



Research paper

Warm needle acupuncture vs. needle acupuncture for osteoarthritis of the knee: A pilot study protocol[☆]



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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.

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1. 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]. The evidence mosaic should also include clinical trials that compare different styles of acupuncture, such as the one already conducted by 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 a solely psychologically mediated mechanism.

[☆] This is a protocol paper as is for the Special Section - Acupuncture and evidence which is part of issue 4 2016 and will be open access

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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 (*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 on warm needling for osteoarthritis of the knee, 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.

2. 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.

3. 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 randomised 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.

3.1. 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]

3.1.1. 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 min.
 - Crepitus.
 - Bony Tenderness.
 - Bony enlargement.
 - No palpable warmth.
- Ability to speak English.
Signed consent form.

3.1.2. 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.

3.2. 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

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