measures ANOVA will be used to investigate change over the four-time points. Initially independent sample t-tests or ANOVA will investigate the relationship between the categorical explanatory variables, group allocation and expectation questions, and change in WOMAC and SF 36. Depending on these results generalised linear models may be used for further exploration of the relationships.

The information obtained from the interviews will be thematically analysed using NVivo. This will provide qualitative information regarding the thoughts, feelings and experiences of the study from the participant perspective. This information will be used in order to evaluate the practicality of the procedures and identify any problems that may have arisen from: implementing the inclusion/exclusion criteria; patient information and consent procedures; staff training; administration of outcome assessments; randomization, allocation and blinding.

Discussion

As noted above the interpretation of acupuncture results remains an area of contention. In light of this it is particularly important to establish the limitations of this study as compromises have been made within the treatment procedures. The protocol is designed to specifically investigate whether heat conducted along the shaft of acupuncture needles brings additional benefits in treating osteoarthritis of the knee.

Chief among these compromises is the use of skin guards to prevent the participants being aware of their group assignment. It is possible that radiated heat typically felt in clinical practice when warm needle acupuncture is employed will have beneficial therapeutic effects. Heat lamps are of course commonly used not just by acupuncturist but also by other healthcare workers such as physiotherapists. It is reasonable to assume that radiated heat experienced during warm needle acupuncture has an effect similar to a heat lamp. Consequently the use of skin guards may reduce the effectiveness of warm needle acupuncture.

In the absence of skin guards participants will certainly be aware that they are receiving warm needle acupuncture. Without adequate blinding it will not be possible to differentiate psychologically mediated effects from the physically mediated. In other words this study is designed to exclude any psychologically mediated (placebo) effect derived from the feeling of warmth. This requires a sacrifice of the potential clinical benefit of the radiated heat in order to isolate the effects derived from heat conducted along the needle. If the blinding procedures are effective this will suggest that any additional clinical benefits are mediated by a physical mechanism.

Given that the study compares two active treatments any difference is likely to be relatively small and this inevitably leads to the possibility of a Type II error. The clinical significance of any difference will also require careful consideration.

A second compromise is the limitation on the selection of acupuncture points. The protocol does allow for a degree of flexibility but it is nevertheless quite restrictive and not reflective the standard practice of all practitioners. This has been confirmed by a survey of practitioners, the results of the survey are being prepared for publication. Many acupuncturists will use distal points and select points to address other signs and

symptoms. The study by Karner et al indicates an acupuncture points prescription based on a 'classical' theory maybe more effective than a simplified 'modern' approach [10]. This would suggest that the acupuncture points protocol in this study might not equate to optimal acupuncture. If the acupuncture protocol was changed to allow the selection of a wide variety of points for some sessions some participants may be required lie down, they would not be able to sit as they are required to do for the blinding procedure. The limitation of acupuncture points is only a compromise in relation to certain styles of acupuncture. The survey indicated that some practitioners only use local points in normal practice. In addition a number of Chinese trials that investigated warm needle acupuncture for osteoarthritis of the knee only used local points [27-31]

It is therefore important to emphasise that this study is narrowly focused on the difference between the two groups. Any reduction in effectiveness due to the limitation of the acupuncture points used will apply to both groups. Restricting the available acupuncture points should reduce the variability between groups, which in turn may improve the chances of detecting any differences.

The reduction in radiated heat as well as the restrictions on the acupuncture points protocol may both reduce the overall effectiveness of the warm needle acupuncture. Therefore the results should not be interpreted as reflecting warm needle acupuncture in clinical practice. It is possible to envisage another study where the acupuncturist would be free to select any acupuncture point they wished and the insulating pads not to used. This will be more in line with practice, however, the study would not be able to delineate effects derived from radiated heat, conducted heat or psychological effects of feeling the warmth.

This protocol has been designed to investigate a specific component of acupuncture practice to contribute to the wider evidence mosaic. It should not be considered a definitive assessment of the effectiveness of warm needle acupuncture.

Trial Registration

The trial has been registered at ClinicalTrials.gov Ref: NCT02680912

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Dongbang Acuprime supplied the moxa at cost price https://www.acuprime.com

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Random block sequence generated by statistician

Trial entrant number	Block
1	A
2	B
3	B
-	-
-	-
-	-
10	A

Cards

There are 15 participants in each cohort
Each participant may receive up to 12 treatments. Therefore the following will be prepared
15 sets of 12 cards labelled Needle acupuncture
15 sets of 12 cards labelled Warm acupuncture

