Acupuncture & moxibustion for osteoarthritis of the knee

A component efficacy approach

Appendices

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A thesis submitted in partial fulfilment of the requirements of

London South Bank University

for the degree of Doctor of Philosophy

July 2018

Appendix A: Publications

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Appendix A1: Appleyard et al (2014) Should systematic reviews assess the risk of bias from sham-placebo acupuncture control procedures

Available online at www.sciencedirect.com

ScienceDirect

European Journal of Integrative Medicine 6 (2014) 234–243

European Journal of INTEGRATIVE MEDICINE

www.elsevier.com/eujim

Review article

Should systematic reviews assess the risk of bias from sham–placebo acupuncture control procedures?☆

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Received 17 December 2013; received in revised form 4 March 2014; accepted 4 March 2014

Abstract

Introduction: Clinical guidelines depend on the analysis of randomised controlled trials in systematic reviews. How to interpret the results of acupuncture vs. sham–placebo procedures is a controversial aspect of the evidence base for acupuncture. Two inferences can be drawn from the acupuncture vs. sham–placebo randomised controlled trials. The first is whether acupuncture has a physiological basis. The second is whether there is any validity in traditional concepts of acupuncture practice. The degree to which sham acupuncture controls can physiologically be considered placebo controls has been challenged. However, whether these procedures should be considered 'inert' in terms of Chinese medicine theory has yet to be fully examined. This review aims to evaluate the extent to which sham–placebo procedures used in randomised controlled trials should be considered inert, with particular reference to traditional Chinese medicine theories. It also considers sham–placebo controls from a biomedical perspective.

Methods: Sham–placebo procedures were identified through reviews examining acupuncture controls.

Results: Four main types of sham–placebo control were identified. The procedures are heterogeneous and should not necessarily be considered as equivalent within systematic reviews.

Conclusion: These procedures cannot be considered as inert controls from either a Chinese medicine or biomedical perspective. There is a need to develop appropriate Acupuncture Control Assessment Guidelines to assess the risk of bias from sham–placebo controls when undertaking systematic reviews. The terminology used to describe control procedures needs to be developed and standardised.

This article belongs to the Special Issue: Clinical Guidelines for Integrated Practice.

Keywords: Acupuncture; Sham; Placebo; Trial; Review; Guideline

Introduction

At the heart of clinical guidelines and evidence-based medicine (EBM) are systematic reviews of randomised controlled trials (RCT). The conventional view is that systematic reviews of double-blind trials provide the most reliable evidence [1]. Consequently, there is a perceived need for acupuncture to be compared with a placebo control in order to for acupuncture to be included in clinical guidelines [2]. The implementation of guidelines will be influenced by health service managers' perceptions of the evidence base [3]. An ideal placebo control should be physiological inactive yet psychologically credible [4]. Various procedures have been utilised as acupuncture placebo controls, however, the degree to which these should be considered physiologically inert has been questioned [5–9]. These procedures have been described as placebo acupuncture, sham acupuncture or minimal acupuncture. The usage of these terms has not been standardised [10]. Consequently, these descriptions are not used consistently to identify clearly delineated procedures; rather, they are used interchangeably to describe a number of different procedures. This lack of consistency may lead to misunderstanding of the currently available evidence.

☆ This article belongs to the Special Issue: Clinical Guidelines for Integrated Practice.

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http://dx.doi.org/10.1016/j.eujim.2014.03.004

Acupuncture developed as part of Chinese medicine and is related to traditional Chinese philosophy. Consequently, the results of placebo–sham acupuncture RCTs have two implications. The first is the conventional proof of efficacy by demonstrating a specific effect. The second is the potential production of evidence that may validate traditional concepts such as acupuncture points.

This article reviews the main placebo–sham-minimal acupuncture methods and assesses to what extent they can be considered inert in terms of traditional Chinese medicine. It will also discuss whether the evidence suggests that acupuncture has a physiological basis. It proposes that guidelines be developed to evaluate acupuncture sham–placebo control methods. Procedures that are similar to real acupuncture may bias the results. It may not be appropriate to regard some procedures as sham or placebo controls within systematic reviews. This issue potentially may lead to acupuncture not being included within clinical guidelines, and/or hinder its acceptance amongst clinicians and managers, for conditions where in fact it is an effective referral option.

The central paradox of acupuncture research

The central difficulty in analysing the results of acupuncture clinical trials is 'the paradoxical finding. . .that verum [real] acupuncture is not better than "sham" acupuncture but both are better than usual care' [11]. The similarity between real and sham acupuncture outcomes has led some researchers to view the clinically relevant benefits as being due to expectation or placebo effects. In a review of peripheral joint osteoarthritis a statistically significant difference between real and sham acupuncture was observed. The difference was interpreted by Manheimer et al. as not being clinically significant and that much of it may be due to expectation or placebo effects [12].

Nevertheless, there is a growing body of evidence to suggest that real acupuncture is better than sham, which may provide clinical evidence that acupuncture has a physiological basis. A recent meta-analysis of data from nearly 18,000 patients demonstrated a statistically significant difference between real and sham acupuncture. "Patients who received acupuncture had less pain, with scores that were 0.23 (95% CI, 0.13–0.33), 0.16 (95% CI, 0.07–0.25) and 0.15 (95% CI, 0.07–0.24) SDs lower than sham controls for back and neck pain, osteoarthritis, and chronic headache, respectively" [13]. However, due to the relatively small effect size of real acupuncture compared to sham, controversy remains.

Methods

Preliminary reading on the current status of acupuncture research identified the development of a placebo control as one of the key challenges faced by the acupuncture research community [14–18]. Commentaries and papers questioning whether or not these controls should be considered as placebo have for the most part focussed on the potentially meaningful physiological responses that they may induce [5–9]. In a commentary on a recent White Paper, by the board of directors the Society of Acupuncture Research, Alraek and Birch note that the description of superficial needling as a sham control derives from a lack of knowledge of the practice of acupuncture [19]. Consequently, we perceived the need to review these controls primarily from the perspective of Chinese medicine in addition to the biomedical perspective.

Reviews that examine the different types of sham–placebo control procedures were studied to identify the different types sham–placebo acupuncture controls previously used in clinical trials [4,9,10,16,20].

Results

The reviews described the same sham–placebo acupuncture controls [4,9,10,16,20]. They varied only in minor differences in terms of expression. For example Langevin et al. identify the 'degree of insertion' as one form of control, this refers to non-insertion and depths believed to be suboptimal [16]. Dincer and Linde use invasive and non-invasive controls as two categories. The category of invasive controls includes three forms of control superficial needling of 'true' acupuncture points, irrelevant acupuncture points and the use of non-acupuncture points [20].

The five reviews all identified the following four characteristics of sham–placebo acupuncture controls. These characteristics are used either individually or in combination [4,9,10,16,20].

i. *Shallow needling*: the needles are not inserted as deeply as the perceived 'real' treatment
ii. *Non-penetrating needles*: the best known is the Streitberger needle that performs like a theatre knife, the shaft recedes into the handle rather than penetrating the skin
iii. *Non acupuncture point*: the needles are inserted at locations away from traditional acupuncture points
iv. Needles are inserted at acupuncture points that are not traditionally indicated for a particular condition

Other types of controls were also identified, for example pseudo interventions such as switched-off lasers and TENS machines [4,20]. There are also attempts to control for other attributes associated with traditional acupuncture such dialogue with the practitioner and palpation. This review focuses on the use of needles as sham–placebo controls.

Shallow needling: the needles are not inserted as deeply as the perceived real treatment

The developments of sham acupuncture techniques have aimed to minimise the physiological effects [21]. By inserting the needles only to a shallow depth without any further stimulation to produce a sensation of tingling or aching (deqi) it is thought less likely to produce a physiological response. However, it is important to note that shallow needling is not a physiologically inert procedure [5,9].

Whilst shallow insertion cannot be considered a placebo in terms of biomedicine some commentators assert that in terms of traditional acupuncture it should be considered a placebo

technique. Singh and Ernst state that in traditional practice 'the penetration depth varies from 1 cm to over 10 cm' [22]. Furthermore that 'superficial needling would seem like the real thing to patients. . .but according to Chinese medical theory it should have no medical benefit because the needles would not reach the meridian'[22].

Their understanding of traditional practice is mistaken. The routine depth of needling differs between different styles of acupuncture. For example, Japanese acupuncture employs routine shallow needling of 1–2 mm [23]. The notion that deeper insertion is more authentic may stem from current practice in China. In traditional Chinese medicine (TCM), the mainstream style in China today, deeper needling is usually considered to be standard practice. However, even this notion is something of a shorthand way of describing how TCM differs from other styles, such as the more shallow insertion of the Japanese tradition. There are numerous points on the body where it is not physically possible to insert a needle to the depth of 1 cm, for example those on the head or at the end of the fingers. However, practice is yet more nuanced. The depth of insertion, as taught in China today, may vary depending on the presenting signs and symptoms [24]. The use of shallow needling has a long tradition, Cheng quotes a 2000 years old text the Yellow Emperor's Internal Classic, 'shallow insertion is used to treat muscle spasm caused by cold' [25]. Indeed routine deep insertion may even be a characteristic of modern practice. The manufacturing of needles has greatly improved. Needles are now sharper, finer and far less likely to break, and so deep needling is now safer. In summary, shallow insertion cannot be considered a sham technique in terms of traditional practice.

Finally within the evidence base of acupuncture, superficial insertion has been assigned to both real and sham acupuncture. For example, in systematic reviews conducted in the late 1990s one review included trials with superficial needling as the sham procedure [26]. A year earlier the same authors included a trial with superficial needling as the real acupuncture in their review of acupuncture for back pain [27].

Non-penetrating needles

The best-known non-penetrating method is the Streitberger needle that is designed to perform like a theatre knife (the shaft recedes into the handle rather than penetrating the skin). It creates a sensation that to the patient feels as if the needle has been inserted. However, because it does not actually penetrate the skin it is considered a sham acupuncture technique.

Many of the criticisms that can be levelled at shallow needling as a form of sham acupuncture can also be made of the non-penetrating needles. Firstly, from the biomedical point of view the needle applies pressure to the skin and as such produces a physiological response [5]. The pressure applied by the Streitberger needle can on occasions cause the needle to pierce the skin [9]. Secondly, from traditional practice point of view it is not true to say the penetration of the skin is always thought to be essential, for example in some forms of Japanese acupuncture non-penetrating techniques are used [28]. Furthermore, there are massage techniques that use simple pressure on acupuncture points, such as tuina, shiatsu and acupressure.

Non-penetrative procedures have also been classified as real acupuncture in clinical research. In a review of the use of the acupuncture point P6 for post-operative nausea and vomiting (PONV) a number of methods of point stimulation have been included such as the non-penetrative acupressure wristbands [29]. This review was positive in favour of acupuncture, with no clear difference between penetrative and non-penetrative acupoint stimulation. [30]

The hypothesis that non-penetrating needling is a sham method is based primarily on a biomedical view of the body not on a review of traditional practice. Namely, that acupuncture analgesia is derived in part from the activation of different pain inhibiting systems; in the frontal cortex and limbic structures as well as through the activation of descending inhibition. Also, part of the effects of needling may in a biomedical perspective be attributed to peripheral inhibition mediated by the release of adenosine.

Many traditional practitioners believe that a dull aching/tingling sensation (deqi) experienced by the patient is an important element of good practice. Similar sensations are felt whether the Streitberger or standard acupuncture needle is used [30,31]. Therefore, the awareness of these sensations may also be relevant component of the therapeutic effect and if so the Streitberger needle is not a placebo.

The Streitberger needle is not the only non-penetrating acupuncture sham control there is a similar device [32]. Others have used a blunt needle especially fashioned from a standard acupuncture needle [33]. It seems unlikely that the application of this particular sham acupuncture technique has radically different physiological effects when compared to the blunt non-penetrating needles that can be bought for use by traditional practitioners. (http://www.harmonymedical.co.uk/category/407-dermal-needles).

Understanding whether needle insertion or depth of insertion has a role to play in the therapeutic effect are important research questions. However, describing the non-penetrating or shallow insertion acupuncture as sham–placebo means that the research questions are not being clearly stated. It should also be born in mind that according to traditional practice the depth of insertion required for optimum benefit will vary depending on the presenting signs and symptoms. In other words one person's back pain may respond better to shallow insertion whereas another person may require deeper insertion.

Non acupuncture point: the needles are inserted at locations away from traditional acupuncture points

This form of sham acupuncture may be regarded as a more valid method of testing traditional theories than purely superficial needling. This is because all traditional styles of acupuncture do recommend placing needles in specific locations on the body. In recent years, a number of trials have used superficial and off point needling in combination.

Some commentators believe that according to the traditional theory misplaced needles cannot 'tap in to the body's meridians' [22]. Trials that have used this sham technique have typically studied musculo-skeletal pain. However, for many traditional practitioners, when treating pain the key is to use a-shi points not the meridian points. A-shi points are simply places that are tender on pressure. In order to locate these points, the practitioner needs to palpate the affected area. The tender points may or may not coincide with a meridian point. As such, traditional acupuncture encompasses the idea that any point on the body can be an acupuncture point. Cheng quoting from the Yellow Emperor's Internal Classic states, 'Where there is pain there is an acupuncture point' [25].

The way in which any point on the body can treat pain and influence the meridian system has a long established theoretical explanation. In traditional practice the meridian system is in fact a lot more elaborate than the familiar 12 meridians depicted on acupuncture charts [34].

Firstly, the Chinese word often translated as meridian is Jingluo (经络) which actually refers to two concepts, Jing and Luo. Jing are the main pathways that are depicted on the charts that are now familiar to many people. Luo means 'net shape' and indicate smaller channels that spread beyond the main meridian. The relationship is similar to the relationship between the arteries and capillaries. According to traditional theory the entire body is connected to the meridian system.

Secondly, the traditional theory of meridians is yet more complex. There are different kinds of meridians beyond the main meridians and the Luo. Of particular importance here are the muscle meridians. These loosely follow the pathways of the main meridians but are much wider than the narrow meridians depicted on acupuncture charts [25,34]. Consequently sham points located a few centimetres away from a classical point may still be affecting the muscle meridian. Muscle meridians are used to treat pain and stiffness [25], the very conditions that most acupuncture research has so far concentrated on. Moreover, needles *should be* inserted superficially in order to stimulate the muscle meridians [34]. Therefore, from the point of view of traditional practice deep needle insertion in some cases would be considered less effective rather than being essential.

In TCM the treatment of painful conditions requires needling locations at, and close to, the site of pain. Consequently, designing a research protocol that uses non-acupuncture points as the sham control requires careful consideration. How far from the site of pain can the needles be placed whilst at the same time convincing patients that they are receiving an active treatment? A large clinical trial investigating acupuncture for lower back pain used sham points on the lateral aspect of the back, some distance from the Bladder Tai Yang meridian that would typically be used [21]. These locations appear to be on the Shao Yang muscle meridian and as such, according to traditional theory, might be thought to have some effect. However, the selection of these locations could not be said to be good practice. A study on knee pain by Suarez-Almazor et al. used sham points much closer to traditional acupuncture points; that would usually be indicated for the knee pain [35].

Accuracy of point location

Research has shown that there is variation in actual point location when practitioners attempt to locate a specific point on the arm [36]. An elliptical area of approximately 8 cm^2 is required to ensure 95% confidence that the practitioners have inserted the needle in the 'same' location [36]. Therefore, it seems reasonable that sham acupuncture points should not be within a similar sized ellipse of a traditional point.

The sham acupuncture points used by Suarez-Almazor et al. [35] can be compared with the location of traditional points on the Stomach Channel, see Fig. 1a. If it is assumed that the points were in fact located with an 8 cm^2 ellipse, we cannot be confident that there was any difference between the real and sham acupuncture. Knee pain is one of the main uses for ST 34 and ST 33. ST 37 is indicated for knee in some traditional texts [24]. Suarez-Almazor et al. claim that the sham acupuncture points lay outside the relevant meridian. However, if the knee pain was accompanied by sciatica then it is possible the sham point AC-LE2 would have been a better point to use than SP 9; SP 9 was part of real acupuncture protocol [35]. Fig. 1b shows the location of the Stomach muscle meridian. The 'sham' points used fall within the Stomach muscle meridian and as such would be thought effective according to traditional theory.

The correct location acupuncture points

Another level of complexity to off-point sham acupuncture is the difficulty in ensuring that the 'correct' locations of the real acupuncture points are consistently employed. Researchers try to ensure consistency in finding the correct anatomical location. However, a consistent anatomical location is not necessarily following best practice in terms of traditional theory.

Many modern textbooks give seemingly unambiguous descriptions of point locations. However, if we look at older Chinese descriptions of acupuncture point locations we can see they are, by modern standards, vague.

For example, LI7 (Wenliu) according to the Great Compendium of Acupuncture and Moxibustion (1601) is located *between 5 and 6 cun behind the wrist* (在腕后五寸,六寸间) [37]. This indicates that the acupuncture point was not perceived as having an absolute fixed anatomical location. Whereas a modern text book offers a more detailed and clear cut location: With the elbow flexed, on the medial side of the dorsal surface of the forearm, on the line connecting LI5 and LI11, 5 cun above the crease of the wrist [38].

It may be the case that originally point locations were considered as general guidance, with the assumption that the practitioner would be able to palpate the most suitable/tender location. This conception of this meaning of acupuncture-point locations is derived from one of the author's (IA) clinical experience in China and Japan. For example GB21, the point description indicates that it is located mid-way between the high point of the acromion and the lower border of C7. However, in practice the acupuncturist will palpate to assess the location which is most tense/knotted, which may be at the mid-way point or slightly to one side. Good practice for many practitioners would be to select the tense point not the strict anatomical mid-point.

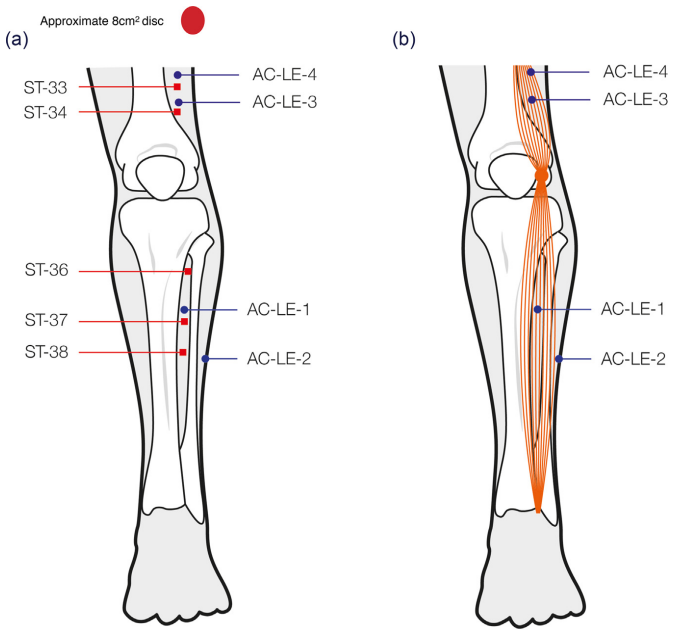

Fig. 1. (a) Comparison of 'sham' acupuncture points (AC-LE 1–4) according to Suarez-Almazor et al. with traditional acupuncture points on Stomach Channel ST33-ST38. (b) Comparison of 'sham' acupuncture points (AC-LE 1-4) according to Suarez-Almazor et al. with Stomach muscle meridian.

We know practitioners do not locate points in exactly the same place and that the traditional notion of an acupuncture point may not be a fixed anatomical location. However, what remains unknown is the importance of accurate location. Does the strength of the effect fall off gradually as one moves away from the ideal position or is it an exponential decline? Therefore we cannot be sure to what extent the real acupuncture delivered in any trial is inferior to optimal practice.

Non-acupuncture point sham procedures are probably the best form of control intervention to test the importance of the traditional idea of acupuncture points. However, results still need to be interpreted with caution due to the ambiguity of the extent to which the sham procedures can be considered sham, and the real acupuncture differs from the optimum.

Acupuncture points that are not traditionally indicated for a particular condition

The notion that individual acupuncture points have specific functions is a belief common to all traditional styles of practice. However, due to the complex and diverse nature of traditional practice, designing trials to investigate these functions is especially difficult. In traditional practice it is rare to use one specific point in isolation for a particular condition. It is commonly thought that a combination of points tailored to an individual will lead to better outcomes. In addition, the perceived functions of points may vary between different styles of practice.

One point, P6 (neiguan) located on the medial aspect of the forearm just above the wrist has been investigated far more than any other acupuncture point. The specific function attributed to P6 is that it reduces nausea and vomiting. Strong clinical evidence exists for the effectiveness of P6 in treating post-operative nausea and vomiting (PONV) [29]. The amount of research evidence regarding P6 is unique. The generation of this evidence is probably due to the convergence of a number of factors. Factors such as the need to find a non-pharmacological solution to PONV; easy access to the location compared to other points [39]; and a certain amount of serendipity that led researchers to begin the process of investigation. Nevertheless, it does illustrate that under the right circumstances point specific functions can be investigated.

Placebo controls to identify a specific physiological effect

The key reason for placebo-controlled trials is the need to establish that any particular therapy has more than a placebo action. It is not appropriate to compare dosage or formulation until it has been established by means of a placebo-controlled trial that dosage and formulation could have anything to do with the intervention's therapeutic effect [4]. A placebo-control is needed to provide evidence that will lead to the inclusion of acupuncture in clinical guidelines, such as the National Institute for Health and Clinical Excellence (NICE) [2].

A large-scale meta-analysis of acupuncture for painful conditions demonstrates not only that acupuncture provides clinical benefits when compared to usual care but also there is a statistically significant difference between the sham procedures and real acupuncture [13], providing evidence that there is a physiological basis for acupuncture. Nevertheless, due to the relatively small effect size of acupuncture when compared to the so-called sham procedures detractors feel the results are primarily due to the placebo [40].

The judgement of what constitutes a clinically significant effect size is a subjective decision. In the case of acupuncture research, it should be remembered that there is no simple dichotomy between real and placebo intervention. As has been described above: sham controls using non-acupuncture point procedures may inadvertently have used relevant traditional points; acupuncture is customarily simplified from standard practice in order to develop a protocol for an RCT; non-penetrating needle techniques may be physiologically similar to sea-sickness bands which have been defined as real acupuncture and shown to be effective for nausea. All of these factors will tend to narrow the gap between the real and the so-called sham–placebo controls, i.e. reduce the effect size. Interestingly, the effect size of acupuncture compared to sham is similar to NSAIDs when compared to placebo [41]. In summary, the sham-controlled trials have compared different formulations. The fact that different formulations lead to different outcomes indicates there is a physiological basis. The judgement of what constitutes a clinically significant effect size should not be based on an understanding that acupuncture has been compared to physiologically inert procedures and that these procedures should have no clinical effect according to Chinese medicine. Judgement should be made on the basis that all acupuncture placebo controls are physiologically active and according to Chinese medicine theory would also be expected to provide some clinical benefit.

It is assumed that the physiological effects of any intervention will be more stable than its placebo component. The outlook of the individual, current fashions, and media hype etc. will affect the placebo component [4]. One may ask whether acupuncture enjoys particularly strong placebo effects in Western countries in the 21st century? Given its lack of plausibility according to the current understanding of biomedicine, is it not equally possible that the placebo effect accrued by acupuncture is at a low ebb? Would not the placebo effect have been stronger in China in the 2nd century or Japan in the 16th century? If the proven clinical benefits are due primarily to the perceived less stable placebo-psychological effects then they appear to be remarkably adaptable to different historical and cultural contexts.

Placebo controls to investigate traditional theory

Acupuncture has its provenance in Chinese medicine and is associated with theories that are deemed, by some, to be unscientific. Consequently, attempts are made to evaluate the validity of traditional theories based on the evidence of RCTs.

In a review of trials comparing the use of acupuncture points with needling at incorrect places for a variety of conditions Moffet found that there were no studies that observed sham acupuncture to be more efficacious than true acupuncture [42]. Of 28 trials, 13 showed a statistically significant result in favour of using acupuncture points whereas in 15 trials no difference was observed. Moffet suggests that these results cast doubt on the validity of traditional theories, as more trials (58%) showed no significant difference. However, of the 15 trials that showed no difference between sham and real acupuncture, 6 resulted in no overall statistically significant improvement in the condition [42]. If there is no statistically improvement for either real or sham acupuncture procedures this may be due to a variety of factors such as inadequate acupuncture intervention, underpowered studies or investigating a condition for which acupuncture is ineffective. Of the six trials identified by Moffet as showing no statistical improvement for either acupuncture or sham acupuncture; one is a pilot study which,actually indicated a trend in favour of acupuncture [43]; another was a prospective study which actually indicated significant benefits for real acupuncture compared to no treatment [44]. We suggest a trial with no improvement due to acupuncture or sham acupuncture fails to shed light upon the relative benefits of using traditional points. If the 6 trials that show no improvement are removed. The rather simple calculation now tilts in favour of using traditional points. In 13 trials statistically significant results in favour of using traditional points were obtained, compared to 9 trials where there was no statistical significance and 0 trials in favour of sham.

In order to further investigate the value of using traditional acupuncture points meta-analyses of trials that used non-acupuncture point sham interventions should be carried out. However, criteria need to be developed to evaluate the sham acupuncture points used. The evaluation should be based on attributes such as their distance from the real acupuncture points and potentially relevant muscle meridians. This would enable reviewers to reject trials that used sham interventions that were too similar to real acupuncture. This would also allow another level of analysis to be undertaken within systematic reviews where sham protocols that are hypothesised to be more active can be compared to those that thought to be less effective.

Sham stimulation methods

The proximity of the sham points to commonly used acupuncture points in the Suarez-Almazor et al. [35] trial is clearly problematic. However, there are other aspects of the sham and real acupuncture protocols where it is not clear why one procedure should be considered active and the other inactive. Suarez-Almazor et al. claim that the needles were inserted more shallowly than the true acupuncture, however, this was not quantified. Moreover, as electro-acupuncture was used it is unlikely that shallow insertion was consistently applied, as the needles will not take the weight of the attached electrodes unless they are inserted relatively deeply. The two procedures also differed in the electrical stimulation as follows: For the real acupuncture, TENS was set to emit a dense disperse wave impulse at 50 Hz, dispersing at 15 Hz, 20 cycles/min. Patients rested for 20 min

with continuing TENS. For sham, instead of a dense disperse wave, a 40 Hz adjustable wave was used. Voltage was increased until the patient could feel it and then immediately turned off. There is evidence that different frequencies produce different physiological effects [45]. However, no rationale is given to justify why one frequency should be considered real whilst the other sham. It is also assumed that 20 min of electrical stimulation is effective whilst a shorter period of time is not. Yet it is common practice for needles to be stimulated manually only for a short time and then the needles are retained for about 20 min. Consequently, the effects of the sham procedure may be more physiologically similar to a *traditional* treatment than the real acupuncture.

The deqi sensations

Placebo controls should be psychologically credible but physiologically inert [4]. The desire to meet these two objectives has lead to inconsistency between acupuncture controls. Shallow needling sham tries to avoid the patient experiencing sensations of aching/tingling at the site of needle insertion, known as deqi. The rationale being that this will minimise the physiological effects [46]. Conversely, it is also argued that for non-penetrating shams the deqi sensations are a good attribute, because they ensure the processes have greater psychologically credibility [31]. (Note: some ideas of deqi include the sensations felt by the practitioner.)

The patients' awareness of not just deqi but the overall experience of treatment may well be of central importance to therapeutic benefit. Detractors of acupuncture have argued that light touch cannot have any relevant physiological effects because this would mean that we would in effect be receiving acupuncture treatments all the time, due to various contacts in daily life [22]. Consider two situations. The shoes that someone wears will exert a certain amount of mechanical pressure on different parts of their feet, the outer edge of the small toe for example. On a day-to-day basis, the first situation, the individual is completely unaware of this light pressure. In the second situation they lie down and relax and a second person gently touches the outer toe. The individual will most likely be very aware of the touch. The response to the pressure will also be modified by factors such as the relationship between the two people, the length of time pressure is applied and whether the room is quiet or not.

Encouraging the development of 'awareness' of the body is a standard part of Qi Gong practice. In Chinese medicine theory the 'awareness' of the body is thought to be therapeutically beneficial [47]. Some practitioners believe that asking patients to do breathing exercises during treatment will enhance the effects. In clinical trial reports it is often simply stated that deqi was obtained. However experience shows it is unlikely that all patients did in fact experience deqi sensations around all needles. In the future nested qualitative studies investigating the patient experience of deqi and the wider treatment process may help shed light on responders and the relative values of deqi and setting.

Physiological effects of sham acupuncture

Acupuncture sham–placebo controls have been developed using assumptions regarding three variables of the needling process, location, depth and deqi. It has been assumed that deeper needling and stronger local sensations mean more effective treatment. As has been described above these assumptions cannot be justified in terms of traditional practice. The notion of acu-point location has also been over simplified. However, it is also the case that current understanding of the physiological effects of the sham needling techniques does not support these assumptions.

Peripheral effects

In *healthy subjects* sham acupuncture (using sham acupuncture needles like the Streitberger needles), activates mechanoreceptors in the skin that conveys the information of light touch to the brain [5–7]. This information is transmitted both in A-beta afferents as well as in C- (non-nociceptive) afferents [5–7] Interestingly from a mechanical/pressure perspective the sham acupuncture procedure evokes a stronger and more widespread response as compared to superficial or deep needling suggesting that it is a "stronger" mechanical stimulus as compared to tapping with the tip of an acupuncture needle (pin prick).

In patients with pain, for example inflammatory burn pain, sham acupuncture activates the same mechanoreceptors, but now the response is perceived as being stronger (hyperesthesia) or even painful (allodynia). This is due to peripheral and central sensitisation. Static (pressure) and dynamic (stroking and/or tapping) allodynia is transmitted via different sensory neurons within the peripheral nervous system. Static allodynia is signalled by nociceptive A delta fibres and involved in central sensitisation, but it may also involve C-fibres (nociceptive) neurons as well as activation of silent nociceptors. Dynamic allodynia is independent of C-fibres activation and is mediated by A-beta fibres activation [48].

Therefore, the peripheral effects of sham acupuncture are dependent on the condition treated. A sham procedure that may evoke sensations of light touch, intense touch (hyperesthesia) or even pain (allodynia) should not be termed sham. It is therefore tempting to suggest that sensory testing (determining the mechanical pressure threshold) should be part of future acupuncture trials carried out.

Central effects

In *healthy subjects* sham acupuncture evokes a light activity in the somatosensory cortex (SI) and an increased activity in the reward system, Fig. 2. Also, decreased levels of stress hormones have been reported after tapping on the skin using a procedure similar to the one used during sham treatment with the Streitberger needle [49].

The visual aspects of seeing the sham (or the verum treatment) procedure being carried out also needs to be considered. When asked to judge, the presence or absence of light tactile stimuli, participants often report a touch experiences even when

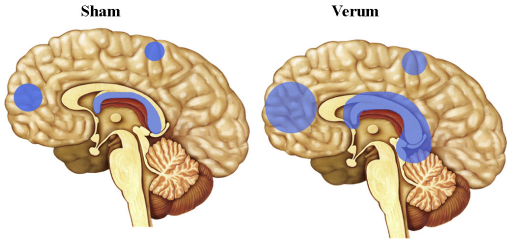

Fig. 2. Schematic illustration of the effects of sham vs. verum acupuncture on brain activity. Areas of activation and/or deactivation.

no tactile stimulation had been delivered. It has been suggested that this may be attributed to the activation of an illusory tactile representation in the medial prefrontal cortex [50]. In subjects that previously had been subjected to acupuncture, deqi was commonly reported following light tapping of the skin (sham acupuncture). This suggests that visual cues and previous experiences of acupuncture may influence the effects of the sham procedure.

In *patients* with pain, sham acupuncture may increase or decrease the pain depending on the degree of central sensitisation. In patients with migraine and fibromyalgia (conditions characterised by central sensitisation) sham acupuncture may actually be more effective as compared to verum acupuncture. It is likely that verum acupuncture (evoking deqi) is a too strong stimulus in some of these patients as it results in the activation of limbic structures and more pain [6] (cf. Harris personal communication) (Fig. 3).

This emphasises the importance of determining the sensitivity of the patient (at least pain patients) before the treatment. In patients with itch the verum and sham effects are more easily separated [51].

Controversy remains regarding the mechanisms of verum and sham acupuncture analgesia. A theory is that it partly involves the activation of endogenous opioid anti-nociceptive systems and mu-opioid receptors (MORs) [52] Interestingly, findings suggest that divergent MOR processes may mediate clinically relevant analgesic effects of verum and sham acupuncture [52,53].

Other "sham techniques" using incorrect points or distant points are not valid as shams as they do set up activity that may result in deactivation of areas involved in the central processing of the complaint (pain, itch, etc.), i.e. the cognitive aspect as well as deactivation of limbic structures, i.e. the affective aspect of the complaint [7,51,53].

Recommendations for future research

Systematic reviews play a fundamental role in the development of clinical guidelines. Greater care needs to be taken in evaluating sham–placebo procedures in systematic reviews and meta-analyses. 'Comparing and interpreting the results of trials with totally heterogeneous interventions by regarding them simply as "placebo-controlled" is highly misleading and scientifically unacceptable' [20].

In recent years the necessity to evaluate the quality of acupuncture delivered in clinical trials has become increasingly recognised. This has lead to the development of the STRICTA Guidelines [54] for reporting clinical trials, which includes the need for a clear description of the sham–placebo procedure. The process of developing an instrument to assess the quality of the acupuncture procedure has already begun [55]. Additionally, it is also important that the sham–placebo procedures are also appraised by using appropriate guidelines.

The development of guidelines will clarify some of the ambiguities surrounding the terms sham–placebo-minimal acupuncture. There is a need for standardisation. Because

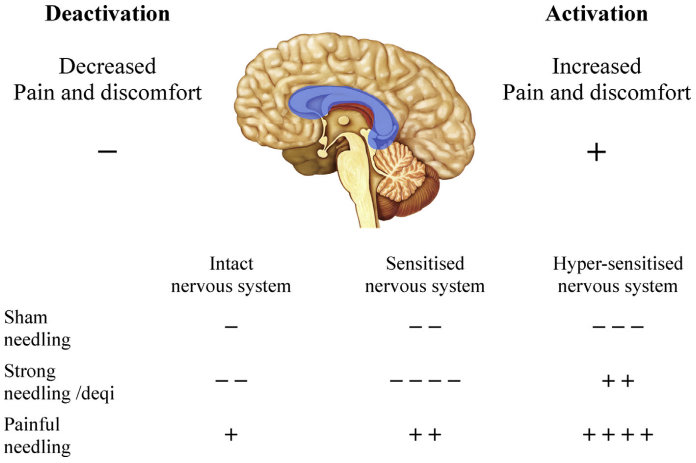

Fig. 3. Schematic illustration of the different responses seen in the limbic structures following needling.

non-penetrative procedures cannot be considered inert in terms of traditional practice or biomedicine, it may be necessary to develop new terms, for example non-penetrative control or off point shallow control. Acupuncture control assessment guidelines would encourage the evaluation of the results that employed similar control procedures. It would also enable results that used different control procedures to be compared. Assessing the sham–placebo procedure should be done both in terms of traditional practice as well as biomedical physiology.

Potentially sham–placebo procedures could be classified on their potential to have a physiological therapeutic effect. There is a clear risk of bias if the placebo control is too similar to the real acupuncture.

The development of guidelines to evaluate sham–placebo acupuncture controls should:

- Enable results from RCTs to be combined more effectively
- Help clarify the specific hypothesis being tested in terms of physiology
- Help clarify the specific concept being tested in terms of traditional Chinese medicine
- Stimulate greater awareness of complexity of acupuncture research which will lead to a better understanding of the evidence base for acupuncture

Conclusion

The term sham acupuncture has become confused with a placebo control. There have been no genuine placebo-controlled trials in acupuncture. The sham-controlled trials have in reality compared different acupuncture formulations. In essence, these are comparative effectiveness trials. The fact that different formulations have lead to different outcomes indicates there is a physiological basis for acupuncture.

Research into acupuncture has historically been poorly funded. Consequently, reviewers have been confronted with a lack of evidence upon which to base judgements. This may have lead to trials of poor methodological rigour and acupuncture protocols with weak external validity being included within systematic reviews. In some areas such as chronic pain the quality of the evidence base has improved greatly over the last decade. Nevertheless, the notion of sham–placebo acupuncture remains an aspect of research that needs more rigorous evaluation. Clear guidelines to assess acupuncture control procedures will improve the quality of RCTs and systematic reviews. These in turn will provide a more reliable evidence base for clinical guidelines.

Financial support

None.

Conflict of interest

None.

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Appendix A2: Appleyard et al (2016) - Warm needle acupuncture vs. needle acupuncture for osteoarthritis of the knee: A pilot study protocol

European Journal of Integrative Medicine 8 (2016) 407–413

Contents lists available at ScienceDirect

European Journal of Integrative Medicine

journal homepage: www.elsevier.com/eujim

Research paper

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

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ARTICLE INFO

Article history:
Received 6 July 2016
Received in revised form 30 July 2016
Accepted 31 July 2016

Keywords:
Acupuncture
Moxibustion
Moxa
Warm needle
Randomized controlled trial
Protocol
Complex intervention

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.

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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http://dx.doi.org/10.1016/j.eujim.2016.07.031
1876-3820/

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 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

reviews [3,4]; treatment protocols that have been used in trials investigating warm needle acupuncture for osteoarthritis of the knee published in Chinese.

3.2.1. 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

3.2.2. 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.

3.2.3. 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 min.

3.3. 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.

3.4. Randomisation

Participants will be randomised to receive either warm needle acupuncture or needle acupuncture. An independent statistician based at London South Bank University 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.

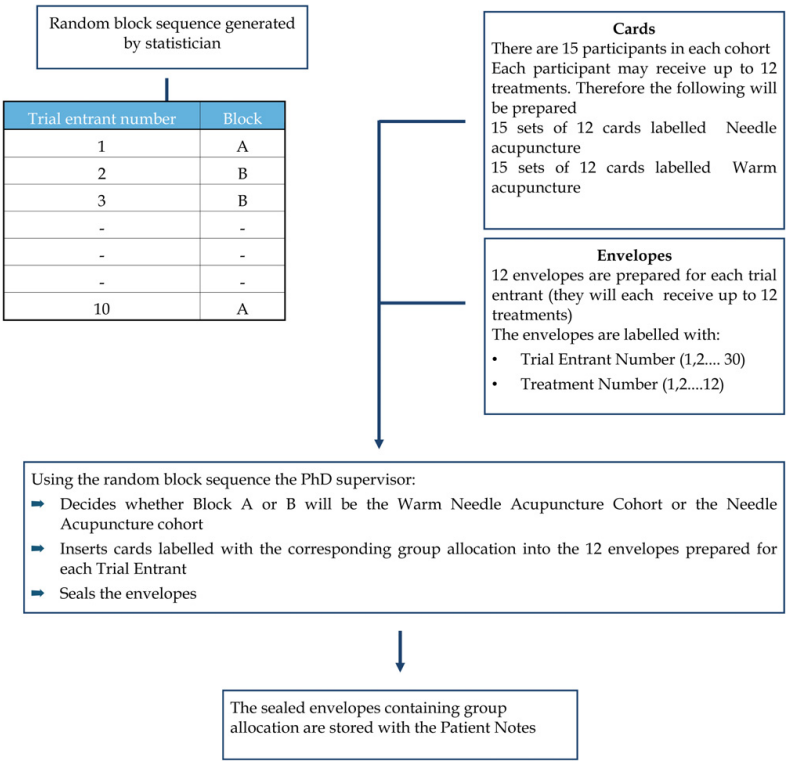

Fig. 1. Preparation of sealed envelopes.

3.5. Blinding

3.5.1. 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 Fig. 1: Preparation of sealed envelopes

3.5.2. 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 will be 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 will leave the room and the assistant acupuncturist will enter. 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

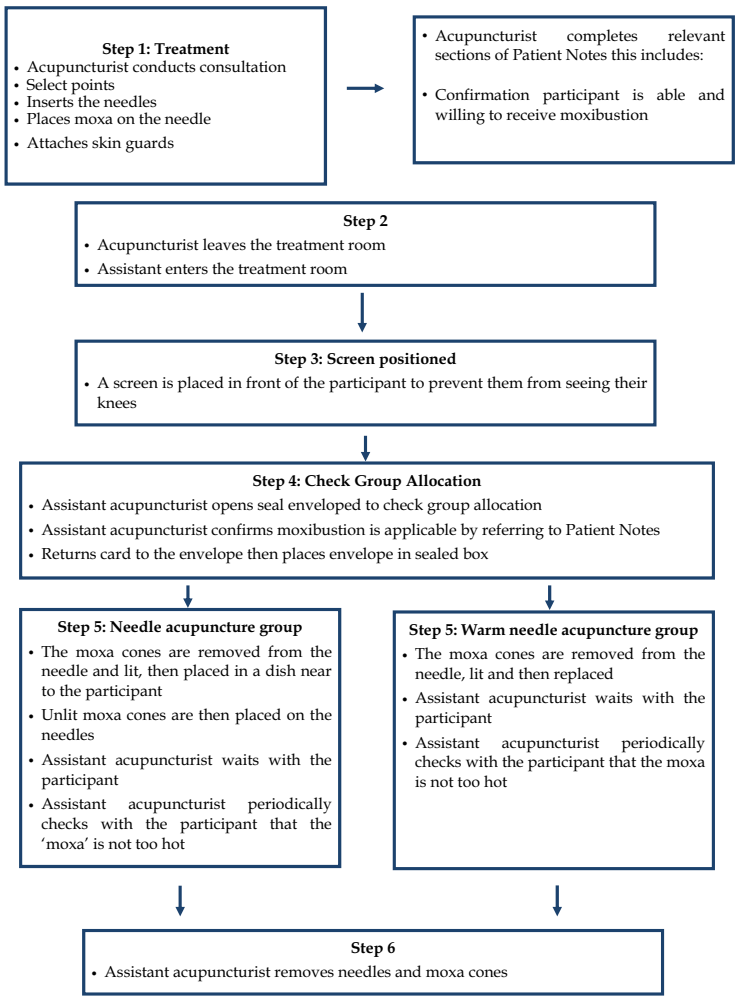

Fig. 2. Blinding procedure.

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 Fig. 2: Blinding procedure

3.6. 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 which will assess 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).

3.6.1. 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
4. This question is asked at the fourth treatment.
5. How confident do you feel that this treatment can alleviate your knee pain? very confident/confident/slightly confident/not confident/don't know.

3.6.2. 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 for 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.

4. 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 of 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 to 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 would not be 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.

Conflict of interest

Acupuncturist and lecturer in Acupuncture at London South Bank University.

Trial registration

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

Funding sources

Funding has been received from British Acupuncture Council (BAcC), 63 Jeddo Road, London W12 9HQ: Reference: BACCR-G_2014IA

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

Acknowledgement

Confucius Institute for Traditional Chinese Medicine at London South Bank University supports the study by providing clinical facilities and staff time.

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Appendix A3: Jun et al (2016) Warm needle acupuncture for osteoarthritis: A systematic review protocol

European Journal of Integrative Medicine 8 (2016) 402–406

Contents lists available at ScienceDirect

European Journal of Integrative Medicine

journal homepage: www.elsevier.com/eujim

Research paper

Warm needle acupuncture for osteoarthritis: A systematic review protocol☆

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ARTICLE INFO

Article history:
Received 10 June 2016
Received in revised form 28 July 2016
Accepted 28 July 2016

Keywords:
Acupuncture
Warm needle acupuncture
Osteoarthritis
Systematic review
Protocol

ABSTRACT

Introduction: Warm needle acupuncture (WA) is widely used the treatment in the East Asian countries. However, there is no critically appraised evidence of the potential benefits and harms. The purpose of this systematic review will be to evaluate the efficacy of WA for osteoarthritis (OA).
Methods and analysis: Electronic databases will be searched: MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL) and AMED, 6 Korean medical databases (Korea Med, the Korean Traditional Knowledge Portal, OASIS, DBPIA, the Research Information Service System and the Korean Studies Information Service System), 3 Chinese databases (CNKI, VIP and Wanfang) and a Japanese database (CiNii Articles) will be searched from their inception. These will be searched from their inception. Selection of the studies and data extraction and validation will be performed independently by two reviewers. Randomised controlled trials (RCTs) and quasi-RCTs using WA for any type of OA will be considered. The studies will independently undertake study selection, extraction of data and assessment of study quality by two authors. Risk of bias will be assessed using the Cochrane risk of bias standards. All data synthesis and subgroup analyses will be conducted using Review Manager Software.
Dissemination: Findings will be published in a peer-reviewed journals. This systematic review may inform the treatment of OA patients in clinical practice.

1. Introduction

1.1. Description of the condition

Osteoarthritis (OA) is a structural and functional failure of whole joint [1] and damage to joint cartilage, deterioration of the bone beneath the joint, swelling of the joint with newly formed bone, and mild inflammation of the synovial membrane [2]. Above all, OA is often associated with significant disability and reduction in quality of life [3]. This affects such as the knees, hips, fingers and lower spine. Researchers have reported that the knee joint is affected especially frequently, and the incidence of knee OA is increasing [4]. Unfortunately, the available treatments for OA are not perfect. Therefore, many studies, both pharmacological and non-pharmacological, focus on reducing pain and limitations to patient's daily functioning [5].

1.2. Description of the intervention

Acupuncture and moxibustion have been used as medical treatments in East Asia, including China, Korea and Japan [6]. Moxibustion includes various techniques. There are two types of moxibustion: predominantly divided into direct moxibustion and indirect moxibustion. When performing direct moxibustion, moxa sticks are burnt at acupoints directly on the skin. In contrast, in indirect moxibustion, the moxa cone does not touch the skin and is burnt while being insulated from the skin by some substance [7]. Warm needle acupuncture (WA) is the combination of acupuncture with moxibustion by stimulating acupoints with a burning moxa (also called Ai Ye) stick on the handle of the acupuncture needle [8]. The use of WA was first documented in *Shang Han Za Bing Lun* (*"Discussion of Cold-Induced Disorders"*), a classical Chinese medical book by Zhongjing Zhang (Eastern Han dynasty, 25–220 C. E.) [9]. WA is often used to treat painful conditions such as arthritis,

☆ Trial registration number: PROSPERO 2015: CRD42015024413
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http://dx.doi.org/10.1016/j.eujim.2016.07.030
1876-3820/

especially rheumatoid arthritis and OA [10,11] as well as musculoskeletal pain conditions [12,13]. WA treatment is transmitted to the acupoint by radiation, moreover, by direction conduction through the shaft of the needle, thereby stimulating deep tissue within the acupoint and warming the acupoint on the surface [14].

1.3. How the intervention might work

WA for OA is widely used for treatment and prevention [15,16]. Studies on the treatment of WA on OA have also shown a greater pain relief compared to manual acupuncture [17]. Furthermore, WA has reduced joint fluid and abnormally high serum levels of interleukin-1 beta (IL-1β) and tumor necrosis factor-alpha (TNF-α), two inflammatory factors in patients with knee OA [18].

1.4. Why it is important to do this review

Many studies have been reported treatment using WA treatment for OA in clinical practice [19,20]. One recent review assessed the efficacy of WA for OA but most of included studies have suffered from high risk of bias [21]. The previous review focused on the WA treatment for knee OA and searched Chinese databases only. Furthermore, the review is outdated. Therefore, the aim of this systematic review is to update, complete and critically evaluate the evidence from randomized clinical trials (RCTs) of WA for OA.

2. Methods

2.1. Study registration

This protocol review has been registered on PROSPERO 2015 (registration number CRD42015024413) [22].

2.2. Criteria for considering studies for this review

2.2.1. Types of studies

This systematic review will only include RCTs and quasi-RCTs. Observational, cohort, case reports, case series, non-RCT, animal and experimental studies will be excluded. No language restrictions will be imposed.

2.2.2. Types of participants

Patients suffering from OA will be included regardless of joint location (e.g., chronic condition of the neck, near the ends of the fingers, at the base of the thumb, back, hip, and knee). We will also include patients with both sexes and any age. Included patients will have been diagnosed with OA according to the American College of Rheumatology (ACR) criteria [23–25], the equivalent European League Against Rheumatism (EULAR) criteria [26–28], or the Clinical Guideline of New Drugs for Traditional Chinese Medicine [29]. Studies will be excluded if they include patients with rheumatoid arthritis, ankylosing arthritis, joint tuberculosis, purulent arthritis, allergic arthritis, Kashin-Beck disease or Podagra.

2.2.3. Types of interventions and controls

Studies that evaluate WA as the sole intervention will be included. Warm needle will be defined as moxa being attached to the needle once it is inserted. Traditionally, traditional medicine practitioners usually attach burning moxa to the handle of the AT needle to improve the effectiveness of the therapy. Electro-warmed needles and infrared radiation will be excluded. The combined intervention include western medicine or rehabilitation or physiotherapy, but exclude alternative therapy such as herbal medicine, Tuina, acupuncture. A combined intervention will include western medicine or rehabilitation or physiotherapy, but will exclude any that combines other alternative therapies such as herbal medicine, Tuina, as well as other types of acupuncture.

2.2.4. Type of outcome measures

- Primary outcomes

1) Treatment efficacy: the number of patients whose OA symptoms improved and treatment effectiveness.
2) Pain: associated scale measured on the visual analogue scale (VAS) [30], Western Ontario and McMaster Universities Arthritis Index (WOMAC) of pain [31], a numerical rating scale (NRS), Verbal Rating Scale (VRS), the Faces Pain Scale-Revised (FPS-R), etc.
3) Function of joint: measured by recognized scales including Western Ontario and MacMaster universities arthritis index (WOMAC), Lequesne score, etc.