Envelopes

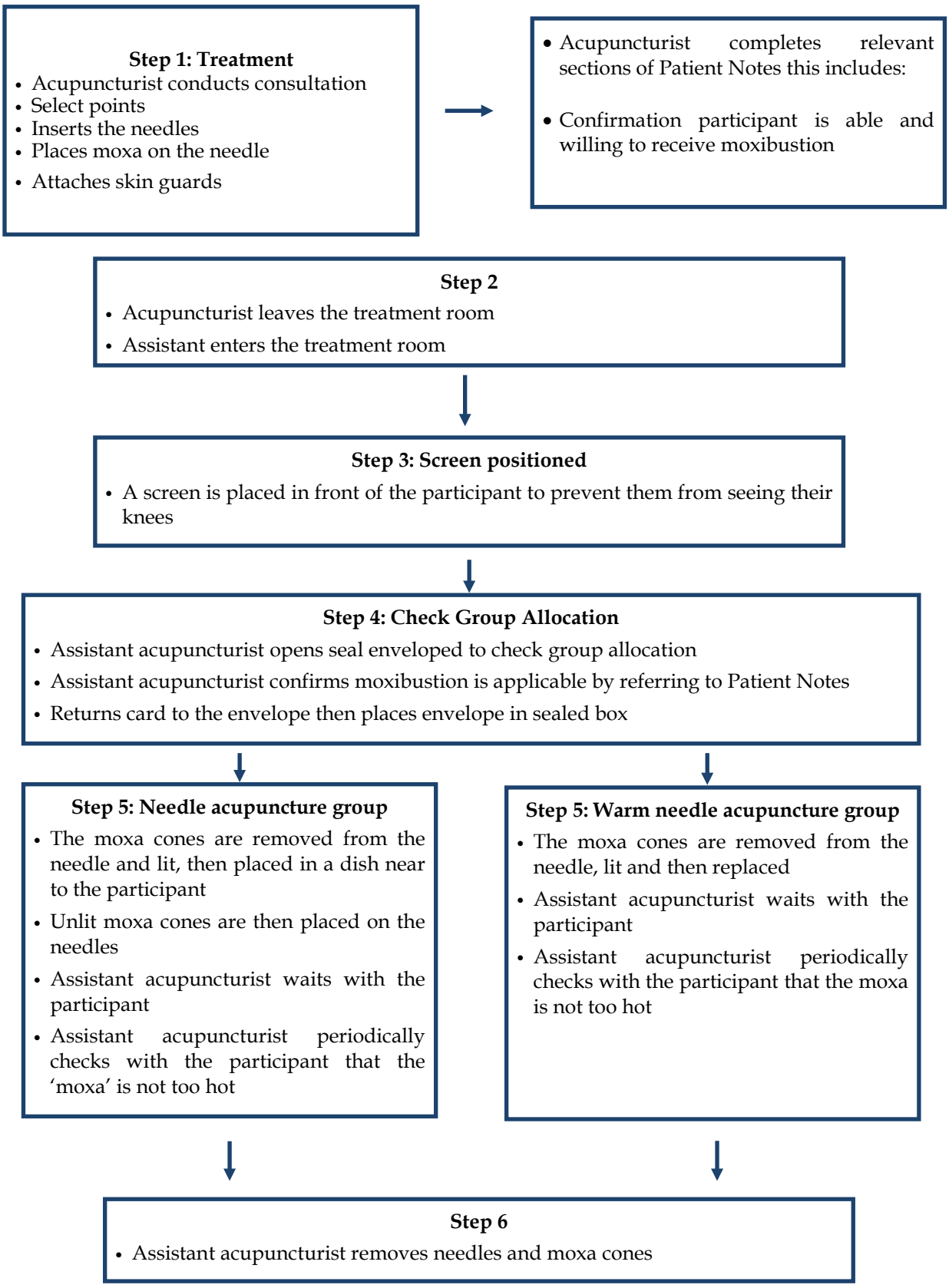
12 envelopes are prepared for each trial entrant (they will each receive up to 12 treatments)
The envelopes are labelled with:

- Trial Entrant Number (1,2.... 30)
- Treatment Number (1,2....12)

Using the random block sequence the PhD supervisor:

- ➡ Decides whether Block A or B will be the Warm Needle Acupuncture Cohort or the Needle Acupuncture cohort
- ➡ Inserts cards labelled with the corresponding group allocation into the 12 envelopes prepared for each Trial Entrant
- ➡ Seals the envelopes

The sealed envelopes containing group allocation are stored with the Patient Notes


Step 1: Treatment
• Acupuncturist conducts consultation
• Select points
• Inserts the needles
• Places moxa on the needle
• Attaches skin guards
• Acupuncturist completes relevant sections of Patient Notes this includes:
• Confirmation participant is able and willing to receive moxibustion
Step 2
• Acupuncturist leaves the treatment room
• Assistant enters the treatment room
Step 3: Screen positioned
• A screen is placed in front of the participant to prevent them from seeing their knees
Step 4: Check Group Allocation
• Assistant acupuncturist opens seal enveloped to check group allocation
• Assistant acupuncturist confirms moxibustion is applicable by referring to Patient Notes
• Returns card to the envelope then places envelope in sealed box
Step 5: Needle acupuncture group
• The moxa cones are removed from the needle and lit, then placed in a dish near to the participant
• Unlit moxa cones are then placed on the needles
• Assistant acupuncturist waits with the participant
• Assistant acupuncturist periodically checks with the participant that the 'moxa' is not too hot
Step 5: Warm needle acupuncture group
• The moxa cones are removed from the needle, lit and then replaced
• Assistant acupuncturist waits with the participant
• Assistant acupuncturist periodically checks with the participant that the moxa is not too hot
Step 6
• Assistant acupuncturist removes needles and moxa cones