- Secondary outcomes

1) Quality of life (QoL): measured using a validated questionnaire, such as the short-form (36-item) health survey (SF-36) [32] or another validated scale.
2) Adverse events.

2.3. Search method for identifying the studies

2.3.1. Electronic searches

Electronic databases will be searched from their inception and will include MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL) and AMED, 6 Korean databases (Korea Med, the Korean Traditional Knowledge Portal, OASIS, DBPIA, the Research Information Service System and the Korean Studies Information Service System), 3 Chinese Databases (CNKI, VIP and Wanfang), and the Japanese database (CiNii Articles). The search strategy will include warm needing acupuncture in English, Chinese and Korean.

2.3.2. Searches of other resources

The authors will scan the reference lists and retrieve additional studies. In addition, authors will search the WHO International Clinical Trials Registry Platform (ICTRP) (http://apps.who.int/trialsearch/) and Google Scholar (http://scholar.google.co.kr/). Dissertations of degrees will be included. The ClinicalTrials.gov registry (http://clinicaltrials.gov/) will be searched for any unpublished trials.

2.3.3. Search strategy

The strategy for searching MEDLINE is described in Appendix A. The strategy for searching CNKI is described in Appendix B. Similar search strategies will be applied to other databases.

2.4. Data collection, extraction and assessment

2.4.1. Selection of studies

Two reviewers (JHJ and TYC) will independently screen the titles and abstracts for searched studies, and perform study selection and record their decisions according to predefined criteria. Another reviewers (MSL) will resolve disagreements of section study. Study selection will be documented and summarised in Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow diagram [33].

2.4.2. Data extraction

Two reviewers (JHJ and TYC) will read studies and independently extract the data using a standard data extraction form. The form will be comprised of type of OA, participants, intervention group treatment, control group treatment, outcome and result. Disagreements of section study will be resolved by another reviewers (MSL). We will use Grading of Recommendations Assessment, Development and Evaluation (GRADE) software to judge the quality of evidence for data from Cochrane Systematic Reviews to create a Summary of Findings table [34]. Additionally, the details of the treatment regimens will be summarised in a table. When reported data are insufficient or unclear, an author will contact the first author or corresponding authors by e-mail or telephone to request missing or clarification data.

2.4.3. Assessment of risk of bias

The quality of included studies will be assessed according to the criteria described in the Cochrane Handbook for Systematic Reviews of Intervention [35]. The following items will be assessed: 1) random sequence generation; 2) allocation concealment; 3) blinding of participants and personnel; 4) blinding of outcome assessment; 5) completeness of outcome data; 6) completeness of reporting; 7) other sources of bias. Each trial will be categorized as having a low (L), unclear (U), or high (H) risk of bias. If necessary, we will contact the authors of assessed trials for clarification. We will resolve any differences in opinion through discussion or consultation with all of the authors.

2.4.4. Data synthesis

All statistical analyses will be performed using the Review Manager (Cochrane Collaboration Software, RevMan) version 5.3. For dichotomous data, we will present the treatment effects and use the risk ratios (RR) with 95% confidence intervals (CIs). For the continuous data, we will use the mean differences (MD) with 95% CIs. If outcome variables are measured on different scales, we will use a standard mean differences (SMD) analysis with 95% CIs.

2.4.5. Unit of analysis issues

The systematic review will include data from parallel-group studies for the meta-analysis. For cross-over trials, the first treatment period of data will be analyzed. In that case if there is more than one control group, each group will constitute a separate unit of analysis. If there are multiple treatment time observations, the data will be analysed as either short term (within 30days) or long term (over 30days). In addition, analysis will be divided into various types of OA.

2.4.6. Assessment of heterogeneity

We will use a fixed model if there is no evidence of heterogeneity; if not we will apply random effect model. If a meta-analysis is possible, we will use the I^2 statistic for quantifying inconsistencies across the included studies. A result 50% cut off point would represent substantial heterogeneity. If heterogeneity is observed, we will conduct subgroup analyses [36].

2.4.7. Subgroup analysis and the investigation of heterogeneity

If studies and data are sufficient, subgroup analyses will be conducted according to:

a Type of OA (e.g, knees, hip, back or fingers)
b Type of control intervention (e.g, western medicine, no treatment or usual care)

2.4.8. Sensitivity analysis

We will use sensitivity analyses to investigate suspected funnel plot asymmetry. Sensitivity analysis will be conducted according to the following criteria:

1.) Methodological qualities (sequence generation, allocation concealment, or blinding in the assessment of outcomes and symptom severity)
2.) Sample size (more or less than 40 participants in each group)

In the analysis, we will exclude high risk of bias studies and compare the results with those using the worst-case scenario to combine studies. Then we will have a discussion to decide whether the high risk of bias studies should be excluded on the bias of sample size, strength of evidence and influence on pooled effect size.

2.4.9. Assessment of reporting biases

If more than 10 studies are available, we will conduct funnel plot for publication bias and small study effects using Egger's method. Funnel plot asymmetry is certainly not same as publication bias. We will attempt to distinguish the possible reasons for the asymmetry, therefore, included poor methodological quality and true heterogeneity of studies [37].

3. Discussion

This protocol for a systematic review will provide a detailed summary of the current state of evidence regarding the effectiveness of the WA in treating the symptoms of patients with OA. The review will be useful to patients and healthcare providers in determining the appropriate role of WA in the treatment of OA.

Contribution of authors

The protocol of a review was drafted by all authors. The search strategy was established by J.H.J., I.A., T.Y.C. and N.R. Copies of studies will be obtained by J.H.J. and T.Y.C. Selection of the studies to include will be performed by J.H.J., J.C. and J.I.K. Lee M.S. will act as an arbiter in the study selection stage. Extraction of data from studies will be conducted by J.H.J., C.J., I.A., and J.I.K. Entering data into RevMan 5.3.0 Version will be conducted by J.H.J. and J.C.I. Interpretation of results will be performed by all authors. The final review will be drafted and revised by all authors. The review will be updated by J.H.J., I.A., N.R., T.Y.C. and M.S.L.

Funding

J.H.J., T.Y.C., J.C. and M.S.L. were supported by the Korea Institute of Oriental Medicine (K162921 and K16111). The authors alone are responsible for the writing and content of paper.

Conflict of interest statement

The authors declare that they have no potential conflict of interest.

Appendix A. MEDLINE search strategy(PubMed)

#1. exp osteoarthritis/
#2. osteoarthr*.tw
#3. (degenerative adj2 arthritis).mp.
#4. arthrosis.mp.

#5. or/#1-4
#6. exp acupuncture therapy/
#7. warm needle thechinique.mp.
#8. warm needle acupuncture.mp
#9. warm needle moxibustion.mp
#10. warm-needling. mp
#11. wen zhen. mp
#12. warm$ acupuncture. mp
#13. or/#6-12
#14. exp Randomized Controlled Trials as Topic/
#15. exp Clinical Trials as Topic/
#16. exp controlled clinical trials as topic/
#17. (randomized controlled trial* or controlled clinical trial* or randomized* or randomly* or placebo or clinical trial* or controlled trial*).mp.
#18. or/#14 – 17
#19. #5 and #13and #18

Appendix B. CNKI search stratege

#1. 温针
#2. 温针灸
#3. warm acupuncture
#4. warm needle acupuncture
#5. warming needle moxibustion
#6./or #1-5
#7.骨关节炎
#8. osteoarthritis OR osteoarthrosis OR ostearthritis OR Degenerative Osteoarthritis OR Knee osteoarthritis OR Hip Osteoarthritis OR spine osteoarthritis OR Lumbar Spine Osteoarthritis OR Primary Hypertrophic Osteoarthropathy OR Atlantoxial Osteoarthritis OR senior osteoarthritis OR anteromedial osteoarthritis OR advanced osteoarthritis OR hand osteoarthritis
#9. OA OR KOA
#10. or/#7-9
#11. 随机
#12. 对照
#13. Randomized trials
#14. or/#11-13
#15. #6 and #10 and #14

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Appendix B: Narrative Review

Appendix B Table of Contents

Appendix-B1: Standard theory - signs and symptoms of the knee

Author	Wind Bi	Damp Bi	Cold Bi	Heat Bi
Legge and Vance, 1997	Soreness in muscles and joints, Pain will move from place to place, pain is varying in intensity, Decreased range of movement	Soreness and heavy sensation of a joint or muscles, numbness in skin over the affected area, pain does not move pain worse in cloudy and wet weather	Pain is the most prominent symptom, no inflammation, pain is fixed in the joint, better for warmth, worse for cold, decreased range of passive movement	Joint pain with redness and swelling, Limitation of movement,
Maciocia, 1994	Soreness and pain of the muscles and joints; limitation of movement; with the pain moving from joint to joint	Pain, soreness and swelling in muscles and joints with a feeling of heaviness and numbness of the limbs, the pain being fixed in one place and aggravated by damp weather	Severe pain in a joint or muscle with limitation of movement, usually unilateral	Pain and heat in the joints which feel hot to the touch, redness and swelling of the joints, Limitation of movement and severe pain
O'Connor and Bensky, 1981	Pain in joints is widespread, moves from one area to another	The pain is localised and does not move. The body and limbs are heavy, there is numbness, oedema	Severe pain one part, all over one half of the body. Worse when exposed to cold, better for warmth.	The flesh is hot, the area of pain is red and swollen. Pain increases on contact
Cheng, 1999	Pain in the joints, especially the wrists, elbows, knees and ankles; limitation of movement	Heavy sensation of the limbs, soreness and fixed pain in the joints, aggravated on cloudy and rainy days	Severe stabbing pain in the joints, Alleviated by warm and aggravated by cold, with fixed localisation but to no local redness and hotness	Arthralgia involving one or several joints, local redness, Swelling and excruciating pain with limitation of movement

Author	Wind Bi	Damp Bi	Cold Bi	Heat Bi
Xu et al., 1988	Pain moving from one area of the body to another, or radiating to a remote area accompanied by pulling sensation and numbness,	Soreness, Pain and heaviness of the limbs; may be induced or aggravated by cloudy, windy, Cold or rainy weather; Slight swelling of the muscles in skin, absence of local redness	Intense pain and a cold sensation; the pain is localised and may worsen with cold and diminish with warmth	Pain, redness, swelling and a burning sensation of the joints, Which are tender on contact and have restricted movement
Zhao, 2002	Describes signs and symptoms of osteoarthritis - not differentiated into bi-syndrome sub-categories			
Zhao and Wang, 2007	Pain in the muscles and joints, limitation of movement, wandering pain with no fixed location;	Pain in the muscles and joints, limitation of movement; aching pain, heavy sensation or swelling of the limbs in joints, aggravated on windy cold cloudy or rainy days	Pain in the muscles and joints, limitation of movement	Pain in the muscles and joints, limitation of movement
Sun, 2000	Pain moves from one joint to another has no fixed location; or there is pain in one particular area radiating to distal area. Dragging and numb sensation that appears like the wind; fear of extending the affected limb, if the limb is extended there is unbearable pain and numbness	The joint is sore and heavy the muscles are slightly swollen, but not red the pain has a fixed location and is made worse in cloudy rainy windy and cold weather	Pain in the muscles and joints, the pain is quite strong, the painful area feels cold, Application of heat reduces the pain, pain is increased by cold. Frequently the pain is relieved by massage	The joints of the forelimbs are sore, Swollen, can't touch the painful area, Limited movement

Author	Wind Bi	Damp Bi	Cold Bi	Heat Bi
Wu and Sheng, 2002	Pain in the muscles and joints of the four limbs, which moves from place to place. Extension and flexion not smooth, always made worse by wind	The joints of the four limbs sore places fixed since especially the lower limbs or there is swelling the skinniest numb on worse on cloudy and rainy days	The pain in the joints of the four limbs is quite strong, it gets worse with a cold the application of heat reduces the pain, the pain is better during the day but worse at night., it is not possible to extend and flex the joint. The painful area is not red and it is not warm to the touch	Abrupt onset painful joints the local area is red and swollen Burning the painful Area cannot be touched, extension and flexion is difficult Cold reduces the pain and is comforting

Appendix-B2: Standard theory - additional signs and symptoms

Author	Wind Bi	Damp Bi	Cold Bi	Heat Bi
Legge and Vance, 1997	Sometimes accompanied by local heat and chills, superficial and rapid pulse, been white sticky timecode	Thick white and sticky tongue coat, soft slow pulse	Thin white tongue coat, deep wiry tense pulse	Fever, thirst, yellow tongue coat and rapid rolling pulse
Maciocia, 1994	Acute cases the pulse floating and slightly rapid	Acute cases the pulse would be slow and slightly slippery	Acute cases the pulse is tight	Acute cases there would be thirst fever which does not abate after sweating and a slippery rapid pulse
O'Connor and Bensky, 1981	There is often fever and chills, rapid pulse and yellow fur on the tongue	Greasy fur on the tongue, moderate pulse	The tongue fur is thin and white, pulse wiry and tight	Mouth and tongue are parched, urine dark, constipation. tongue fur is yellow and greasy, rapid pulse
Cheng, 1999	Chills and fever, Fingers sticky tongue coating, Superficial and tight or superficial and slow pulse	White and sticky tongue coating and soft pulse	Thin and white tongue coating, string taut and intense pulse	Fever and thirst, yellow tongue coating, Rolling and rapid pulse
Xu et al., 1988	The time coating is yellow or light yellow and thin; pulse is superficial and wiry; in some cases chills and fever may also be present	Soreness, Pain and heaviness of the entire body; Are white and sticky tongue coating and a softer pulse	**There may be a** white tongue coating and attends wiry polls	Symptoms may include fever, sore throat and profusely sweating which does not reduce body temperature. There is also a yellow and sticky tongue coating and a rapid pulse
Zhao, 2002	Describes signs and symptoms of osteoarthritis - not differentiated into bi-syndrome sub-categories			

Author	Wind Bi	Damp Bi	Cold Bi	Heat Bi
Zhao and Wang, 2007	sometimes aversion to wind, fever; pale tongue with thin and white coating; floating and slippery pulse	White and greasy tongue coating; soggy and slow pulse	White tongue coating; wiry and tight pulse	Yellow and dry tongue coating; slippery and rapid pulse
Sun, 2000	Sometimes there is accompanying chills and fever, thin white all pale yellow tongue coat, pulse superficial and wiry	Greasy white Tongue coat, soft pulse	Thin white tongue coat, pulse floating and tight	Accompanied by sore throat, hot feeling with increased sweating that does not reduce the body temperature, scant red urine, Think greasy yellow tongue coats soft and fast pulse
Wu and Sheng, 2002	Thin white tongue coat superficial pulse	Soft and leisurely pulse greasy white tongue coated	White and slippery tongue coat tight and wiry pulse	Frequently there is a feeling of heat and an aversion to wind, excess sweating vexation and dry mouth, the time body is red with a yellow coat the pulses slippery and fast

Appendix-B3: Standard theory - mechanisms and aetiology

Author	Mechanism	Further notes	Aetiology
Legge and Vance, 1997	• Invasion of Wind, Cold, Damp • Deficiency of Qi and Blood allows pathogens to invade	• Heat Bi - Wind Cold Damp Bi leads Heat • Long standing Wind Bi can influence the Heart • Bi can progress to affect the zangfu • Major deficiencies Qi, Blood and Kidney	
Maciocia, 1994	• Invasion of Wind, Cold, Damp • Deficiency of Qi and Blood allows pathogens to invade • Cou li - space skin and muscle important • Relative balance of internal external factors	• Heat Bi - Wind, Cold, Damp transform to Heat: likely if there is underlying Yin deficiency • Wind is seen as key pathogen • Internal factors important in elderly • Invasion more likely if joint malnourished • 'Wind' can be a sudden change of weather • Alternative method of classification, Skin Muscle, Tendon, Vessel, Bone Bi	• Not wearing sufficient clothing • Joggers sweating on cold days • Sitting of damp surfaces, wading in water, living in a damp environment • Overuse can weaken the joints • Accidents can predispose people to invasions • Emotions such as stress can play a role in predisposition

Author	Mechanism	Further notes	Aetiology
O'Connor and Bensky, 1981	• Invasion of Wind, Cold, Damp	• Heat Bi - Wind Cold Damp Bi leads Heat • Can effect organs typically leads to Heart Bi	
Cheng, 1999	• Invasion of Wind, Cold, Damp • General weakness of the body and deficiency of Yang Qi • Dysfunction of the pores and weakness of defensive Yang	• Heat Bi - If body constitution is Yang can lead to Heat • Heat Bi - Long-standing Wind Cold Damp Bi leads to Heat • Alternative method of classification, Skin Muscle, Tendon, Vessel, Bone Bi	• Common in areas where the weather is cold, wet and windy • Affects both sexes • Any age
Xu et al., 1988	• Invasion of Wind, Cold, Damp • Body is weak • Body surface is loose	• Heat Bi - Wind Damp Bi can turn to Heat • Prolonged Bi can move inward to affect the organs	
Zhao, 2002	• Obstruction by Wind, Cold, Damp, Heat • Deficiency of Liver and Kidney • Obstruction by Phlegm due to Spleen Deficiency • Long term stagnation of Blood in the joints		• Elderly more likely to be affected

Author	Mechanism	Further notes	Aetiology
Zhao and Wang, 2007	• Invasion of Wind, Cold, Damp • Deficient Root Excess Branch	• Prolonged stagnation transforms into Heat (apparent typing error in the flow chart Page 239)	
Sun, 2000	• Invasion of Wind, Cold, Damp • Unstable defensive Qi • Couli empty and dispersed	• Heat Bi - Wind Cold Damp can transform to Heat • Long-standing conditions can progress to affect the zangfu • Example given of Heart Bi	• When exhausted • Sweating and is being exposed to the wind • Waiting in water • Exposure to cold • Lying in a damp Area
Wu and Sheng, 2002	• Invasion of Wind, Cold, Damp • Heat Bi direct invasion. • Deficiency pattern • Unstable defensive Qi • Couli empty and dispersed	• Heat Bi - Cold can transform to Heat	• When exhausted • Sweating and is being exposed to the wind • Waiting in water • Exposure to cold • Lying in a damp Area

Appendix-B4: Standard theory - treatment methods

Author	General	Wind	Cold	Damp	Heat
Legge and Vance, 1997	Herbs	• relatively more points are used • along the channel • reducing method • don't retain the needles • treat every day	• Used mainly local and A-shi points • Distal points not necessary for every treatment • Direct moxibustion and warm needle • Or needles only	• Acupuncture and moxibustion • Retain needles for 20 minutes • Treat every second day	• Prick congested veins then cupping • Reducing method • Treat every day
Maciocia, 1994	• In elderly important to nourish Blood and Yin • Use Shu stream, Jing River, Luo points • Distal/ local (including A-shi points)/ adjacent points/ points according to pattern/ General points • Nourish Blood, nourish Liver and Kidneys, resolve Phlegm, move Blood	• Expel Wind • Tonify Blood • Reducing method in acute cases • Even method in chronic cases	• Scatter Cold • Tonify Kidney Yang • Moxibustion • Warm needle • Reinforcing method	• Resolved Damp • Strengthen Spleen • Moxibustion • Plum blossom needle • Reducing method in acute cases • Even method in chronic cases	• No moxibustion • Reducing method in acute cases • Even method in chronic cases

Author	General	Wind	Cold	Damp	Heat
O'Connor and Bensky, 1981	• select both contiguous and distant points on channels which traversed the area of pain • Ear acupuncture • Electroacupuncture • Severe cases treat once-a-day, for most cases treat on alternating days • Cupping with cutaneous acupuncture	Needling is the primary method	Combination of needling and moxibustion	Combination of needling and moxibustion	Let a few drops of blood at related points
Cheng, 1999	• Remove obstruction from the meridians and collaterals • A-shi points along with local and distal points on the Yang meridians crossing the affected area • When bones and tendons are affected deep insertion with retention • In severe cases a long period of treatment maybe required	• Disperse Wind • Reducing method	• Disperse Cold • Moxibustion with needling as an adjunctive therapy • Moxibustion with ginger • Intradermal needles	• Resolve Damp • Warm needle • Tapping plus cupping	• Clear Heat • Reducing method

Author	General	Wind	Cold	Damp	Heat
Xu et al., 1988	• Removal obstruction • Regulate circulation of Qi and Blood • Select local and distal points on meridians that traverse the area • A-shi points can also be selected Treatment every other day or daily in severe cases	• Disperse Wind • Reducing method • Shallow needling	• Disperse Cold • Needles retained for longer • Moxibustion - emphasised	• Resolve Damp • Needles and moxibustion	• Clear Heat • Reducing method • Shallow needling • Pricking method
Zhao, 2002	• Local points are needled with reducing technique • Points to the syndrome reinforcing technique • Moxibustion and cupping can be used • Ear acupuncture	-	-	-	-
Zhao and Wang, 2007	• Primarily local points, combined with points from the effected channels and according to syndrome differentiation.	• Dispel wind to remove obstruction • draining with filiform needles	• Dissipate cold to remove obstruction • deep insertion and needle retention, Plus moxibustion	• Eliminate dampness to remove obstruction • combination of needles and moxibustion, warm needling	• Clear Heat to remove obstruction • draining with filiform needles

Author	General	Wind	Cold	Damp	Heat
Sun, 2000	• Use acupuncture and moxibustion • Unblock tendons and vessels/ harmonise the [flow of] Qi and Blood • Primarily local points and points selected according to the channel • Accompanied by A-shi points • If the illness is in the skin all muscle shallow needling should be used • If the illness is in the bones and tendons deep needling with a needle retention should be used • If the the illness is in the blood vessels then vessels should be pricked.	• Disperse Wind	• Dispel Cold	• Transform Damp	• Clear Heat • Use acupuncture but not moxibustion • Pricking of blood vessels
Wu and Sheng, 2002	-	-	-	-	-

Appendix-B5: Local points recommended by TCM textbooks

Author	A-Shi	BL 40	heding	neixiyan	GB 33	GB 34	KI 10	LR 7	LR 8	SP 10	SP 9	ST 34	ST 35	ST 36
Legge and Vance, 1997	1	1	1	1						1	1	1	1	1
Maciocia, 1994	1	1		1	1	1	1	1	1	1	1	1	1	1
O'Connor and Bensky, 1981			1	1		1					1	1	1	1
Cheng, 1999	1		1	1		1				1	1		1	1
Xu et al., 1988	1				1	1					1	1	1	1
Zhao, 2002	1		1	1	1	1				1		1	1	1
Zhao and Wang, 2007					1	1				1		1	1	1
Sun, 2000					1	1						1	1	1
Wu and Sheng, 2002		1				1				1	1			1

Appendix-B6: Distal points recommended by TCM textbooks

Author	BL 10	BL 11	BL 12	BL 17	BL 18	BL 20	BL 21	BL 23	BL 25	BL 57	BL 58	BL 60	BL 62	CV 4
Legge and Vance, 1997			1	1		1	1	1						1
Maciocia, 1994	1	1	1	1	1	1		1				1		1
O'Connor and Bensky, 1981														
Cheng, 1999		1		1				1					1	1
Xu et al., 1988			1	1	1	1		1						1
Zhao, 2002					1			1						
Zhao and Wang, 2007				1				1						1
Sun, 2000			1	1	1	1		1						1
Wu and Sheng, 2002												1		1
Author	**CV 6**	**CV 9**	**CV 12**	**AH4***	**CO10***	**TF4***	**GB 20**	**GB 30**	**GB 31**	**GB 38**	**GB 39**	**GB 40**	**GB 41**	**GV 3**
Legge and Vance, 1997	1		1				1		1		1			
Maciocia, 1994	1	1	1					1	1	1	1	1	1	1
O'Connor and Bensky, 1981														
Cheng, 1999							1	1			1			
Xu et al., 1988														
Zhao, 2002				1	1	1								
Zhao and Wang, 2007														
Sun, 2000														
Wu and Sheng, 2002							1				1			

* Ear points

Appendix-B6: Distal points recommended by TCM textbooks- continued-1

Author	GV 14	GV 16	KI 3	KI 4	KI 7	LI 4	LI 10	LI 11	LI 15	LR 3	LR 4	LR 5	LU 5	LU 6
Legge and Vance, 1997	1	1	1			1		1						
Maciocia, 1994	1		1	1				1			1	1	1	
O'Connor and Bensky, 1981														
Cheng, 1999						1		1	1					
Xu et al., 1988	1							1						
Zhao, 2002														
Zhao and Wang, 2007	1							1						
Sun, 2000	1							1						
Wu and Sheng, 2002	1					1		1						

Author	LU 7	PC 6	SI 3	SI 5	SI 8	SI 10	SP 4	SP 5	SP 6	SP 21	ST 32	ST 40	ST 41	ST 43
Legge and Vance, 1997		1						1	1			1		1
Maciocia, 1994	1	1		1				1	1			1	1	1
O'Connor and Bensky, 1981														
Cheng, 1999			1					1		1			1	
Xu et al., 1988														
Zhao, 2002									1					
Zhao and Wang, 2007								1						
Sun, 2000														
Wu and Sheng, 2002									1				1	

Appendix-B6: Distal points recommended by TCM textbooks- continued-2

Author	ST 44	ST 6	TE 4	TE 5	TE 6	TE 14								
Legge and Vance, 1997					1									
Maciocia, 1994					1									
O'Connor and Bensky, 1981														
Cheng, 1999			1											
Xu et al., 1988														
Zhao, 2002														
Zhao and Wang, 2007														
Sun, 2000														
Wu and Sheng, 2002					1									

Appendix C: Systematic Review

Appendix - C1: Risk of bias assessment of individual trials

Cui Hw 2013

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Apart from a simple statement to say the groups were randomised no information is given	Unclear Risk	将100 例膝骨关节炎患者随机分为观察组和对照组各50 例
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	An interval of only one week was required between receiving another therapy for the knee condition and entering the trial.	Unclear Risk	
	Medication use not reported	Unclear Risk	
	Outcome measurement scale not clearly explained and apparently contradicts the reference provided. (See discussion)	High Risk	

Ding Jx 2016

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Computer-generated	Low Risk	采用 SPSS19.0 生成随机数字表
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	Unclear Risk	
Blinding of assessment	No detailed information given. Stated participants complete the VAS	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	VAS for pain, Lysholm for function, State administration measure	Low Risk	
	Medication use not reported.	Unclear Risk	

Hu Jh 2015

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Randomly allocated into two groups by the order in which they came for treatment	High Risk	根据患者的接诊顺序，将其随机分为两组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Medication use not reported.	Unclear Risk	
	VAS and Lysholm, plus State administration measure	Low Risk	

Huang Cx 2007

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Randomisation Table	Low Risk	按随机表法随机分组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Medication use not reported.	Unclear Risk	
	Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear who decides to which category an individual belongs or how borderline case were dealt with. (See discussion)	High Risk	

Li Cd et al 2006

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Randomisation table was used to create block randomisation sequence, participants were allocated to each group depending in the order in which they sought medical attention.	Low Risk	按随机数字表填写随机分配卡, 注明序号,.., 遵照随机方案, 按就诊时间顺序随机入组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. Clear statement is given regarding the attrition. Baseline data and post treatment data on the pain scores is reported.	Low Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Medication use not reported. Legenese scale used. Responder rates also reported but the actual scale used is unclear.	Low Risk	
	Medication use is not reported.	Unclear Risk	

Li L et al 2011

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Random numbers table	Low Risk	根据随机数字表法分为2
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Point scale described, however, not clear how it was assessed. There appears to be a contradiction between the two methods of reporting the results. Table 3.2 indicates no statistically significant change - however the researcher claims there is. These figures also appear not to match those given in Table 3.3.	Unclear Risk	
	Medication use is not reported.	Unclear Risk	

Li Zh and Li Dm 2010

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement to say they were randomised	Unclear Risk	随机分为两组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear who decides to which category an individual belongs or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Liu B 2016

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Participants were randomised according to whether their medical records' Number was odd or even	High Risk	根据病历号末位号的奇偶数将以上患者随机分为对照组..和实验组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	VAS for pain, VAS for quality of life, Lysholm , baseline scores not presented. Scale-responder rates	High Risk	
	Medication use not reported.	Unclear Risk	

Liu La et al 2003

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Minimal information given, simply stating the lots were drawn	Low Risk	抽签发
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Outcome measure uses a points based scale, developed in Japan. However, minimal information is provided regarding how the parameters were operationalised (See discussion)	Unclear Risk	
	Medication use not reported.	Unclear Risk	

Lu Xh 2015

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Not randomised - unclear statement regarding allocation	High Risk	按治疗方法不同分为对照组30例与观察组81
Allocation concealment	Not randomised	High Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear who decides to which category an individual belongs or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Luo Xf and Mao Hr 2011

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement that groups were randomised according to the order in which they sought medical advice	Unclear Risk	就诊先后次序随机分治疗组，对照组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Lv M 2000

Criteria	Support for judgement	Judgement	Chinese
Randomisation	No information is given	Unclear Risk	
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment. Unclear as when the assessment was made - no time point	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear who decides to which category an individual belongs or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Qin D 2016

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement that groups were randomised, no further information given	Unclear Risk	随机分为治疗组合对照组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Tan Hy and Feng Yl 2016

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Randomisation table	Low Risk	随机数字表
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	VAS for pain when walking on flat, Japanese knee function measure not clearly referenced (See discussion)	Unclear Risk	
	Medication use not reported.	Unclear Risk	

Wang Gz 2007

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement that groups were randomised, no further information given	Unclear Risk	随机分为2组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Outcome measure uses responder rate scale. Unclear how the assessment was made. Appears to missing category (See Discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Wang Gz and Zhu Lj 2009

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement that groups were randomised, no further information given	Unclear Risk	随机分为2组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Outcome measure uses responder rate scale. Unclear how the assessment was made. Appears to missing category (See Discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Wu Hm 2015

Criteria	Support for judgement	Judgement	Chinese
Randomisation	The order in which they entered the hospital.	High Risk	入院顺序
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Xia Qf 2011

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Randomised according to when the participant sought medical help	High Risk	根据就诊先后秩序随机分为两组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Uses two outcome measures. One use the Lysholm scale. The other uses categories of improvement that are identified with associated signs and symptoms, however there is no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	Unclear Risk	
	Medication use not reported.	Unclear Risk	

Xu Gy 2016

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement	Unclear Risk	随机分为观察组合对照组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Uses two outcome measures. VAS used to measure pain. The other uses categories of improvement that are identified with associated signs and symptoms, however there is no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	Unclear Risk	
	Medication use not reported.	Unclear Risk	

Yan Xl et al 2013

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Random numbers table, equal rank	Low Risk	纳入病例案随机数字表法分为两组 / 采用随机平行对照方法
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. Includes clear statements that indicated that all participants received the full course of treatment. Baseline data for pain pain scores is reported.	Low Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Used validated outcome measures WOMAC converted to responder rates	Low Risk	
	Medication use reported.	Low Risk	

Yang D 2014

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Random numbers were, generated by a random numbers table, assigned the ordinal numbers participants seeking medical help, i.e. there was a random number assigned to the first, second, third participant and so on. If the assigned number was odd the participant was randomised to the treatment group, if even to the comparison group.	Low Risk	采用数字表法，据患者就诊顺序号查所对应的随机数字，末尾数字为1,3, 5, 7, 9 者分到治疗组，为2, 4, 6, 8, 0 者分到对照组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Medication use is not reported. Appears to use a scale converted to responder rates, however the scale is in not clear.	Unclear Risk	
	Medication use not reported.	Unclear Risk	

Yang Ky and Qu Xx 2015

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Random numbers table,	Low Risk	随机数字表法
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Uses three outcome measures. VAS used to measure pain. Point scale to measure function (unclear and not referenced). Also uses categories of improvement that are identified with associated signs and symptoms, however there is no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	Unclear Risk	
	Medication use not reported.	Unclear Risk	

Yang Xs 2016

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Random numbers table	Low Risk	随机数字表法
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Uses 2 outcome measures. HSS point scale to measure function (cites another trial). Also uses categories of improvement that are identified with associated signs and symptoms, however, there is no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	Unclear Risk	
	Medication use not reported.	Unclear Risk	

Yang Ys and Zhong Tl 2016

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple sttatement	Unclear Risk	随机分为对照组和观察组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Yao Zf et al 2003

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement that participants were randomised	Unclear Risk	随机分为对照组和观察组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Yu B 2015

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement that participants were randomised	Unclear Risk	随机分为对照组和实验组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Reports 2 outcome measures. One scale but with no explanation. In addition, categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Yu J 2009

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement that participants were randomised	Unclear Risk	随机分为两组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Yue R 2010

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement that participants were randomised	Unclear Risk	随机分为两组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants were blinded using heat lamp to mask the heat. Practitioners were not blinded. This is author assumed as no information given.	Unclear Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Zhang Gc 2015

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement that participants were randomised	Unclear Risk	随机分为对观察组和照组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Uses 2 outcome measures. HSS point scale to measure function; no description no citation. Also uses categories of improvement that are identified with associated signs and symptoms, however there is no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	Unclear Risk	
	Medication use not reported.	Unclear Risk	

Zhang J 2013

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement that participants were randomised using a random numbers table	Low Risk	按照随机数字表分为试验组和对照组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	WOMAC used as the outcome measure; reported as scale data. (no citation)	Low Risk	
	Medication use not reported.	Unclear Risk	

Zhang Jf et al 2009

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement that participants were randomised	Unclear Risk	随机单盲法分为两组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants were blinded using heat lamp to mask the heat. Practitioners were not blinded. This is author assumed as no information given..	Unclear Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Uses 3 outcome measures. Legnesne (assumed as written as Lequene) and WOMAC; no citation description of how they were used not clear. Also uses categories of improvement that are identified with associated signs and symptoms, however there is no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	Unclear Risk	
	Medication use not reported.	Unclear Risk	

Zhang Zp 2003

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement that participants were randomised	Unclear Risk	随机分成治疗组治疗与对照组
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Medication use is not reported. Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Zhao M 2014

Criteria	Support for judgement	Judgement	Chinese
Randomisation	Simple statement that participants were randomised	Unclear Risk	我们做了随机对照临床试验
Allocation concealment	No information given	Unclear Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported, although this trial also has a Western medication group.	Unclear Risk	

Zhao Xt et al 2008

Criteria	Support for judgement	Judgement	Chinese
Randomisation	No information given - assumed not randomised	High Risk	
Allocation concealment	No information given - assumed not randomised	High Risk	
Blinding of participants and personnel	Participants and practitioners were not blinded. This is author assumed as no information given.	High Risk	
Blinding of assessment	No information given	Unclear Risk	
Incomplete outcome data	Data for all participants is recorded. However no clear statement is given regarding the lack of attrition or confirmation that all participants received the full course of treatment.	Unclear Risk	
Selective reporting	No evidence of the protocol being pre-specified	Unclear Risk	
Other	Categories of improvement are identified with associated signs and symptoms, however, there appears to be no scale. It is unclear how decisions were made regarding to which category an individual should belong or how borderline case were dealt with. (See discussion)	High Risk	
	Medication use not reported.	Unclear Risk	

Appendix-C2: Participant characteristics

	N	Experiment n	Control n	Mean Age experiment/control	Age Range	Mean duration experiment/control	Duration Range experiment/control
Cui Hw 2013	100	50	50	57.51 +/- 9.86	45-80	x	x
Ding Jx 2016	70	35	35	50/50	44-75	2.6/ 2.5 yr	1mth-5yr / 2mth-5yr
Hu Jh 2015	54	27	27	50	x	3.5 yr	x
Huang Cx 2007	85	52	33	x	40-72	x	2wk - 3yr
Li Cd 2006	120	60	60	60/58	40-70	x	x
Li L 2011	80	40	40	61/59	x	x	x
Li Zh 2010	110	55	55	x	78-53	x	x
Liu B 2016	99	51	48	52	36-78	9.5	2-16.5yr
Liu La 2003	112	60	52	62/60	41-72	8/9mth	4mth - 4yr
Lu Xh 2015	111	81	30	62/62	41-72	8.4/7.3 mth	4mth - 3.5yr
Luo Xf 2011	88	45	43	x	x	x	5mth - 12yr
Lv M 2000	68	48	20	x	41-74	x	2mth - 7yr
Qin D 2016	70	35	35	62/62	48-80	2.3yrs	0.4-4.2yr
Tan Hy 2016	80	40	40	53/52	45-70	x	1-10 yr/ 1-12 yr
Wang Gz 2007	96	50	46	x	41-75	x	2mth - 20yr
Wang Gz 2009	67	35	32	x	61-75	x	2mth - 20yr
Wu Hm 2015	114	57	57	54/57	41-81	4.5/3.6 yr	7mth-15yr/3mth-12yr
Xia Qf 2011	76	38	38	60	39-80	5yr	3yr - 15yr
Xu GY 2016	64	32	32	58/58	42-76	2.1mth / 2.3mth	3d - 3 yr

	N	Experiment n	Control n	Mean Age experiment/control	Age Range	Mean duration experiment/control	Duration Range experiment/control
Yan Xl 2013	60	30	30	58/56	48-75	7.1/ 6.8 yr	6mth - 15yr
Yang D 2014	60	30	30	56/56	43-67	84/79 mth	6mth - 15yr
Yang Ky 2015	136	68	68	59/59	40-75	5.6yr/5.5yr	0.5-10yr/0.3-10yr
Yang Xs 2016	120	60	60	66/66	60-77	1.6/1.6yr	8mth-4yr/6mth-5yr
Yang Ys 2016	58	29	29	63/62	48-76	x	x
Yao Zf 2003	155	98	57	x	39-78	x	1wk - 3 years
Yu B 2015	98	49	49	76	60-85	9.8 mth	6 - 45 mth
Yu J 2009	62	32	32	56	43-74	7.5mth	1mth - 8yr
Yue R 2010	65	33	32	45/45	39-78	x	6mth-3yr /5mth - 3yr
Zhang Gc 2015	80	40	40	56/56	54-75	2.3yr/ 2.5yr	5mth-4yr / 4mth-5yr
Zhang J 2013	90	45	45	58	42-69	x	x
Zhang Jf 2009	300	150	150	54/56	41-72	3.3/4 yr	3mth - 6yr / 4mth - 5.5 yr
Zhang Zp 2013	86	43	43	60 +/- 5.5	48-76	x	6mth - 5yr
Zhao M 2014	97*	35	32	x	50-72	x	1mth - 3yr
Zhao Xt 2008	100	50	50	60	38-81	18.4mth	6mth - 5yr

Appendix-C3: Trial design characteristics

Trial	Diagnosis			Entry criteria			Baseline Score	Recruitment		Safety	Fund -ing
	Clinical	x-ray	CM	Pain	Duration	Age		Method	Setting		
Cui Hw 2013	Signs and symptoms described	x ray signs described	x	x	x	40	x	x	Hospital outpatient	x	x
Ding Jx 2016	ACR 1995	x	Described	x	x	x	Reported	x	Hospital outpatient	Reported	x
Hu Jh 2015	ARA 1995	x	Described	x	1 mth	> 38	Reported	x	Hospital	x	x
Huang Cx 2007	ACR 1995	ACR 1995	x	x	< 10 yr	< 80 yr	x	x	Hospital outpatient		x
Li Cd 2006	ACR 1991	ACR 1991	Referenced	Pain scale > 4 Condition Index > 6	x	40-70	Reported	x	Hospital outpatient ?		x
Li L 2011	ACR 1995	Kellgren Lawrence	Referenced	x	x	45-75	Reported	x	Hospital outpatient Hospital inpatient		x
Li Zh 2010	Signs and symptoms described	x ray signs described		x	x	x	x	x	Hospital outpatient ?		
Liu B 2016	x	x	x	x	x	x	x	x	x	x	x
Liu La 2003	ARA 1986	ARA 1986		x	x	x	x	x	Hospital outpatient		

Trial	Diagnosis			Entry criteria			Baseline Score	Recruitment		Safety	Fund -ing
	Clinical	x-ray	CM	Pain	Duration	Age		Method	Setting		
Lu Xh 2015	Cited another trial	x	x	x	x	x	x	x	Hospital	x	x
Luo Xf 2011	ACR ?	x ray signs described		x	x	x	x	x	Hospital outpatient		
Lv M 2000	Signs and symptoms described	x ray signs described		x	x	x	x	x	x		
Qin D 2016	ARA		x		> 2 weeks	40	Reported	x	x	x	x
Tan Hy 2016	China criteria 2007	x ray used	x	Yes	Yes	40		x	Hospital outpatient	x	x
Wang Gz 2007	ARA 1986	ARA 1986	x	x	x	x	x	x	Hospital outpatient	x	x
Wang Gz 2009	ARA 1986	ARA 1986		x	x	Over 60	x	x	Hospital outpatient		
Wu Hm 2015	Signs and symptoms described	x	x	x	x	x	x	x	Hospital	x	x
Xia Qf 2011	ACR 1995	x		x	x	x	x	x	Hospital outpatient		
Xu GY 2016	China criteria	x	Cold Bi	x	x	x	Reported	x	Hospital	x	x

Trial	Diagnosis			Entry criteria			Baseline Score	Recruitment		Safety	Fund -ing
	Clinical	x-ray	CM	Pain	Duration	Age		Method	Setting		
Yan Xl 2013	PRC Chinese medicine standards	PRC Chinese medicine standards		x	x	40-70	x	x	Hospital outpatient	x	x
Yang D 2014	Chinese criteria			x	x	40-68	x	x	Hospital outpatient and inpatient		
Yang Ky 2015	ARC	x ray used	x	x	max 10 yr	max 75	Reported	x	Hospital outpatient	x	x
Yang Xs 2016	ARC	x	x	x	x	x	Reported	x	Hospital	x	x
Yang Ys 2016	x	x		x	x	x	x	x	Hospital	x	x
Yao Zf 2003	Signs and symptoms described	x ray signs described		x	x	x	x	x	Hospital outpatient		
Yu B 2015	x	x	x	x	x	x	Reported	x	Hospital	x	x
Yu J 2009	ARA 1986	ARA 1986		x	x	x	x	x	x		
Yue R 2010	x	x	x	x	x	x	x	x	Hospital outpatient ?	x	x
Zhang Gc 2015	x	x	x	x	x	x	Reported	x	Hospital	x	x
Zhang J 2013	x	x		x	x	x	Reported		Hospital outpatient		

Trial	Diagnosis			Entry criteria			Baseline Score	Recruitment		Safety	Fund -ing
	Clinical	x-ray	CM	Pain	Duration	Age		Method	Setting		
Zhang Jf 2009	ACR ?	ACR ?	x	x	x	40-75	Reported	x	Hospital outpatient and inpatient	x	x
Zhang Zp 2013	x	x		x	x	x	x	x	Hospital outpatient		
Zhao M 2014	The Chinese Western integrative medicine manual of orthopaedics 2008 ref 1	Medical science of rehabilitation 2008 ref 2		x	x	x	x	x	Hospital outpatient Came for check-up		
Zhao Xt 2008	ACR ?	x ray used		x	x	x	x	x	Hospital outpatient ?		

Appendix-C4: Physical parameters of interventions 1

	Number of points used			Moxibustion		Insertion		Needles	
Trial	Mean	Range	Protocol	per needle	Nō points	Depth	Time (minutes)	Diameter mm	Length mm
Cui Hw 2013	x	x	x	2	x	x	40	x	x
Ding Jx 2016	x	x	x			25mm		0.35	40
Hu Jh 2015	x	x	x	2	x	25mm	30	0.35	40
Huang Cx 2007	x	x	x	x	x	To point	x	0.3	40
Li Cd 2006	x	x	x	2	x	x	40	0.35	40-50
Li L 2011	x	x	x	2	x	x	30	0.3	40
Li Zh 2010	x	x	3-4	1-2	3-4	x	30	x	x
Liu B 2016	x	x	x	2	x	x	40	0.35	25-40
Liu La 2003	x	x	x	x	x	x	(moxa + 15)	0.3	40
Lu Xh 2015	x	x	x	x	x	1.5 cun	30	0.3	50
Luo Xf 2011	x	x	x	x	x	1.5 cun	30	0.3	50
Lv M 2000	x	x	x	2-3	x	x	x	0.35	40-50
Qin D 2016	x	x	x	1	x	x	15	0.3	40
Tan Hy 2016	x	x	x	2	x	2.5 cun	30	x	75
Wang Gz 2007	x	x	x	3	6?	x	30	0.3	40
Wang Gz 2009	x	x	x	3	6	x	30	0.25	40
Wu Hm 2015	x	x	x	3	x	x	40	x	x

	Number of points used			Moxibustion		Insertion		Needles	
Trial	Mean	Range	Protocol	per needle	Nō points	Depth	Time (minutes)	Diameter mm	Length mm
Xia Qf 2011	x	x	6?	x	6?	x	30	0.25	40
Xu Gy 2016	x	x	x	2	4+	25	30	0.35	40
Yan Xl 2013	x	x	x	x	x	To point	(moxa+15)	0.3	40
Yang D 2014	x	x	x	x	x	x	30	x	x
Yang Ky 2015	x	x	x	x	9?	x	30	x	x
Yang Xs 2016	x	x	x	x	x	x	(moxa+15)	0.3	40
Yang Ys 2016	x	x	x	3	x	x	40	x	x
Yao Zf 2003	x	x	3-4	2	3-4?	x	30	x	50
Yu B 2015	x	x	x	x	x	x	(moxa+15)	0.3	40
Yu J 2009	x	x	x	x	x	1-1.5 cun	(moxa + 15)	0.3	40
Yue R 2010	x	x	x	3	x	through	30	0.3	40
Zhang Gc 2015	x	x	x	x	x	x	(moxa+15)	0.3	40
Zhang J 2013	x	x	x	x	4	x	30	x	40
Zhang Jf 2009	x	x	x	3	x	through	30	0.3	40
Zhang Zp 2013	x	x	x	x	x	x	30	x	x
Zhao M 2014	x	x	x	2	3-5	x	40	0.35	50
Zhao Xt 2008	x	x	5-6	x	3	x	20-30	0.35	40-50

Appendix-C5: Physical parameters of interventions 2

Trial	Deqi response	Needle - Brand	Sessions - Total	Sessions - Frequency	Sessions - Rest days
Cui Hw 2013	Deqi	x	14	1/day	1
Ding Jx 2016	Deqi	Huatuo	15	1/day	2
Hu Jh 2015	Deqi	Huatuo	9	1/ 2day	2
Huang Cx 2007	Deqi	x	10	1/day	x
Li Cd 2006	Deqi	Huatuo	14	1/day	1
Li L 2011	Deqi	Huatuo	30	1/day	3
Li Zh 2010	Deqi	x	20	1/day	2
Liu B 2016	Deqi	Huatuo	20	1/day	3
Liu La 2003	Deqi	x	20	1/day	3
Lu Xh 2015	Deqi	Huatuo	20	1/day	2
Luo Xf 2011	Deqi	Huatuo	20	1/day	2
Lv M 2000	Deqi	x	12	3/week	0
Qin D 2016	Deqi	x	x	x	x
Tan Hy 2016	Deqi	x	15	1/day	2
Wang Gz 2007	Deqi	环球	10	2/week	0
Wang Gz 2009	Deqi	环球	10	2/week	0
Wu Hm 2015	Deqi	x	20	1/ 2day	3
Xia Qf 2011	x	天械	20	1/ 2day	0

Trial	Deqi response	Needle - Brand	Sessions - Total	Sessions - Frequency	Sessions - Rest days
Xu GY 2016	Deqi	x	9	1/ 2day	2
Yan Xl 2013	Deqi	x	20	1/day	1
Yang D 2014	x	x	20	1/day	x
Yang Ky 2015	x	x	10?	1/day	x
Yang Xs 2016	Deqi	x	20	1/day	3
Yang Ys 2016	Deqi	x	20	1/ 2day	3
Yao Zf 2003	Deqi	x	12	1/day	x
Yu B 2015	Deqi	x	20	1/day	3
Yu J 2009	Deqi	x	20	1/day	3
Yue R 2010	Deqi	x	20	1/ 2day	up to 1 week
Zhang Gc 2015	Deqi	x	20	1/day	3
Zhang J 2013	Deqi	x	40	3/week	x
Zhang Jf 2009	Deqi	x	20	1/ 2day	up to 1 week
Zhang Zp 2013	x	x	x	1/ 2day	x
Zhao M 2014	Deqi	Huatuo	12	1/day	1
Zhao Xt 2008	Deqi		14	1/day	3-5

In the following tables, three pieces of information are presented regarding each outcome measure. These are arranged in three boxes See example.

(1) The name of the outcome measure and/or which aspect of the disease was measured: for example WOMAC, pain or 'treatment effectiveness'
(2) The citation given in the trial report to indicate the origin of the outcome measure
(3) Whether the outcome measure was an ordinal category, a scale responder-rate, or mean score (section-IV.4.4). This box has been colour coded to indicate the risk of bias assessment (section-IV.4.3). Red was high risk, yellow was unclear risk and green was low risk

When a trial used more than one outcome measure these have been presented in the additional columns 2 and 3 See example.

Example

Trial	1	2	3
First author Date	(1)	(1)	
	(2)	(2)	
	(3)	(3)	

Appendix-C6: Outcome measures - overview

Trial	1	2	3
Cui Hw 2013	Treatment effectiveness - Unclear		
	Zhang Jf et al (2009) Observations on the efficacy of Point through Point acupuncture and moxibustion in treating genual osteoarthritis		
	Scale responder-rates		
Ding Jx 2016	Clinical effectiveness evaluation - State Administration of TCM Standards - Unclear	Knee joint function evaluation - [Lysholm]	Pain level evaluation - [VAS]
	No citation	No citation	No citation
	Scale responder-rates	Mean score	Mean score
Hu Jh 2015	Clinical effectiveness - [Chinese medicine standards for diagnosis and clinical effectiveness] - Possibly State Administration of TCM Standards - Unclear	Knee ligament damage [Lysholm]	Pain - [VAS]
	Wang L and HanJy (2011) Comparative study on clinical curative effect of warm needling on rehabilitation of knee osteoarthritis. *Guangming Journal of Chinese Medicine 2*	No citation	No citation
	Scale responder-rates	Mean score	Mean score
Huang Cx 2007	Clinical effectiveness		
	Zeng Qx and Xu Jc (1998) Classification and Epidemiology of Osteoarthritis. *Chinese Journal of Practical Internal Medicine*		

Trial	1	2	3
	Ordinal category		
Li Cd 2006	Pain score - [Lequesne]	Condition severity index - [Lequesne]	
	Zeng Qy (1999) Osteoarthritis. Tianjin. Tianjin Science and Technology Publishing House	Zeng Qy (1999) Osteoarthritis Tianjin. Tianjin Science and Technology Publishing House	
	Mean score	Mean score	
	Evaluation of the disease severity index - unclear	Cold pattern pattern differentiation quantitative factor scale	
	Possibly Zheng Xy (2002) The Guide to clinical Chinese medicine research for new medicines. Beijing. China Medical Science Press. p385-387. - not cited clearly	Wang Mq et al (2003) Research on Operationalising Factor Level Standards for Deficiency Cold Syndrome Differentiation. *Liaoning Chinese Medicine Journal.*	
	Scale responder-rates	Mean score	
Li L 2011	Symptom score -The guide to clinical Chinese medicine research for new medicines	Clinical effectiveness [same scale]	
	Zheng Xy (2002) Guiding principles of clinical research of new medicine in Chinese medicine. Beijing. China Medical Science Press p349-353	Zheng Xy (2002) Guiding principles of clinical research of new medicine in Chinese medicine. Beijing. China Medical Science Press p349-353	
	Mean score	Scale responder-rates	
Li Zh 2010	Clinical effectiveness		
	No citation		
	Ordinal category		

Trial	1	2	3
Liu B 2016	Clinical effectiveness	Score - Quality of life measure [VAS]	Knee score - [Lysholm]
	Qiu L et al (2003) Treatment of knee osteoarthritis with warm needle acupuncture combined with rehabilitation training. Long term Effectiveness Observation. *Chinese Acupuncture & Moxibustion*	No citation	No citation
	Ordinal category	Mean score	Mean score
Liu La 2003	Treatment effectiveness [Japanese point system]		
	Zhang Gb and Li Zs (1991) Knee function evaluation. *Chinese journal of rehabilitation medicine.*		
	Scale responder-rates		
Lu Xh 2015	Clinical effectiveness	Relapse rates	
	Wang L et al (2012) Evaluation of curative effect of Jianbu Tongluo fumigation liquid on knee osteoarthritis. *Chinese journal of information on traditional Chinese medicine*	Wang L et al (2012) Evaluation of curative effect of Jianbu Tongluo fumigation liquid on knee osteoarthritis. *Chinese journal of information on traditional Chinese medicine*	
	Ordinal category	Ordinal category	
Luo Xf 2011	Clinical effectiveness		
	Xu Wd et al (2004) Diagnosis and treatment of osteoarthritis. Shanghai. The second military medical university publishing house. p140-141		
	Ordinal category		
Lv M 2000	Treatment effectiveness		
	No citation		

Trial	1	2	3
	Ordinal category		
Qin D 2016	Clinical effectiveness - Guiding principles of clinical research of new medicine in Chinese medicine	Knee joint function evaluation - unclear	
	Chen Ml (2013) Clinical Treatment of old aged Knee Osteoarthrosis Treated by Warm needle Acupuncture and needle Acupuncture. *Essential Reading in Health.*	No citation	
	Ordinal category	Mean score	
Tan Hy 2016	Pain walking VAS	Lower limb function Assessment Form (Japanese)	
	No citation	No citation	
	Mean score	Mean score	
Wang Gz 2007	Treatments effectiveness - Points system		
	Xu Wd et al (2004) Diagnosis and treatment of osteoarthritis. Shanghai. The second military medical university publishing house. p140-141		
	Scale responder-rates		
Wang Gz 2009	Treatments effectiveness - points system		
	Xu Wd et al (2004) Diagnosis and treatment of osteoarthritis. Shanghai. The second military medical university publishing house. p140-141		
	Scale responder-rates		

Trial	1	2	3
Wu Hm 2015	Overall treatment effectiveness		
	No citation		
	Ordinal category		
Xia Qf 2011	Overall treatment effectiveness - State Administration of TCM Standards	Lysholm - Knee joint function evaluation	
	No citation	Lysholm，J. and Gillquist, J. (1982) Evaluation of knee ligament surgery results with special emphasis on use of a scoring scale *Am J sports Med*	
	Ordinal category	Scale responder-rates	
Xu GY 2016	Symptom treatment effectiveness	Pain scale VAS	
	No citation	Zhang Df et al (2014) Comparative Study on the Clinical Efficacy of Massage Technique and Acupuncture and Moxibustion in the Treatment of Osteoarthritis of Knee Joint. *Hainan Medical Journal*	
	Ordinal category	Mean score	
Yan Xl 2013	Clinical effectiveness WOMAC		
	Zhang Sj et al (2012) Clinical analysis of the rules for palpating the diseased sinews to find a locus of illness in osteoarthritis of the knee. *Chinese Acupuncture and Moxibustion*		
	Scale responder-rates		

Trial	1	2	3
Yang D 2014	Overall effectiveness - Guiding principles of clinical research of new medicine in Chinese medicine (Unclear)		
	Zheng Xy (2002) Guiding principles of clinical research of new medicine in Chinese medicine. Beijing. China Medical Science Press p349-353		
	Scale responder-rates		
Yang Ky 2015	Treatment effect - State Administration of TCM Standards	Pain when walking VAS	Point test Lower limb function [unclear]
	Xiong Gp (2011) Treatment of Knee with warm needle acupuncture of 30 cases of osteoarthritis of the joint *Chinese Acupuncture and Moxibustion*	No citation	No citation
	Ordinal category	Mean score	Mean score
Yang Xs 2016	Treatment effectiveness - Guiding principles of clinical research of new medicine in Chinese medicine	Knee joint function HSS 100 point scale	
	Zheng Xy (2002) Guiding principles of clinical research of new medicine in Chinese medicine. Beijing. China Medical Science Press p349-353	Bai Y (2010) Clinical experience on treatment of old aged knee joint disease with warm needle acupuncture combined with herbal medicine. *Journal of Aerospace Medicine*	
	Ordinal category	Mean score	
Yang Ys 2016	Clinical effectiveness		
	No citation		

Trial	1	2	3
	Ordinal category		
Yao Zf 2003	Treatment effectiveness	Treatment effectiveness - comparison by differential pattern	
	No citation	No citation	
	Ordinal category	Ordinal category	
Yu B 2015	Clinical effectiveness - Unclear	Knees score - Unclear	
	No citation	No citation	
	Ordinal category	Mean score	
Yu J 2009	Treatment results		
	Sun Cx et al (1987) Clinical disease diagnosis based on standards for improvement and curative effect. Beijing. People's Military Medical Press		
	Ordinal category		
Yue R 2010	Clinical effectiveness		
	No citation		
	Ordinal category		
Zhang Gc 2015	Clinical effectiveness	Observation index HSS	
	Fang J (2012) Clinical effect of warm needling and needle acupuncture on old aged knee osteoarthrosis. *Medical Innovation of China*.	No citation	
	Ordinal category	Mean score	

Trial	1	2	3
Zhang J 2013	WOMAC		
	No citation		
	Mean score		
Zhang Jf 2009	Overall treatment effectiveness - State Administration of TCM Standards 1995	Pain score WOMAC - Lequesne [confused]	Knee function score WOMAC - Lequesne [confused]
	No citation	No citation	No citation
	Ordinal category	Mean score	Mean score
Zhang Zp 2013	Treatment effectiveness		
	No citation		
	Ordinal category		
Zhao M 2014	Treatments effectiveness		
	No citation		
	Ordinal category		
Zhao Xt 2008	Overall treatment effectiveness - State Administration of TCM Standards 1994		
	No citation		
	Ordinal category		

Appendix-C7: Ordinal category criteria

Trial	3	2	1	0
Huang Cx 2007		The pain and stiffness of the affected knee has disappeared. When moving the sound of crepitus has disappeared or only occasionally seen. Normal movement and function has been recovered	The pain of the affected knee has reduced. There is the sound of crepitus when moving the joint. Movement and function has clearly improved	There is no obvious change in the pain and stiffness of the affected joint. There is no improvement in the movement and function.
Li Zh 2010		There is no pain when moving the joint. The sound of crepitus as reduced or disappeared. There is no obvious pain when going up or down the stairs or a slope.	During movement the pain of the need joint has reduced and the crepitus sound has reduced. Occasionally there is pain when going up or down the stairs or a slope	There has been no improvement in the signs and symptoms
Lu Xh 2015		Joint pain and swelling disappear, normal function of the knee joint recovered	The joint pain is relieved or disappears, the swelling has significantly subsided, ability to flex and extend has been recovered	The joint symptoms have not improved and may even have got worse
Luo Xf 2011		The pain and stiffness of the affected knee has disappeared. When moving the joint the sound of crepitus has disappeared or only occasionally seen. Normal movement and function has been recovered.	The pain has reduced, there is still crepitus. Joint function has clearly improved	There is no obvious change in the pain and stiffness of the affected joint. There is no improvement in the movement and function.

Trial	3	2	1	0
Lv M 2000	The pain has disappeared. Joint functions normally on flexion and extension. There is no relapse within three months.	The pain has disappeared there is no obvious limitation of movement in the joint. There is occasional loss of strength when walking.	There is a clear reduction in pain sometimes there is limitation in the movement of the joint. After too much movement the pain returns.	After two courses of treatment the person does not feel there has been any change in the signs and symptoms when compared to pre-treatment
Qin D 2016	The knee pain and swelling have disappeared, the joint function has returned to normal. An x-ray scan reveals no bony spurs.	The knee pain and joint swelling have been significantly alleviated, the joint function has returned to normal. An x-ray scan reveals no bony spurs.	The knee pain and joint swelling have been alleviated, there is also joint function recovery. An x-ray scan reveals no obvious bony spurs.	The knee pain and swelling have not improved, the joint function has not recovered. Bony spurs are revealed after an x-ray scan.
Wu Hm 2015	The clinical symptoms have completely disappeared. The knee can move through 135°	The signs and symptoms have disappeared	There is fundamental improvement in the clinical symptoms	The symptoms have not changed or have even got worse
Xia Qf 2011	Pain and swelling of the knee joint have disappeared. The joint has recovered its normal movement and function.		Pain and swelling of the joint have reduced. Improvement in the function and movement of the joint.	No change in the pain and swelling of the joint.

Trial	3	2	1	0
Xu GY 2016	The knee swelling, pain and other symptoms have disappeared. The knee function has returned to normal activities can be conducted easily.	The knee swelling and pain symptoms have been significantly reduced. The new function is normal.	The knee swelling, pain and other symptoms have reduced. The joint function has partly recovered but will relax when fatigued.	There is no change in the knee or it may have got worse.
Yang Ky 2015	Crepitus, pain and other clinical symptoms have disappeared. There is no swelling or deformity of the joint. Can conduct a normal activity.	When walking on the flat there is no pain. When going up and downstairs the knee can sometimes gives way or there is pain. There is no longer any swelling.	The knee symptoms have been significantly reduced and activity significantly improved	Yet to meet the previous criteria.
Yang Xs 2016	The knee pain, swelling and other symptoms have disappeared. The knee has recovered its normal function	In general the patient does not appear to have knee pain or swelling or other symptoms. When fatigued there is mild pain. The knee has basically recovered its normal function.	The knee pain, swelling and other symptoms have been alleviated. The function of the knee has improved.	The clinical symptoms and joint function have not yet improved or have even got worse
Yang Ys 2016	Clinical symptoms have completely disappeared. The knee can flex and extend through a range of 135°	Clinical symptoms have significantly improved. The knee can flex and extend to a range of 135°	Symptoms have improved. Knee movement is limited	The clinical symptoms have basically not changed or may even be worse

Trial	3	2	1	0
Yao Zf 2003	Pain and swelling of the knee joint have disappeared. The joint has recovered it's normal movement and function and this is maintained for over a year.	Pain and swelling of the knee joint markedly reduced. The joint basically functions normally.	Pain and swelling of the knee joint reduced. The function of the joint has partly recovered but relapses when tired or exposed to cold.	The clinical symptoms and joint function have not yet improved when compare to pre-treatment.
Yu B 2015		No information		
Yu J 2009	The clinical signs and symptoms have completely disappeared. The joint has basically recovered its function.		Clinical signs and symptoms have partly recovered. There is some improvement in the joint function.	Some improvement in the signs and symptoms but it is not obvious
Yue R 2010	The knee pain and stiffness have disappeared. The crepitus has either disappeared or only appears occasion. The joint function is normal		The knee pain has reduced. Crepitus still exist. Joint function has significantly improve	There has been no improvement in the pain or stiffness. No improvement in the joint function
Zhang Gc 2015	The knee swelling and pain have completely disappeared. Function has returned to normal	Swelling and pain have been significantly reduced. Joint function has returned to normal	The knee swelling and pain had been reduced, the joint function has improved.	The clinical symptoms and joint function have not improved or have even got worse.
Zhang Jf 2009	Joint pain and swelling disappear. Normal function and movement are recovered		Reduction in pain and swelling of joint. The function and movement have improved	There is no change in pain and swelling of joint

Trial	3	2	1	0
Zhang Zp 2013	After the complete clinical cure of the joint pain disappearing and the recovery of joint function there is no relapse	Clinically they joint pain has markedly improved and the joint has basically recovered its function*	Clinically the patient's pain has slightly reduced and the joint function has partly recovered. There is the possibility of relapse*	No change or worsening
Zhao M 2014	Pain and swelling of the knee joint have disappeared. The joint has recovered it's normal movement and function and this is maintained for over a year.	Pain and swelling of the knee joint markedly reduced. The joint basically functions normally.	Pain and swelling of the knee joint reduced. The function of the joint as partly recovered but relapses when tired or exposed to cold.	The clinical symptoms and joint function have not yet changed when compare to pre-treatment.
Zhao Xt 2008		Pain and swelling of the joint have disappeared. The joint function is normal	Pain and swelling of the joint have markedly reduced. The joint function has markedly improved.	There is no improvement in the signs and symptoms after treatment

Appendix-C8: Scale responder-rates criteria

Trial	3	2	1	0
Cui Hw 2013	Condition severity index ≥ 80%	Condition severity index ≥ 50%	Condition severity index ≥ 25%	Condition severity index < 25%
Ding Jx 2016	Effectiveness index ≥ 90%	Effectiveness index ≤ 60 < 90%	20%≤ effectiveness index<60%	Effectiveness index <20%
Hu Jh 2015	Effectiveness index ≥ 90%	Effectiveness index ≤ 60 < 90%	20%≤ effectiveness index<60%	Effectiveness index <20%
Li Cd 2006	Condition severity index ≥ 80%	Condition severity index ≥ 50%	Condition severity index ≥ 25%	Condition severity index < 25%
Li L 2011	Score reduced to 0-1 points	Score reduced by 2/3	Scored reduced by 1/3	Score not reduced by at least 1/3
Liu La 2003	After treatment the overall score was above 85 or had risen by more than 25 points.	After treatment the overall score was above 70 or had risen by more than 15 points.	After treatment the overall score was above 55 or had risen by not by 15 points	After treatment the overall score was below 55 or there was no increase in the score.
Wang Gz 2007	The total score has reduced by > 95%	The total score has reduced by more than 70% but less than 95%	**?**	The reduction in pain score has not reached 30%
Wang Gz 2009	The total score has reduced by > 95%	The total score has reduced by more than 70% but less than 95%	**?**	The reduction in pain score has not reached 30%
Xia Qf 2011	The difference between the before and after treatment scores ≥ 30	The difference between the before and after treatment scores 11-29	The difference between the before and after treatment scores 6-10	The difference between the before and after treatment scores < 5

Trial	3	2	1	0
Yan Xl 2013	Cured: Signs and symptoms have disappeared or fundamentally disappeared, the index has reduced by ≥ 95%	Markedly effective: signs and symptoms have obviously improved, the index has reduced by more than ≥ 70% < 95%	Effective: the signs and symptoms have improved, the index has reduced by ≥ 30% < 70%	Ineffective: no obvious improvement in signs and symptoms, they may have even got worse, the index has not reduced by 30%
Yang D 2014	The reduction in the symptom score ≥ 95%	The reduction in the symptom score ≥ 70% < 95%	The reduction in the symptom score ≥ 30% < 70 %	Reduction in the symptom score did not reach 30%

Appendix-C9: Ordinal category results

First author	Group	3 n (%)	2 n (%)	1 n (%)	0 n (%)	Effectiveness Rate
Huang Chaoxi 2007	Warm	23 (44.23)	26 (60.00)		3 (5.77)	94.23
	Needle	10 (3.00)	16 (48.48)		7 (21.22)	78.78
Li Zhihong 2010	Warm	36		17	2	96.36
	Needle	33		14	8	85.45
Luo Xinfu 2011	Warm	32	10		3	93.3
	Needle	16	20		7	83.7
Lv Mei 2000	Warm	33	11	4	0	100.0
	Needle	8	7	3	2	90.0
Peng Liang 2009	Warm	56	17		8	69.14
	Needle	5	13		12	16.67
Xia Qiufang 2011	Warm	23		15	0	X
	Needle	17		19	2	X
Yao Zhifang 2003	Warm	17 (17.3)	43 (44.0)	31 (31.6)	7 (7.1)	92.9
	Needle	5 (8.8)	20 (35.1)	19 (33.1)	13 (22.8)	80.8
Yu Jian 2009	Warm	25 (78.1)		6 (18.8)	1 (3.1)	96.9
	Needle	16 (53.3)		9 (30.0)	5 (16.7)	83.3
Yue Rong 2010	Warm		8 (24.2)	22 (66.7)	3 (9.1)	90.9
	Needle		6 (18.8)	20 (62.5)	6 (18.8)	81.3

First author	Group	3 n (%)	2 n (%)	1 n (%)	0 n (%)	Effectiveness Rate
Zhang Zhiping 2013	Warm	14	16	12	1	97.67
	Needle	8	15	14	6	86.05
Zhao Min 2014	Warm	7 (20)	16 (45.7)	9 (22.8)	3 (11.4)	91.4
	Needle	5 (15.6)	12 (37.5)	9 (28.1)	6 (18.8)	81.3
Zhao Xuetian 2008	Warm	14 (28.0)	32 (64.0)		4 (8.0)	92. 0
	Needle	12 (24.0)	26 (52.0)		12 (24.0)	76. 0

3,2,1,0 - numeric system identifying ordinal categories. n - number of participants (%) - Number of participants as a percentage

Appendix-C10: Scale responder-rates results

First author	Group	3 n (%)	2 n (%)	1 n (%)	0 n (%)	Effectiveness Rate
Cui Hw 2013	Warm	16	20	12	2	96.0%
	Needle	5	15	18	12	76.0%
Ding Jx 2016	Warm	13 (37.14)	18 (51.43)	3 (8.57)	1 (2.86)	34 (97.14)
	Needle	6 (17.14)	17 (48.57)	6 (17.14)	6 (17.14)	29 (82.86)
Hu Jh 2015	Warm	7 (25.93)	14 (51.85)	5 (18.52)	1 (3.70)	96.30%
	Needle	4 (14.82)	14 (51.85)	5 (18.52)	4 (14.81)	85.19%
Li Cd 2006	Warm	18 (32.1)	22 (39.3)	14 (25.0)	2 (3.6)	96.4%
	Needle	4 (7.4)	21 (38.9)	25 (46.3)	4 (7.4)	92.6%
Li L 2011	Warm	3	24	9	4	90%
	Needle	1	8	23	8	80%
Liu La 2003	Warm	75 (76.5)	10 (10.2)	7 (7.2)	6 (6.1)	x
	Needle	36 (43.4)	18 (21.7)	16 (19.3)	13 (15.6)	x
Wang Gz 2007	Warm	33 (66.0)	16 (32.0)	0*	1 (2.0)	98.0%
	Needle	15 (32.6)	21 (45.7)	0*	10 (21.8)	78.3%
Wang Gz 2009	Warm	23 (65.7)	11 (31.4)	0*	1 (2.9)	97.1%
	Needle	10 (31.3)	15 (46.9)	0*	7 (21.9)	78.2%
Xia Qf 2011	Warm	19	15	4	0	89.5%
	Needle	13	16	9	0	76.3%

First author	Group	3 n (%)	2 n (%)	1 n (%)	0 n (%)	Effectiveness Rate
Yan Xl 2013	Warm	6	25	8	2	95.12 (39/41)
	Needle	3	20	12	5	87.50 (35/40)
Yang D 2014	Warm	0*	20	8	2	92.5%
	Needle	0*	12	15	3	85.0%

3,2,1,0 - numeric system identifying ordinal categories. n - number of participants (%) - Number of participants as a percentage
Figures have been prevented to the same number of decimal places as in the original reports
* original table did not report the number of participants in this category - 0 was derived through calculation

Appendix-C11: Physical parameters of interventions - Vickers et al trials 1

Trial	Acupuncture points			Stimulation			Needles	
	Range	Local	Distal	Deqi?	Depth	Time	Diameter mm	Length mm
Berman et al 2004	x	5	4	Yes (all)	0.3-1 inch	20	0.25	25-40
Foster et al 2007	6-10	x	x	Yes	5-25mm	25-30	0.3	30
Lansdown et al 2009	x	x	x	x	x	x	x	x
Scharf et al 2007	7-15	7-11	2	Yes	5-35	20-30	0.3	25-40
Suarez et al 2010	6	5	1	x	0.2 - 1.2 cun	20	0.22	25-40
Tukmachi et al 2004	9	6	3	Yes	10-15	20-30	0.3	30
Vas et al 2004	9	5	4	Yes	x	x	0.3	45
Williamson et al 2007	x	5	1	Yes	x	20	0.25	25
Witt et al 2005	16	> 6	> 2	Yes	x	30	x	x
Witt et al 2006	x	x	x	x	x	x	x	x
Hinman et al 2014	x	x	x	x	x	20	0.25	40
Mavrommatis et al 2012	10	6	4	Yes	x	20	0.3	30

Appendix-C12: Physical parameters of interventions - Vickers et al trials 2

Trial	Sessions		Control			
	Total	Frequency	Sham	Non - acupuncture	Stimulation	Practitioners
Berman et al 2004	23	Tapered 2/ week to 1/4weeks	Non-insertion	Education 6 session	Electro & manual	Licensed 2 year experience
Foster et al 2007	6	2/week	Non-insertion	advice exercise	manual	AACP
Lansdown et al 2009	10	weekly	None	usual care	manual	BAcC
Scharf et al 2007	10-15	10 in 6 weeks	shallow non-point	physiotherapy	manual	Physician
Suarez et al 2010	12	2/week	shallow non-point	waiting list	Electro & manual	Acupuncturist
Tukmachi et al 2004	10	2/week	None	-	Electro & manual	Acupuncturist
Vas et al 2004	12	1/week	Non-insertion	x	Electro & manual	Acupuncturist
Williamson et al 2007	6	1/week	None	physiotherapy/ advice	manual	Physiotherapist
Witt et al 2005	12	12 in 8 weeks	shallow non-point	waiting list	manual	Physician

Trial	Sessions		Control			
	Total	Frequency	Sham	Non - acupuncture	Stimulation	Practitioners
Witt et al 2006	15	15 in 3 months	None	waiting list	manual	Physician
Hinman et al 2014	12	12 in 8 weeks	placebo laser	laser/ no treatment	manual	Physician
Mavrommatis et al 2012	16	2/week	Non-insertion	medication	Electro & manual	Physician

Appendix-C13: Trial design characteristic - Vickers et al trials

	Setting	Recruit-ment	N	Experiment n	Control - Sham n	Control - Non sham n	Outcome measure	Data collection points
Berman et al 2004	Multi-site Outpatients	Print and radio adverts	460	173	163	124	WOMAC SF36 (physical component) Global assessment/ walk time	8 and 26 weeks
Foster et al 2007	Multi-site Outpatients	Referred by GP	352	117	119	116	WOMAC	2 and 6 weeks / 6 and 12 months
Lansdown et al 2009	Private acupuncture	Via GP	30	15	x	15	WOMAC,OKS, SF36 (v2) EQ-5D	3 and 12 months
Scharf et al 2007	Multi-site Outpatients	Via GP	1007	326	365	316	WOMAC, SF-12, Global patient assessment	13 and 26 weeks
Suarez et al 2010	Clinic	x	527	75/78	151/151	72	Joint-specific multidimensional assessment plan (J-MAP) WOMAC SF36, VAS	4 and 6 weeks and 3 months
Tukmachi et al 2004	Single site	via hospital	29	19	x	10	VAS, WOMAC	5 and 10 weeks

	Setting	Recruit-ment	N	Experiment n	Control - Sham n	Control - Non sham n	Outcome measure	Data collection points
Vas et al 2004	Single site	health centres	97	48	49	x	WOMAC, Profile of quality of life (PQLC)	week 12
Williamson et al 2007	Group setting - single site	via hospital	181	60	x	60/61	OKS, timed walk	week 7, 12 and 3 months
Witt et al 2005	Multi-site Outpatients	outpatient centres	224	150	76	74	WOMAC, SF36, ADS depression scale	8,26,52 weeks
Witt et al 2006	Multi-site Outpatients	outpatient centres	3633	357	x	355	WOMAC, SF36	3 and 6 months
Hinman et al 2014	Multi-site Outpatients	outpatient centres	282	70	70	71/71	WOMAC, multiple others	12 weeks, 12 months
Mavrommatis et al 2012	Single site	outpatient centres	120	40	40	40	WOMAC, SF36 v2, VAS	4,8,12 weeks

Appendix D: Expert Interviews

Appendix D Table of Contents

Appendix D1: Ethics approval (Expert interviews)

London South Bank University

[redacted]

Ref: UREC 1258

Ian Appleyard

Wednesday, March 06, 2013

Dear Ian,

Re: Acupuncture and moxibustion in practice for the treatment of osteoarthritis OA of the knee: Expert Interviews

Thank you for submitting this proposal and for your response to the reviewers' comments.

I am pleased to inform you that your application to the University Research Ethics Committee for the above study has been reviewed. The Chair is able to confirm that the study was completed in keeping with the London South Bank University Code of Practice for Research with Human Participants.

I wish you every success with your research.

Yours sincerely,

Sharon Dippenaar
Secretary, LSBU Research Ethics Committee

cc:

Prof Joan Curzio, Chair, LSBU Research Ethics Committee

Appendix D2: Interview schedule (Expert Interviews)

Interview Schedule

Hello I would just like to double-check a couple of things with you before we start.

You use YYY style of practice to treat OA of the knee?

Approximately how many people do see with OA of the knee in a week?

1. Please describe in as much detail as possible the process of treating osteoarthritis of the knee with acupuncture from the moment a person walks into your consulting room to the end of their course of treatment?

Prompts

Could you please describe (your use of)

- Moxibustion
- Electro-acupuncture
- Local points
- Adjacent points
- Distal points
- Cupping
- Needle stimulation
- Needles used
- Diagnostic methods
- The length of a typical course of treatment
- Typical lifestyle recommendations
- Other techniques/ medications
- Contraindications

Thank you for your time.

Have you got any questions you would like to ask me?

As you know I will be designing a questionnaire based on the information obtain from these interviews. Would you be willing to look at the questionnaire and give me some feedback?

Interview Schedule: Ian Appleyard PhD research project. Expert Interviews 2013

Appendix D3: Participant information sheet (Expert interviews)

London South Bank University

Participant Information Sheet

The title of the Research Project is: Acupuncture and moxibustion in practice for the treatment of osteoarthritis (OA) of the knee: Expert Interviews

Dear

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

This research is one component of my PhD research, which is looking at the use of acupuncture and moxibustion for the treatment of OA of the knee.

As I am sure you are aware the practice of acupuncture is diverse and pluralistic. This research is aimed at developing a comprehensive understanding of practice among all practitioners regardless of their training or background. The emphasis is on trying to understand what actually happens in practice rather than the theory/ recommendations that can be derived from textbooks.

The data derived from these interviews will be used to formulate a questionnaire for use in a comprehensive survey of the use of acupuncture to treat OA of the knee.

Why have I been chosen?

In order to ensure that a comprehensive understanding is developed it is proposed that 8 experts will be interviewed, who represent different styles of practice and professional organisations.

You have been chosen because you are a member of BAcC and practice Stems and Branches acupuncture.

Furthermore the eligibility criteria include the following:

- You are in current practice
- You have a minimum of 5 years' experience of using acupuncture
- You have recent, within the last year, experience of treating OA of the knee
- You are in current practice
- You are well-known in the field as an educator or author

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will be involved?

Once we have arranged a mutually convenient time I will travel to meet you. It is proposed that the interview will last approximately 1 hour. The interview will be recorded to help data analysis.

What are the possible benefits of taking part?

I will be happy to send you a report on the findings of the study.

What if something goes wrong?

If the you wish to make a complaint about the conduct of the study could you please contact-

Professor Joan Curzio
Faculty of Health and Social Care
London South Bank University
103 Borough Road
SE 1 0AA
Tel 020 7815 6126
Email: ethics@lsbu.ac.uk

Professor Nicola Robinson
Faculty of Health and Social Care
London South Bank University
103 Borough Road
SE 1 0AA
Tel 020 7815 7940
Email: nicky.robinson@lsbu.ac.uk

Will my taking part in this study be kept confidential?

All information collected from you during the course of the research will be kept strictly confidential. The data will be stored on a password-protected computer at LSBU until 2020. Any information that is shared with others (e.g. in reports and publications) will have your name and address removed so that you cannot be recognised from it. If in any report or publication I wish to use a quote that could possibly identify you as an interviewee, or I believe you should be referenced, then I will contact you in order to seek your permission.

In the unlikely event that you describe something that appears to constitute unsafe practice I may contact you after the interview to raise my concerns and ensure I have not misunderstood. Following these discussions it might be necessary for me to refer the matter to your professional organisation. I will inform you immediately if the decision is made to refer the matter to your professional organisation.

London South Bank University Research Ethics Committee has reviewed and approved this Research Proposal.

If you require further information please don't hesitate to contact me

Ian Appleyard
Faculty of Health and Social Care
London South Bank University
103 Borough Road
SE 1 0AA
Tel 020 7815 8014
Email: appleyai@lsbu.ac.uk

Participant Information Sheet. Ian Appleyard PhD research project. Expert Interviews 2013

Appendix E: Practitioner Survey

Appendix E Table of Contents

Appendix E1: Ethics confirmation (Practitioner survey)

London South Bank University

[redacted]

Ref: UREC 1531

Ian Appleyard

[redacted]

Friday 21 August 2015

Dear Alex

RE: Acupuncture and moxibustion in practice for the treatment of osteoarthritis OA of the knee: practitioners survey

Thank you for submitting this proposal and for your response to the reviewers' comments.

I am pleased to inform you that Full Chair's Approval has been given by Vice Chair on behalf of the University Research Ethics Committee.

I wish you every success with your research.

Yours sincerely,

N Mitchell

Nicola Mitchell

Secretary, LSBU Research Ethics Committee

cc:

Prof Shushma Patel, Chair, LSBU Research Ethics Committee

Appendix E2: Participant information sheet (Practitioner survey)

London South Bank University

Participant Information Sheet

ACUPUNCTURE AND MOXIBUSTION IN PRACTICE FOR THE TREATMENT OF OSTEOARTHRITIS OF THE KNEE: PRACTITIONER SURVEY

You are being invited to complete a questionnaire as part of a research study.

The aim of this study is to gather descriptive data on the components of the practice of acupuncture and associated techniques used to treat osteoarthritis of the knee in clinical practice, in the UK.

[**You were randomly selected** from the British Acupuncture Council's/ British Medical Acupuncture Society's/Acupuncture Association of Chartered Physiotherapists/ Association of TCM public registers of practitioners. In total 100 practitioners have been selected through randomisation]
THIS SENTENCE ONLY INCLUDED FOR RANDOMISED PARTICIPANTS

Participants need to use acupuncture as part of their scope of practice and belong to a professional organisation.

The questionnaire should take approximately 15 minutes to complete.

Do I need to complete the survey?
It is up to you to decide whether or not to take part. Completion of the survey will be taken as giving consent. Please contact me if there is anything that is not clear or if you would like more information.

Will the questionnaire be confidential? Yes. The questionnaire should be completed anonymously. In addition, all information received from you will be handled in a confidential manner and stored in a locked filing cabinet and on a password protected computer in an environment locked when not occupied. Only the researcher and supervisor will have direct access to the information.

This study is being completed as part of a PhD at London South Bank University. It has been reviewed and ethically approved by the London South Bank University Research Ethics Committee.

If you have a concern about any aspect of this study, please feel free to contact me or my academic supervisor Prof Nicola Robinson (Contact details are below).

Finally, if you remain unhappy and wish to complain formally, you can contact the Chair of the University Research Ethics Committee. Details can be obtained from the university website: http://www.lsbu.ac.uk/rbdo/external/index.shtml

Contact Details

Ian Appleyard
School of Health and Social Care
London South Bank University
103 Borough Road

SE1 0AA

Tel: 0207 815 8014

Email: appleyai@lsbu.ac.uk

Prof Nicola Robinson

School of Health and Social Care
London South Bank University
103 Borough Road

SE1 0AA

Tel: 0207 815 7940

Email: nicky.robinson@lsbu.ac.uk

Appendix E3: Snowballing email to contacts - Method 2

Dear

I am currently doing a PhD looking at acupuncture for osteoarthritis of the knee. One element of this research is a practitioner survey which aims to gather information on how acupuncture and associated techniques are used in practice.

I wonder if you would be kind enough to do two things for me.

- Complete the survey using survey monkey Click here to begin
- Forward this email to your friends and colleagues who practice acupuncture

Please note the survey will take about 15 minutes and is completed anonymously.

If you have any questions regarding the survey please do not hesitate to contact me.

kind regards

[Insert Participation Information Sheet]

Appendix E4: Cover letters - Methods 3 and 4

Method 3: Letter format

Dear

I am currently doing a PhD looking at acupuncture for osteoarthritis of the knee. One element of this research is a practitioner survey which aims to gather information on how acupuncture and associated techniques are used in practice.

You were randomly selected from the British Acupuncture Council's/ British Medical Acupuncture Society's/Acupuncture Association of Chartered Physiotherapists/ Association of TCM public registers of practitioners. In total 100 practitioners have been selected through randomisation.

I wonder if you would be kind enough to do complete the survey by clicking on the following link to Survey Monkey. Click Here

Please note the survey will take about 15 minutes and is completed anonymously. Please see the enclosed participant information sheet for further details.

If you have any questions regarding the survey please do not hesitate to contact me.

kind regards

Method 4: Email format

Dear

I am currently doing a PhD looking at acupuncture for osteoarthritis of the knee. One element of this research is a practitioner survey which aims to gather information on how acupuncture and associated techniques are used in practice.

You were randomly selected from the British Acupuncture Council's/ British Medical Acupuncture Society's/Acupuncture Association of Chartered Physiotherapists/ Association of TCM public registers of practitioners. In total 100 practitioners have been selected through randomisation.

I wonder if you would be kind enough to complete the survey and return it to me using the stamped addressed envelope.

Please note the survey will take about 15 minutes and is completed anonymously. Please see the enclosed participant information sheet for further details.

If you have any questions regarding the survey please do not hesitate to contact me.

kind regards

[Insert Participation Information Sheet]

Appendix E5: Free text answers to question 1 - Style(s) of practice

	Options chosen	Free text answer	Allocated Group
1		Western acupuncture	Medical
2		Western approach	Medical
3		Western acupuncture	Medical
4*	Medical	Western medical acupuncture	Medical
5*		? Western approach	Medical
6	TCM	Trigger point	TCM
7		TCM and medical	TCM
8	TCM - Medical	MSK meridian approaches	TCM
9	TCM - Medical	Dry needling	TCM
10	TCM	Ashi	TCM
11*	TCM - Medical	Gunn IMS	TCM
12*		Integrated approach Chinese and Western medical	TCM
13*	TCM	Musculoskeletal	TCM
14*	TCM	Dr Tan	TCM
15		Hybrid	Com
16		Three Korean acupuncture techniques, Saam, VST, and kinetic acupuncture	Com
17*		All	Com
18		Classical acupuncture (TMC, five elements, TCM, and stems and branches)	Com
19		tan wu bian	Com
20	TCM	Balance method, Tung	Com
21		Classical	Com
22		I do a combination of five elements and TCM	Com
23	Five elements - Japanese - TCM	Dr Tung	Com
24		Combination of above plus stems and branches	Com

	Options chosen	Free text answer	Allocated Group
25*	Five element - TCM	Sometimes use stems and branches	Com
26*		Traditional five phase and yin yang Chinese medicine	Com
27*		Tung	Com
28*	Five element	a hybrid of 25 years of learning	Com

Appendix E6: Free text answers to question 3-Acupuncture organisation

Initials	Organisation	Respondents
NCCAOM	National Certification Commission for Acupuncture and Oriental Medicine (USA)	3
	Norwegian acupuncture assosiation	1
ATMS	Australian Traditional Medicine Society	1
AACMA	Australian Acupuncture and Chinese Medicine Association	1
FSOMA	Florida State Oriental Medicine Association	1
ACI	Acupuncture Council of Ireland	2
	Allied Health	1
ACMC	Acupunctura Médica Contemporânea (Portugal)	1
	Did not answer the question	5
Total		**16**

Safety and further information

25. Have you ever encountered an adverse event whilst treating chronic knee pain with acupuncture? Please describe what happened

26. Please provide further information on how you treat knee pain. Please indicate what you feel is important for effective treatment.

Please use the enclosed stamp addressed envelope to return this survey form

Thank you for completing the survey

Acupuncture for OA of the knee Practitioner Survey

Please complete this survey

The survey focuses on what **physically happens** in the treatment of osteoarthritis of the knee with acupuncture. There are also some questions about your training and style of practice.

The questionnaire should take approximately 15 minutes to complete.

Do I need to complete the questionnaire?
It is up to you to decide whether or not to take part. Completion of the questionnaire will be taken as giving consent. Please contact me if there is anything that is not clear or if you would like more information.

Will the questionnaire be confidential? Yes. The questionnaire should be completed anonymously. In addition, all information received from you will be handled in a confidential manner and stored in a locked filing cabinet and on a password protected computer in an environment locked when not occupied. Only the researcher and supervisor will have direct access to the information.

This study is being completed as part of a PhD at London South Bank University. It has been reviewed and ethically approved by the London South Bank University Research Ethics Committee.

If you require further information please don't hesitate to contact me:

Ian Appleyard
School of Health and Social Care
London South Bank University
103 Borough Road
SE 1 0AA
Tel 020 7815 8014

Email: appleyai@lsbu.ac.uk

Background Information

Please circle to indicate your answers

1. How would you describe the style(s) of acupuncture you practice?

Five-Element Japanese TCM Medical-acupuncture Other

If other please specify _____

2. How long have you been using acupuncture as part of your scope of practice?

_____ Years _____ Months (if recently started using acupuncture)

3. Which acupuncture organisation(s) do you belong to?

AACP ATCM BAcC BMAS Other

If other please specify _____

4. What is your main acupuncture qualification?

PhD Masters BSc/equivalent 80+ Hour course Short course

Other If other please specify _____

5. Are you a healthcare professional belonging to a statutorily regulated body?

Chiropractor Doctor Nurse Osteopath Physiotherpist No

Other If other please specify _____

6. Approximately how many people do you treat each month with osteoarthritis of the knee?

_____

Section E: Miscellaneous

Please tick to indicate your answers

25. The proportion of chronic knee pain treatment sessions for which:

	Never	Less than 25%	25-75%	More than 75%	Always
I use cupping locally to the knee					
I use cupping at places other than locally to the knee					
I use a heat lamp over the knee					
I use a heat lamp at places distal to the knee					
I use massage					
I use TENS					

Please tick to indicate your answers

26. The proportion of chronic knee pain patients for which:

	None	Less than 25%	25-75%	More than 75%	All
I give dietary advice					
I give exercise advice					
I advise the knee should be kept warm					

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Section C: Course of treatment

21. On <u>average</u> how many sessions would you expect an initial course of treatment to be? ____

22. If the patient shows <u>no sign</u> of improvement, after how many sessions do you consider discontinuation or referral? _____

Please tick to indicate your answers

23. The proportion of chronic knee pain <u>patients</u> for which:

	None	Less than 25%	25-75%	More than 75%	All
I treat once a week					
I treat 2 times a week or more frequently					
I will suggest to the patient that they come back for top up treatments/ or decrease the frequency of treatment to once a fortnight/ month etc					

Section D: Adaption of treatment

Please tick to indicate your answers

24. The proportion of chronic knee pain <u>patients</u> for which:

	None	Less than 25%	25-75%	More than 75%	All
I modify the first 1 or 2 treatments to allow the patient to get used to acupuncture e.g. using fewer needles or gentler stimulation					
I will reduce the number of needles because I feel the patient is anxious					
I will reduce the number of needles because the patient is sensitive to needling					
I will use fewer distal points because I feel the patient believes it is not logical to place needles away from the knee.					
Expense or difficulty in attending prevent them from having an adequate number of treatment sessions					
Limited appointment time prevents what I believe to be optimal acupuncture being delivered					

Scenario

When answering the questions please consider this scenario

The typical case is someone over 50

They suffer from chronic pain and stiffness in **<u>one</u>** knee.

They have been told by their GP they have osteoarthritis of the knee.

The knee does **not feel hot** to touch or to the patient. The pain is **not made** worse by warmth.

There has been **no** recent fall or twisting of the joint.

Section A - Point Distribution

Total number of needles used

7. The most needles in total I might insert is _____

8. The fewest needles in total I might insert is _____

9. On average the total number of needles I insert is typically _____

Number of needles inserted <u>locally</u> to the affected knee (within 10 cm of the knee joint)

10. The most needles I might insert locally to an affected knee is _____

11. The fewest needles I might insert locally to an affected knee is _____

12. On average the number of needles I insert locally to an affected knee is typically _____

Section A - Point Distribution continued

Please tick to indicate your answers

13. The proportion of chronic knee pain treatment sessions for which:

	Never	Less than 25%	25-75%	More than 75%	Always
I use A-shi points					
I insert needles at local points (within 10 cm of the knee)					
I insert needles distal to the knee, on the affected leg, selected according to the meridian affected/distribution of pain					
I insert needles around the unaffected knee					
I insert needles at the elbow to reduce knee pain					
I use distal points to help support/strengthen general health, such as SP6 *sanyinjiao*					
I use distal points to help calm/ relax the patient, such as LI4 *hegu* or *yintang*					
I insert needles at points to address other signs and symptoms (such as insomnia, indigestion, breathing difficulties etc)					
I use Back Shu points eg BL11, BL20, BL23					

Section B - Stimulation

Please circle to indicate your answers

14. The approximate length of time the needles are normally retained is

Less than 5mins 5mins 10mins 15mins

20mins 25mins 30mins More than 30mins

15. The thickness of the needles I normally use is

mm	<0.18	0.18	0.20	0.22	0.25	0.30	0.35
Gauge	<38	38	36	34	32	30	28

16. The approximate depth of needle insertion at points local to knee is

Less than 2mm 2-5mm 5-15mm More than 15mm

Section B - Stimulation

Please tick to indicate your answers

17. The proportion of chronic knee pain treatment sessions for which:

	Never	Less than 25%	25-75%	More than 75%	Always
I try to obtain a tingling or aching sensations felt by the patient (deqi)					
I manipulate the needle in order to 'tonify' or 'reduce'					
I use electro-acupuncture on points local/adjacent to the affected knee					
I use electro-acupuncture at distal points on the affected leg					
I use electro-acupuncture on the opposite leg/hands/arms/torso/head					

18. Are you able to use moxibustion in your clinic? Please circle to indicate your answers

A. Yes **B: Yes** in some of my practice locations **C. No**

If you answered C - go to Section 3 Course of Treatment

19. Do you use moxibustion? Please circle to indicate your answers

Yes **No** → **If no go to Section 3 Course of Treatment**

Please answer the following questions for the clinics where you are able to use moxibustion

Please tick to indicate your answers

20. The proportion of chronic knee pain treatment sessions for which:

	Never	Less than 25%	25-75%	More than 75%	Always
I use moxa local to the knee					
I use moxa at points distal to the knee					
I use moxa on the end of the needles 'warm needle technique'					
I use a moxa stick					
I use moxa placed directly on the skin					
I use moxa placed on a slice of ginger/salt/etc					
I use moxa (any method or location)					

Table of Contents Appendix E

Section A: Questions 7-12 Number of needles used

		Range	Minimum	Maximum	Mean	Std. Deviation
The most needles in total I might insert is	Medical	21	4	25	9.4	4.1
	TCM	66	4	70	13.5	8.6
	Combined	27	3	30	10.0	5.2
The fewest needles in total I might insert is	Medical	8	1	9	3.9	1.6
	TCM	20	0	20	5.4	3.4
	Combined	14	1	15	4.2	2.8
A average the total number of needles	Medical	12	3	15	7.0	2.5
	TCM	31	4	35	9.8	5.1
	Combined	27	3	30	7.7	4.7
The most needles I might insert locally to an affected knee is	Medical	8	2	10	5.8	1.7
	TCM	19	1	20	6.6	2.5
	Combined	10	0	10	5.0	2.5
The fewest needles I might insert locally to an affected knee is	Medical	7	0	7	3.2	1.5
	TCM	7	0	7	2.7	1.5
	Combined	6	0	6	1.9	1.6
A average the number of needles locally	Medical	8	2	10	4.9	1.6
	TCM	9	1	10	4.9	1.7
	Combined	10	0	10	4.2	2.3

Appendix-E.8.2: Q13a - A-shi

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	14	20.6	20.6
	Less than 25%	17	25.0	45.6
	25-75%	22	32.4	77.9
	More than 75%	8	11.8	89.7
	Always	7	10.3	100.0
	Total	68	100.0	
	Missing	5		
	Total	73		
TCM	Never	4	4.7	4.7
	Less than 25%	18	21.2	25.9
	25-75%	16	18.8	44.7
	More than 75%	17	20.0	64.7
	Always	30	35.3	100.0
	Total	85	100.0	
	Missing	11		
	Total	96		
Combined	Never	3	8.3	8.3
	Less than 25%	9	25.0	33.3
	25-75%	10	27.8	61.1
	More than 75%	6	16.7	77.8
	Always	8	22.2	100.0
	Total	36	100.0	
	Missing	6		
	Total	42		

Appendix-E.8.3: Q13b - Local

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	1	1.4	1.4
	25-75%	10	14.3	15.7
	More than 75%	15	21.4	37.1
	Always	44	62.9	100.0
	Total	70	100.0	
	Missing	3		
	Total	73		
TCM	Never	1	1.1	1.1
	Less than 25%	2	2.3	3.4
	25-75%	6	6.9	10.3
	More than 75%	30	34.5	44.8
	Always	48	55.2	100.0
	Total	87	100.0	
	Missing	9		
	Total	96		
Combined	Never	2	5.9	5.9
	Less than 25%	5	14.7	20.6
	25-75%	8	23.5	44.1
	More than 75%	9	26.5	70.6
	Always	10	29.4	100.0
	Total	34	100.0	
	Missing	8		
	Total	42		

Appendix-E.8.4: Q13c - Meridian

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	7	10.1	10.1
	Less than 25%	8	11.6	21.7
	25-75%	16	23.2	44.9
	More than 75%	19	27.5	72.5
	Always	19	27.5	100.0
	Total	69	100.0	
	Missing	4		
	Total	73		
TCM	Never	1	1.1	1.1
	Less than 25%	6	6.9	8.0
	25-75%	19	21.8	29.9
	More than 75%	29	33.3	63.2
	Always	32	36.8	100.0
	Total	87	100.0	
	Missing	9		
	Total	96		
Combined	Less than 25%	5	14.3	14.3
	25-75%	10	28.6	42.9
	More than 75%	10	28.6	71.4
	Always	10	28.6	100.0
	Total	35	100.0	
	Missing	7		
	Total	42		

Appendix-E.8.5: Q13d - Unaffected knee

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	34	48.6	48.6
	Less than 25%	26	37.1	85.7
	25-75%	6	8.6	94.3
	More than 75%	4	5.7	100.0
	Total	70	100.0	
	Missing	3		
	Total	73		
TCM	Never	21	25.0	25.0
	Less than 25%	36	42.9	67.9
	25-75%	15	17.9	85.7
	More than 75%	8	9.5	95.2
	Always	4	4.8	100.0
	Total	84	100.0	
	Missing	12		
	Total	96		
Combined	Never	2	7.4	7.4
	Less than 25%	14	51.9	59.3
	25-75%	9	33.3	92.6
	More than 75%	1	3.7	96.3
	Always	1	3.7	100.0
	Total	27	100.0	
	Missing	15		
	Total	42		

Appendix-E.8.6: Q13e - Elbow

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	60	85.7	85.7
	Less than 25%	7	10.0	95.7
	25-75%	1	1.4	97.1
	Always	2	2.9	100.0
	Total	70	100.0	
	Missing	3		
	Total	73		
TCM	Never	34	41.5	41.5
	Less than 25%	27	32.9	74.4
	25-75%	14	17.1	91.5
	More than 75%	6	7.3	98.8
	Always	1	1.2	100.0
	Total	82	100.0	
	Missing	14		
	Total	96		
Combined	Never	7	22.6	22.6
	Less than 25%	13	41.9	64.5
	25-75%	5	16.1	80.6
	More than 75%	3	9.7	90.3
	Always	3	9.7	100.0
	Total	31	100.0	
	Missing	11		
	Total	42		

Appendix-E.8.7: Q13f - General health

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	24	34.3	34.3
	Less than 25%	12	17.1	51.4
	25-75%	18	25.7	77.1
	More than 75%	10	14.3	91.4
	Always	6	8.6	100.0
	Total	70	100.0	
	Missing	3		
	Total	73		
TCM	Less than 25%	14	16.3	16.3
	25-75%	15	17.4	33.7
	More than 75%	25	29.1	62.8
	Always	32	37.2	100.0
	Total	86	100.0	
	Missing	10		
	Total	96		
Combined	Never	2	5.9	5.9
	Less than 25%	2	5.9	11.8
	25-75%	7	20.6	32.4
	More than 75%	12	35.3	67.6
	Always	11	32.4	100.0
	Total	34	100.0	
	Missing	8		
	Total	42		

Appendix-E.8.8: Q13g - Relaxation

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	13	18.8	18.8
	Less than 25%	19	27.5	46.4
	25-75%	15	21.7	68.1
	More than 75%	17	24.6	92.8
	Always	5	7.2	100.0
	Total	69	100.0	
	Missing	4		
	Total	73		
TCM	Never	3	3.4	3.4
	Less than 25%	24	27.3	30.7
	25-75%	20	22.7	53.4
	More than 75%	20	22.7	76.1
	Always	21	23.9	100.0
	Total	88	100.0	
	Missing	8		
	Total	96		
Combined	Never	4	12.5	12.5
	Less than 25%	6	18.8	31.3
	25-75%	9	28.1	59.4
	More than 75%	6	18.8	78.1
	Always	7	21.9	100.0
	Total	32	100.0	
	Missing	10		
	Total	42		

Appendix-E.8.9: Q13h - Other Signs and symptoms

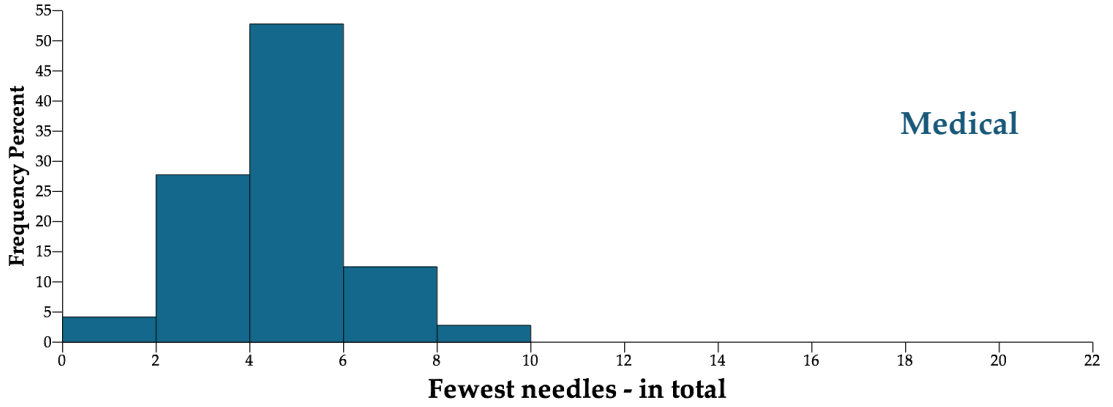
Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	42	60.0	60.0
	Less than 25%	20	28.6	88.6
	25-75%	4	5.7	94.3
	More than 75%	3	4.3	98.6
	Always	1	1.4	100.0
	Total	70	100.0	
	Missing	3		
	Total	73		
TCM	Never	5	5.7	5.7
	Less than 25%	18	20.5	26.1
	25-75%	29	33.0	59.1
	More than 75%	16	18.2	77.3
	Always	20	22.7	100.0
	Total	88	100.0	
	Missing	8		
	Total	96		
Combined	Never	4	11.8	11.8
	Less than 25%	3	8.8	20.6
	25-75%	6	17.6	38.2
	More than 75%	8	23.5	61.8
	Always	13	38.2	100.0
	Total	34	100.0	
	Missing	8		
	Total	42		

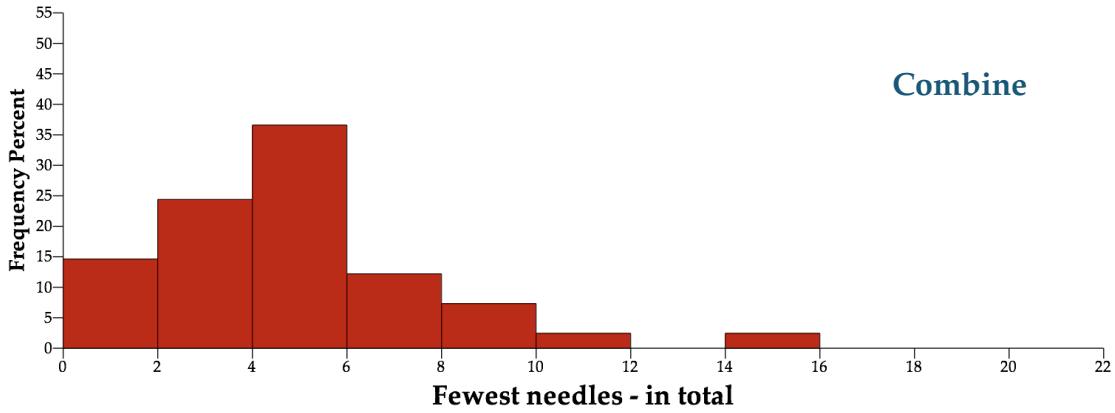
Appendix-E.8.10: Q13i - Back shu

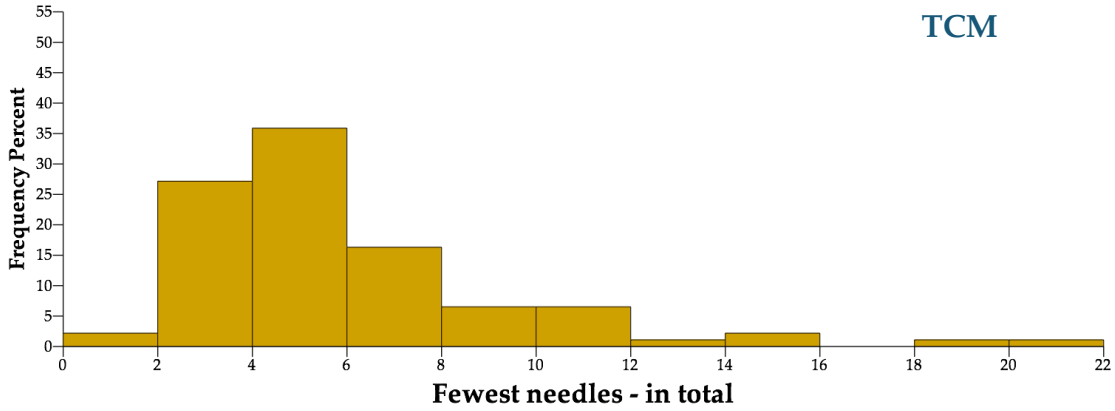
Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	47	67.1	67.1
	Less than 25%	14	20.0	87.1
	25-75%	9	12.9	100.0
	Total	70	100.0	
	Missing	3		
	Total	73		
TCM	Never	22	25.6	25.6
	Less than 25%	36	41.9	67.4
	25-75%	19	22.1	89.5
	More than 75%	7	8.1	97.7
	Always	2	2.3	100.0
	Total	86	100.0	
	Missing	10		
	Total	96		
Combined	Never	4	12.9	12.9
	Less than 25%	17	54.8	67.7
	25-75%	5	16.1	83.9
	More than 75%	3	9.7	93.5
	Always	2	6.5	100.0
	Total	31	100.0	
	Missing	11		
	Total	42		

Appendix E.9 Section A: Distribution graphs

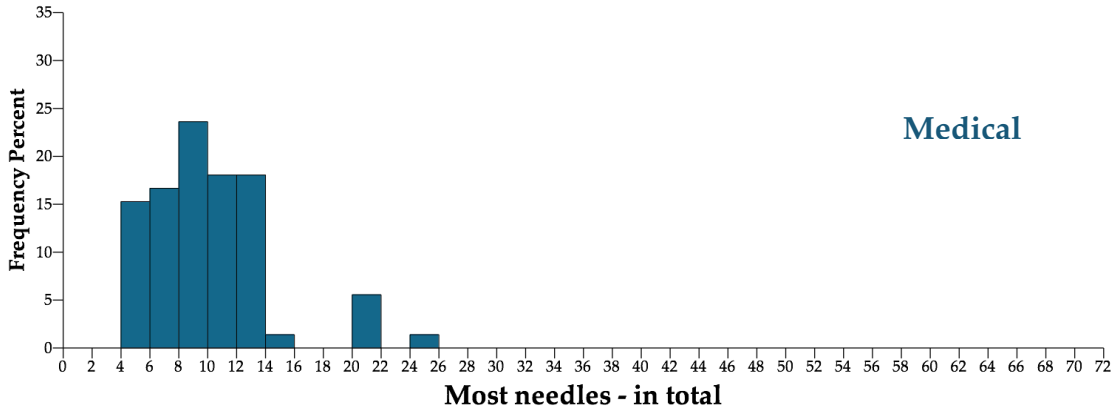
Appendix E.9.1 Fewest needles in total

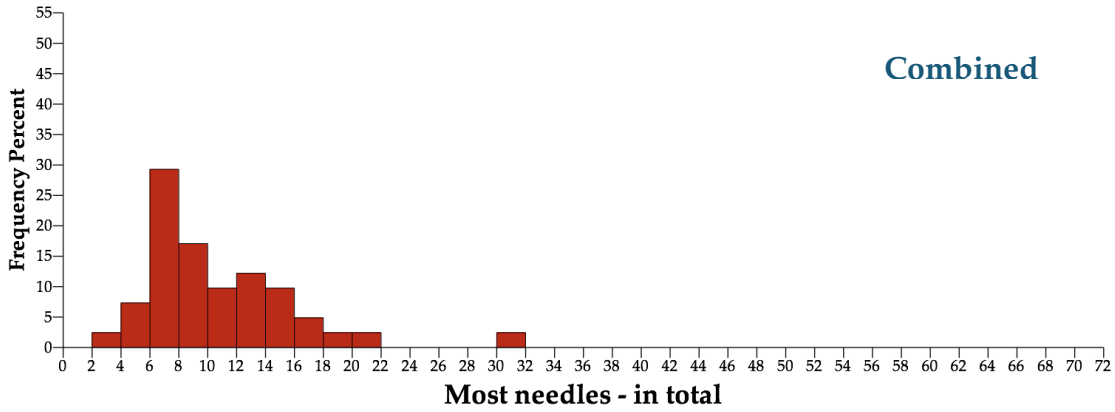


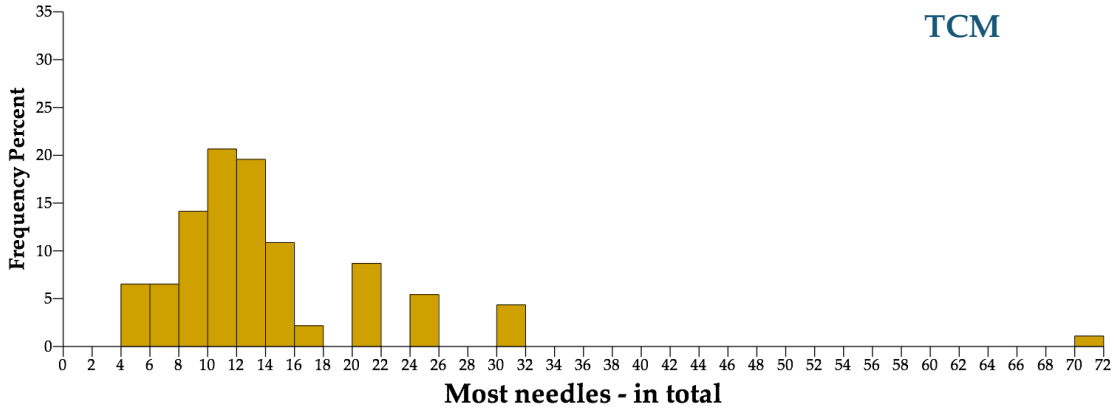




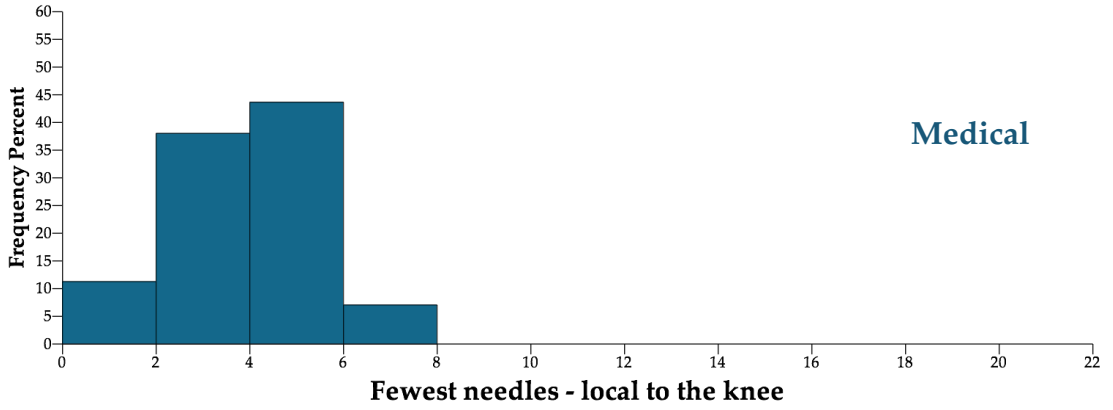
Appendix E.9.2: Most needles in total

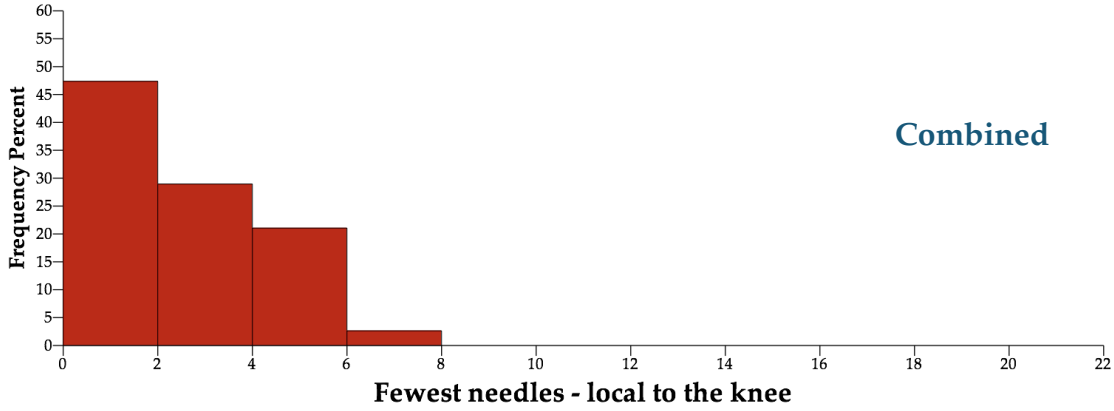


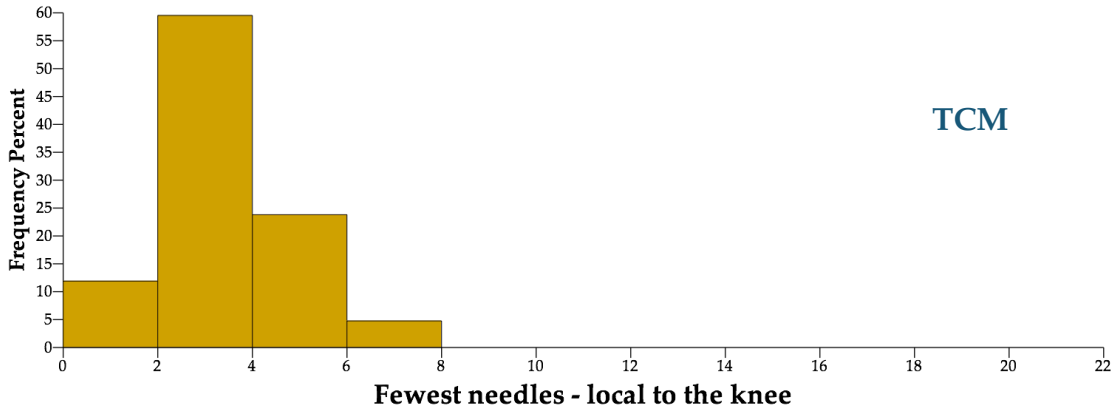




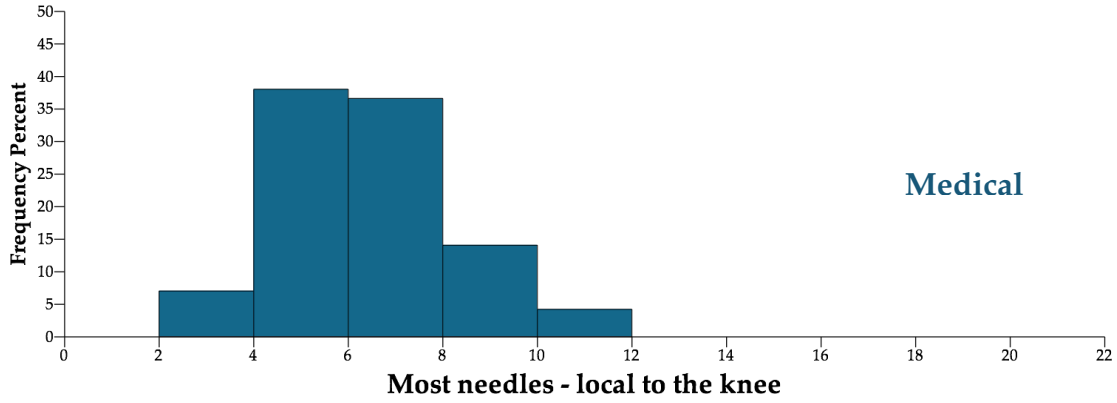
Appendix E.9.3 Fewest needles local to the knee

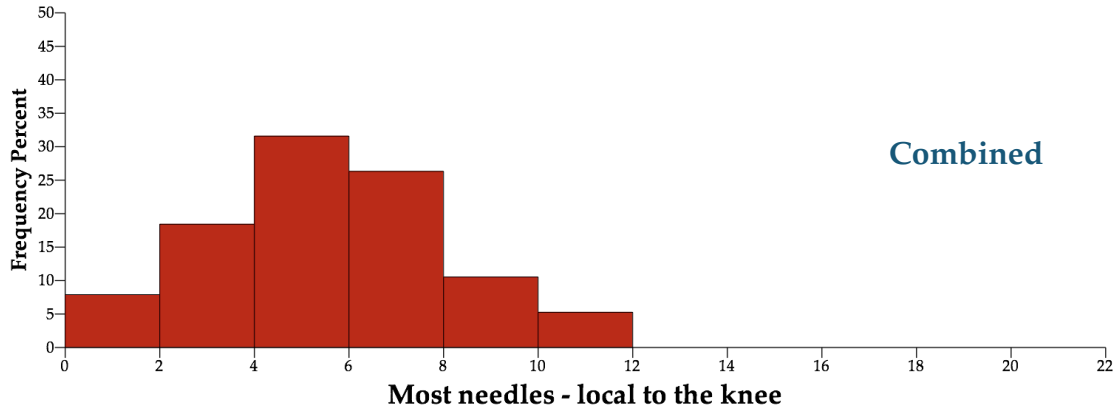


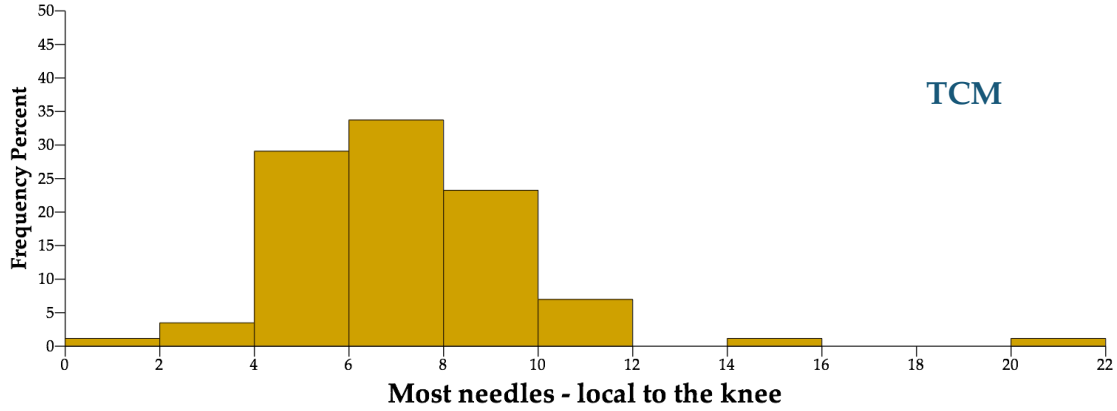




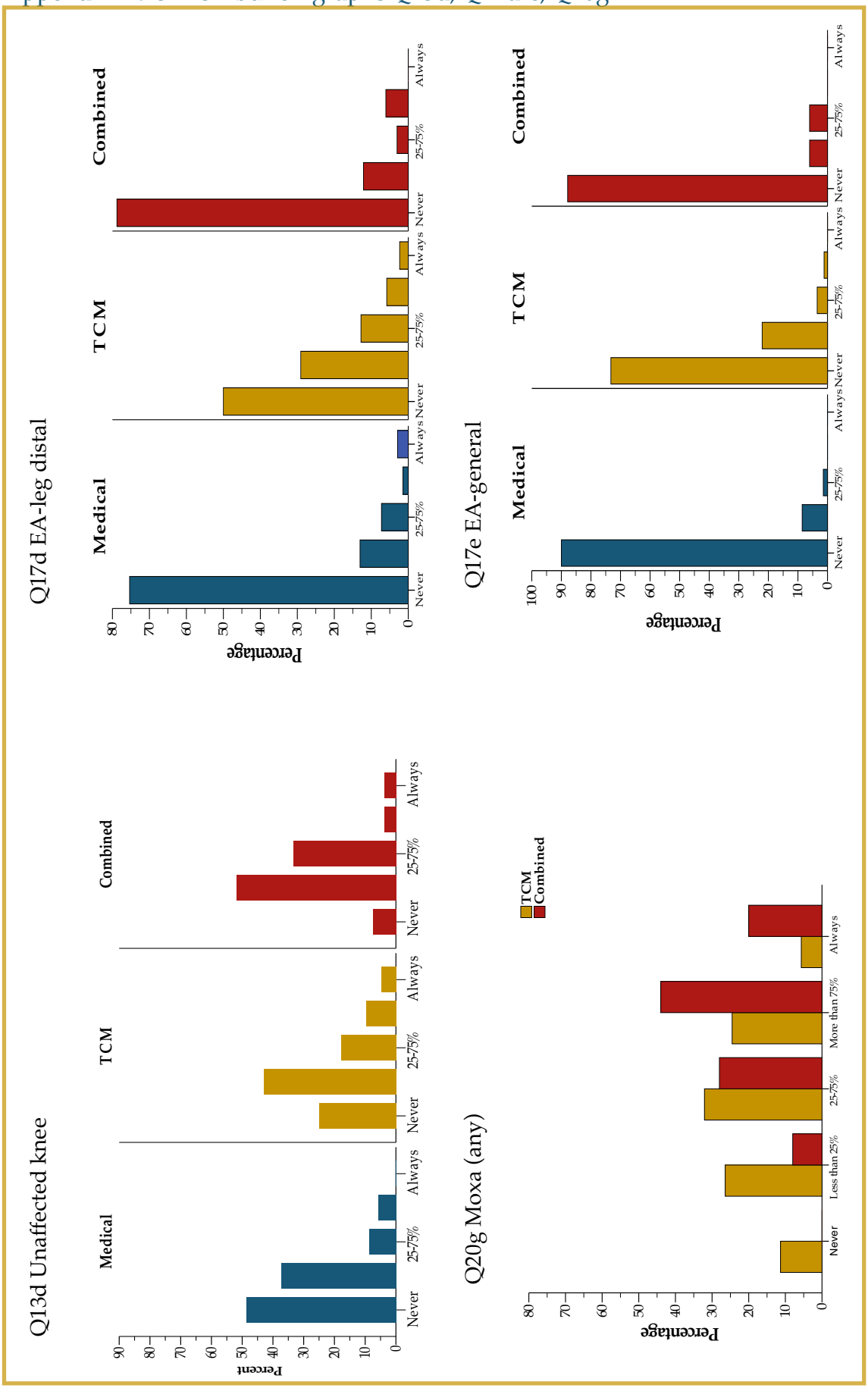
Appendix E.9.4 Most needles local to the knee







Appendix E.9.5 Distribution graphs Q13d, Q17d-e, Q20g



Appendix-E.10.1: Kruskal-Wallis Q7-12 Number of needles

Question	Allocated style	N	Mean Rank	Chi-Square	p
The most needles in total I might insert is	Medical	72	85	19.52	< 0.001
	TCM	92	123		
	Combined	41	90		
	Total	205			
The fewest needles in total I might insert is	Medical	72	93	7.77	0.021
	TCM	92	116		
	Combined	41	93		
	Total	205			
On average, the total number of needles	Medical	72	83	22.67	< 0.001
	TCM	92	125		
	Combined	41	89		
	Total	205			
The most needles I might insert locally to an affected knee is	Medical	71	92	13.00	0.002
	TCM	86	113		
	Combined	38	75		
	Total	195			
The fewest needles I might insert locally to an affected knee is	Medical	71	112	16.38	< 0.001
	TCM	84	97		
	Combined	38	68		
	Total	193			
On average, the number of needles locally	Medical	71	102	4.14	0.126
	TCM	86	101		
	Combined	37	81		
	Total	194			

df = 2 Non significant results shaded $p < 0.05$

Appendix-E.10.2: Kruskal-Wallis Q13 Stem questions

Component	Allocated Style	N	Mean Rank	Chi-Square	p
A-shi points	Medical	68	74	18.0	< 0.001
	TCM	85	111		
	Combined	36	95		
	Total	189			
Local points	Medical	70	105	16.4	< 0.001
	TCM	87	101		
	Combined	34	65		
	Total	191			
Meridian	Medical	69	86	5.1	0.078
	TCM	87	105		
	Combined	35	92		
	Total	191			
Unaffected knee	Medical	70	72	18.7	< 0.001
	TCM	84	99		
	Combined	27	114		
	Total	181			
Elbow	Medical	70	64	43.7	< 0.001
	TCM	82	104		
	Combined	31	124		
	Total	183			
General health	Medical	70	62	43.7	< 0.001
	TCM	86	116		
	Combined	34	114		
	Total	190			
Relaxation	Medical	69	80.06	8.9	0.012
	TCM	88	105.39		
	Combined	32	98.64		
	Total	189			
Other signs and symptoms	Medical	70	51.29	77.4	< 0.001
	TCM	88	119.36		
	Com	34	130.40		
	Total	192			
Back shu	Medical	70	66.43	33.6	< 0.001
	TCM	86	107.78		
	Combined	31	118.02		
	Total	187			

df = 2 Non significant results shaded$p < 0.05$

Appendix E.11: Stimulation - Descriptives

Appendix-E.11.1: Q17a - Deqi

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	6	9	9
	Less than 25%	4	6	14
	25-75%	6	9	23
	More than 75%	19	27	50
	Always	35	50	100
	Total	70	100	
	Missing	3		
	Total	73		
TCM	Never	4	5	5
	Less than 25%	10	12	16
	25-75%	17	20	36
	More than 75%	22	26	62
	Always	32	38	100
	Total	85	100	
	Missing	11		
	Total	96		
Combined	Never	7	19	19
	Less than 25%	5	14	33
	25-75%	4	11	44
	More than 75%	4	11	56
	Always	16	44	100
	Total	36	100	
	Missing	6		
	Total	42		

Appendix-E.11.2: Q17b - Tonify

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	17	25	25
	Less than 25%	4	6	31
	25-75%	8	12	43
	More than 75%	11	16	59
	Always	28	41	100
	Total	68	100	
	Missing	5		
	Total	73		
TCM	Never	8	10	10
	Less than 25%	18	21	31
	25-75%	20	24	55
	More than 75%	20	24	79
	Always	18	21	100
	Total	84	100	
	Missing	12		
	Total	96		
Combined	Never	8	22	22
	Less than 25%	5	14	36
	25-75%	2	6	42
	More than 75%	6	17	58
	Always	15	42	100
	Total	36	100	
	Missing	6		
	Total	42		

Appendix-E.11.3: Q17c - EA-local

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	38	54	54
	Less than 25%	10	14	69
	25-75%	6	9	77
	More than 75%	9	13	90
	Always	7	10	100
	Total	70	100	
	Missing	3		
	Total	73		
TCM	Never	25	29	29
	Less than 25%	13	15	44
	25-75%	27	31	76
	More than 75%	14	16	92
	Always	7	8	100
	Total	86	100	
	Missing	10		
	Total	96		
Combined	Never	21	64	64
	Less than 25%	4	12	76
	25-75%	5	15	91
	More than 75%	3	9	100
	Total	33	100	
	Missing	9		
	Total	42		

Appendix-E.11.4: Q17d - EA-leg distal

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	52	75	75
	Less than 25%	9	13	88
	25-75%	5	7	96
	More than 75%	1	1	97
	Always	2	3	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	Never	43	50	50
	Less than 25%	25	29	79
	25-75%	11	13	92
	More than 75%	5	6	98
	Always	2	2	100
	Total	86	100	
	Missing	10		
	Total	96		
Combined	Never	26	79	79
	Less than 25%	4	12	91
	25-75%	1	3	94
	More than 75%	2	6	100
	Total	33	100	
	Missing	9		
	Total	42		

Appendix-E.11.5: 17e - EA-general

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	63	90	90
	Less than 25%	6	9	99
	25-75%	1	1	100
	Total	70	100	
	Missing	3		
	Total	73		
TCM	Never	63	73	73
	Less than 25%	19	22	95
	25-75%	3	3	99
	More than 75%	1	1	100
	Total	86	100	
	Missing	10		
	Total	96		
Combined	Never	29	88	88
	Less than 25%	2	6	94
	25-75%	2	6	100
	Total	33	100	
	Missing	9		
	Total	42		

Appendix-E.11.6: Q17f - Intra-dermal

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	64	91	91
	Less than 25%	2	3	94
	25-75%	1	1	96
	More than 75%	1	1	97
	Always	2	3	100
	Total	70	100	
	Missing	3		
	Total	73		
TCM	Never	69	83	83
	Less than 25%	10	12	95
	25-75%	4	5	100
	Total	83	100	
	Missing	13		
	Total	96		
Combined	Never	26	81	81
	Less than 25%	4	13	94
	25-75%	2	6	100
	Total	32	100	
	Missing	10		
	Total	42		

Appendix-E.11.7: Q20a - Moxa-local

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Always	1	100	100
	Missing	72		
	Total	73		
TCM	Never	1	2	2
	Less than 25%	13	24	26
	25-75%	20	37	63
	More than 75%	16	30	93
	Always	4	7	100
	Total	54	100	
	Missing	42		
	Total	96		
Combined	Never	1	4	4
	Less than 25%	3	11	15
	25-75%	11	41	56
	More than 75%	7	26	81
	Always	5	19	100
	Total	27	100	
	Missing	15		
	Total	42		

Appendix-E.11.8: Q20b - Moxa-distal

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	1	100	100
	Missing	72		
	Total	73		
TCM	Never	6	11	11
	Less than 25%	28	52	63
	25-75%	16	30	93
	More than 75%	3	6	98
	Always	1	2	100
	Total	54	100	
	Missing	42		
	Total	96		
Combined	Never	2	8	8
	Less than 25%	7	28	36
	25-75%	11	44	80
	More than 75%	3	12	92
	Always	2	8	100
	Total	25	100	
	Missing	17		
	Total	42		

Appendix-E.11.9: Q20c - Warm needle

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	1	100	100
	Missing	72		
	Total	73		
TCM	Never	16	29	29
	Less than 25%	13	24	53
	25-75%	15	27	80
	More than 75%	6	11	91
	Always	5	9	100
	Total	55	100	
	Missing	41		
	Total	96		
Combined	Never	7	27	27
	Less than 25%	5	19	46
	25-75%	6	23	69
	More than 75%	4	15	85
	Always	4	15	100
	Total	26	100	
	Missing	16		
	Total	42		

Appendix-E.11.10: Q20d - Moxa stick

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Always	1	100	100
	Missing	72		
	Total	73		
TCM	Never	6	11	11
	Less than 25%	14	26	37
	25-75%	14	26	63
	More than 75%	11	20	83
	Always	9	17	100
	Total	54	100	
	Missing	42		
	Total	96		
Combined	Never	2	8	8
	Less than 25%	9	36	44
	25-75%	6	24	68
	More than 75%	3	12	80
	Always	5	20	100
	Total	25	100	
	Missing	17		
	Total	42		

Appendix-E.11.11: Q20e - Moxa skin

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	1	100	100
	Missing	72		
	Total	73		
TCM	Never	39	72	72
	Less than 25%	11	20	93
	25-75%	4	7	100
	Total	54	100	
	Missing	42		
	Total	96		
Combined	Never	5	19	19
	Less than 25%	5	19	38
	25-75%	5	19	58
	More than 75%	9	35	92
	Always	2	8	100
	Total	26	100	
	Missing	16		
	Total	42		

Appendix-E.11.12: Q20f - Moxa ginger

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	1	100	100
	Missing	72		
	Total	73		
TCM	Never	40	74	74
	Less than 25%	14	26	100
	Total	54	100	
	Missing	42		
	Total	96		
Combined	Never	11	46	46
	Less than 25%	7	29	75
	25-75%	5	21	96
	More than 75%	1	4	100
	Total	24	100	
	Missing	18		
	Total	42		

Appendix-E.11.13: Q20g - Moxa (any)

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Always	1	100	100
	System	72		
	Total	73		
TCM	Less than 25%	17	32	32
	25-75%	19	36	68
	More than 75%	14	26	94
	Always	3	6	100
	Total	53	100	
	System	43		
	Total	96		
Combined	Less than 25%	3	12	12
	25-75%	7	27	38
	More than 75%	11	42	81
	Always	5	19	100
	Total	26	100	
	System	16		
	Total	42		

Appendix E.12: Section B: Stimulation - Kruskal-Wallis

Appendix-E.12.1: Kruskal-Wallis Q14-16

Component	Style	N	Mean Rank	Chi-Square	p
Needle retention time	Medical	70	78.60	18.0	< 0.001
	TCM	87	113.53		
	Combined	36	92.82		
	Total	193			
Needle thickness	Medical	70	117.19	28.1	< 0.001
	TCM	85	93.95		
	Combined	36	59.65		
	Total	191			
Insertion depth	Medical	70	97.83	10.1	0.006
	TCM	87	103.86		
	Combined	34	72.12		
	Total	191			

df = 2

Appendix-E.12.2: Kruskal-Wallis Q17 Stem questions

Component	Style	N	Mean Rank	Chi-Square	Asymp. Sig.
Deqi	Medical	70	105	3.4	0.179
	TCM	85	92		
	Combined	36	87		
	Total	191			
Tonify or reduce	Medical	68	99	1.4	0.504
	TCM	84	89		
	Combined	36	99		
	Total	188			
EA-local	Medical	70	87	13.9	0.001
	TCM	86	109		
	Combined	33	73		
	Total	189			
EA-leg distal	Medical	69	84	12.9	0.002
	TCM	86	108		
	Combined	33	81		
	Total	188			
EA-general	Medical	70	87	8.0	0.019
	TCM	86	103		
	Combined	33	90		
	Total	189			
Intra-dermal	Medical	70	88	2.4	0.304
	TCM	83	95		
	Combined	32	97		
	Total	185			

df = 2 Non significant results shaded $p < 0.05$

Appendix E.13 Course of treatment - Descriptives

Appendix-E13.1: Initial course of treatment Q21

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	2	1	1	1
	3	6	9	10
	4	10	14	24
	5	11	16	40
	6	32	46	86
	7	1	1	87
	8	5	7	94
	10	4	6	100
	Total	70	100	
	Missing	3		
	Total	73		
TCM	3	3	4	4
	4	13	15	19
	5	15	18	36
	6	29	34	71
	7	1	1	72
	8	9	11	82
	10	12	14	96
	12	2	2	99
	15	1	1	100
	Total	85	100	
	Missing	11		
	Total	96		
Combined	3	2	6	6
	4	3	9	14
	5	13	37	51
	6	12	34	86
	7	1	3	89
	10	4	11	100
	Total	35	100	
	Missing	7		
	Total	42		

Appendix-E13.2: Discontinuation or refer Q22

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	2	9	13	13
	3	29	42	55
	4	21	30	86
	5	1	1	87
	6	6	9	96
	7	1	1	97
	8	2	3	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	2	4	5	5
	3	15	18	23
	4	23	27	50
	5	14	17	67
	6	20	24	90
	8	4	5	95
	10	3	4	99
	16	1	1	100
	Total	84	100	
	Missing	12		
	Total	96		
Combined	2	1	3	3
	3	8	22	25
	4	12	33	58
	5	9	25	83
	6	3	8	92
	7	1	3	94
	8	1	3	97
	10	1	3	100
	Total	36	100	
	Missing	6		
	Total	42		

Appendix-E13.3: Treat once a week

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	None	2	3	3
	Less than 25%	10	15	18
	25-75%	8	12	29
	More than 75%	32	47	76
	All	16	24	100
	Total	68	100	
	Missing	5		
	Total	73		
TCM	None	1	1	1
	Less than 25%	9	10	12
	25-75%	17	20	31
	More than 75%	41	48	79
	All	18	21	100
	Total	86	100	
	Missing	10		
	Total	96		
Combined	None	2	6	6
	Less than 25%	5	14	20
	25-75%	11	31	51
	More than 75%	9	26	77
	All	8	23	100
	Total	35	100	
	Missing	7		
	Total	42		

Appendix-E13.4: Treat twice a week or more frequently

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	None	30	45	45
	Less than 25%	21	31	76
	25-75%	11	16	93
	More than 75%	5	7	100
	Total	67	100	
	Missing	6		
	Total	73		
TCM	None	22	28	28
	Less than 25%	35	44	72
	25-75%	18	23	95
	More than 75%	3	4	99
	All	1	1	100
	Total	79	100	
	Missing	17		
	Total	96		
Combined	None	11	34	34
	Less than 25%	13	41	75
	25-75%	6	19	94
	More than 75%	1	3	97
	All	1	3	100
	Total	32	100	
	Missing	10		
	Total	42		

Appendix-E13.5: Top up treatments

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	None	7	10	10
	Less than 25%	14	20	30
	25-75%	13	19	49
	More than 75%	20	29	78
	All	15	22	100
	Total	69	100	
	System	4		
	Total	73		
TCM	None	4	5	5
	Less than 25%	15	18	23
	25-75%	15	18	41
	More than 75%	26	32	73
	All	22	27	100
	Total	82	100	
	System	14		
	Total	96		
Combined	None	1	3	3
	Less than 25%	1	3	6
	25-75%	6	17	23
	More than 75%	13	37	60
	All	14	40	100
	Total	35	100	
	System	7		
	Total	42		

Appendix-E.14: Section C Course of treatment Kruskal-Wallis test

Component	Style	N	Mean Rank	Chi-Square	Asymp. Sig.
Q21 Number of sessions	Medical	70	89.26	3.8	0.152
	TCM	85	103.79		
	Combined	35	87.84		
	Total	190			
Q22 Discontinuation	Medical	69	70.51	23.7	< 0.001
	TCM	84	111.74		
	Combined	36	102.86		
	Total	189			
I treat once a week	Medical	68	98	2.1	0.346
	TCM	86	97		
	Combined	35	84		
	Total	189			
I treat 2 times a week or more frequently	Medical	67	83	2.5	0.285
	TCM	79	95		
	Combined	32	90		
	Total	178			
Top up treatments	Medical	69	83	8.6	0.013
	TCM	82	93		
	Combined	35	115		
	Total	186			

df = 2 Non significant results shaded $p < 0.05$

Appendix E.15 Section D: Adaption of treatment - Descriptives

Appendix-E.15.1: Q24a - Early treatments

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	None	7	10	10
	Less than 25%	10	14	25
	25-75%	12	17	42
	More than 75%	19	28	70
	All	21	30	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	None	8	9	9
	Less than 25%	16	19	28
	25-75%	23	27	55
	More than 75%	23	27	81
	All	16	19	100
	Total	86	100	
	Missing	10		
	Total	96		
Combined	None	5	14	14
	Less than 25%	15	43	57
	25-75%	9	26	83
	More than 75%	5	14	97
	All	1	3	100
	Total	35	100	
	Missing	7		
	Total	42		

Appendix-E.15.2: Q24b -Anxiety

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	None	9	13	13
	Less than 25%	21	30	43
	25-75%	19	28	71
	More than 75%	6	9	80
	All	14	20	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	None	5	6	6
	Less than 25%	33	39	45
	25-75%	16	19	64
	More than 75%	14	16	80
	All	17	20	100
	Total	85	100	
	Missing	11		
	Total	96		
Combined	None	6	17	17
	Less than 25%	17	49	66
	25-75%	6	17	83
	More than 75%	4	11	94
	All	2	6	100
	Total	35	100	
	Missing	7		
	Total	42		

Appendix-E.15.3: Q24c - Sensitivity

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	None	4	6	6
	Less than 25%	27	39	45
	25-75%	14	20	65
	More than 75%	8	12	77
	All	16	23	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	None	3	4	4
	Less than 25%	36	42	46
	25-75%	12	14	60
	More than 75%	19	22	82
	All	15	18	100
	Total	85	100	
	Missing	11		
	Total	96		
Combined	None	5	15	15
	Less than 25%	13	38	53
	25-75%	11	32	85
	More than 75%	2	6	91
	All	3	9	100
	Total	34	100	
	Missing	8		
	Total	42		

Appendix-E.15.4: Q24d - Not logical

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	None	44	64	64
	Less than 25%	15	22	86
	25-75%	3	4	90
	More than 75%	2	3	93
	All	5	7	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	None	58	67	67
	Less than 25%	19	22	90
	25-75%	7	8	98
	More than 75%	2	2	100
	Total	86	100	
	Missing	10		
	Total	96		
Combined	None	27	77	77
	Less than 25%	7	20	97
	All	1	3	100
	Total	35	100	
	Missing	7		
	Total	42		

Appendix-E.15.5: Q24e - Time and money

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	None	15	22	22
	Less than 25%	41	59	81
	25-75%	7	10	91
	More than 75%	4	6	97
	All	2	3	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	None	9	11	11
	Less than 25%	33	40	51
	25-75%	28	34	84
	More than 75%	10	12	96
	All	3	4	100
	Total	83	100	
	Missing	13		
	Total	96		
Combined	None	7	20	20
	Less than 25%	15	43	63
	25-75%	10	29	91
	More than 75%	2	6	97
	All	1	3	100
	Total	35	100	
	Missing	7		
	Total	42		

Appendix-E.15.6: Q24f - Appointment time

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	None	39	57	57
	Less than 25%	12	17	74
	25-75%	7	10	84
	More than 75%	2	3	87
	All	9	13	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	None	41	49	49
	Less than 25%	23	28	77
	25-75%	11	13	90
	More than 75%	5	6	96
	All	3	4	100
	Total	83	100	
	Missing	13		
	Total	96		
Combined	None	18	53	53
	Less than 25%	12	35	88
	25-75%	4	12	100
	Total	34	100	
	Missing	8		
	Total	42		

Appendix-E.16: Section D: Adaption of treatment - Kruskal Wallis

Component	Allocated style	N	Mean Rank	Chi-Square	Asymp. Sig.
Early treatments	Medical	69	109	16.8	< 0.001
	TCM	86	97		
	Combined	35	64		
	Total	190			
Anxiety	Medical	69	97	6.8	0.034
	TCM	85	102		
	Com	35	75		
	Total	189			
Sensitivity	Medical	69	98	4.0	0.133
	TCM	85	98		
	Com	34	78		
	Total	188			
Not logical	Medical	69	101	2.6	0.276
	TCM	86	96		
	Com	35	86		
	Total	190			
Time & money	Medical	69	79	12.7	0.002
	TCM	83	108		
	Com	35	92		
	Total	187			
Appointment time	Medical	69	94	0.7	0.718
	TCM	83	96		
	Com	34	88		
	Total	186			

df = 2 Non significant results shaded $p < 0.05$

Appendix E.17 Section E: Miscellaneous - Descriptives

Appendix-E.17.1: Q25a - Cupping-local

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	69	100	100
	Missing	4		
	Total	73		
TCM	Never	53	61	61
	Less than 25%	22	25	86
	25-75%	10	11	98
	Always	2	2	100
	Total	87	100	
	Missing	9		
	Total	96		
Combined	Never	21	60	60
	Less than 25%	9	26	86
	25-75%	4	11	97
	More than 75%	1	3	100
	Total	35	100	
	Missing	7		
	Total	42		

Appendix-E.17.2: Q25b - Cupping-distal

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	67	97	97
	Less than 25%	2	3	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	Never	53	61	61
	Less than 25%	18	21	82
	25-75%	10	11	93
	More than 75%	6	7	100
	Total	87	100	
	Missing	9		
	Total	96		
Combined	Never	20	57	57
	Less than 25%	12	34	91
	25-75%	3	9	100
	Total	35	100	
	Missing	7		
	Total	42		

Appendix-E.17.3: Q25c - Heat lamp-local

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	67	97	97
	Less than 25%	1	1	99
	25-75%	1	1	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	Never	29	34	34
	Less than 25%	7	8	42
	25-75%	22	26	67
	More than 75%	17	20	87
	Always	11	13	100
	Total	86	100	
	Missing	10		
	Total	96		
Combined	Never	19	54	54
	Less than 25%	4	11	66
	25-75%	5	14	80
	More than 75%	5	14	94
	Always	2	6	100
	Total	35	100	
	Missing	7		
	Total	42		

Appendix-E.17.4: Q25d - Heat lamp-distal

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	68	100	100
	Missing	5		
	Total	73		
TCM	Never	46	53	53
	Less than 25%	25	29	83
	25-75%	10	12	94
	More than 75%	2	2	97
	Always	3	3	100
	Total	86	100	
	Missing	10		
	Total	96		
Combined	Never	23	66	66
	Less than 25%	8	23	89
	25-75%	3	9	97
	More than 75%	1	3	100
	Total	35	100	
	Missing	7		
	Total	42		

Appendix-E.17.5: Q25e - Massage

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	40	58	58
	Less than 25%	14	20	78
	25-75%	9	13	91
	More than 75%	4	6	97
	Always	2	3	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	Never	15	17	17
	Less than 25%	22	25	43
	25-75%	14	16	59
	More than 75%	24	28	86
	Always	12	14	100
	Total	87	100	
	Missing	9		
	Total	96		
Combined	Never	14	40	40
	Less than 25%	8	23	63
	25-75%	4	11	74
	More than 75%	3	9	83
	Always	6	17	100
	Total	35	100	
	Missing	7		
	Total	42		

Appendix-E.17.6: Q25f - TENS

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	Never	41	59	59
	Less than 25%	20	29	88
	25-75%	5	7	96
	More than 75%	3	4	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	Never	59	69	69
	Less than 25%	12	14	84
	25-75%	6	7	91
	More than 75%	6	7	98
	Always	2	2	100
	Total	85	100	
	Missing	11		
	Total	96		
Combined	Never	28	82	82
	Less than 25%	3	9	91
	25-75%	1	3	94
	More than 75%	1	3	97
	Always	1	3	100
	Total	34	100	
	Missing	8		
	Total	42		

Appendix-E.17.7: Dietary advice

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	None	25	36	36
	Less than 25%	15	22	58
	25-75%	18	26	84
	More than 75%	8	12	96
	All	3	4	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	None	8	9	9
	Less than 25%	21	24	34
	25-75%	27	31	65
	More than 75%	16	19	84
	All	14	16	100
	Total	86	100	
	Missing	10		
	Total	96		
Combined	None	3	8	8
	Less than 25%	6	17	25
	25-75%	10	28	53
	More than 75%	7	19	72
	All	10	28	100
	Total	36	100	
	Missing	6		
	Total	42		

Appendix-E.17.8: Exercise advice

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	None	4	6	6
	Less than 25%	1	1	7
	25-75%	5	7	14
	More than 75%	16	23	38
	All	43	62	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	None	4	5	5
	Less than 25%	6	7	12
	25-75%	25	29	41
	More than 75%	27	31	72
	All	24	28	100
	Total	86	100	
	Missing	10		
	Total	96		
Combined	Less than 25%	6	17	17
	25-75%	9	25	42
	More than 75%	7	19	61
	All	14	39	100
	Total	36	100	
	Missing	6		
	Total	42		

Appendix-E.17.9: Advise to keep knee warm

Practice Allocated		Frequency	Valid Percent	Cumulative Percent
Medical	None	24	35	35
	Less than 25%	16	23	58
	25-75%	15	22	80
	More than 75%	8	12	91
	All	6	9	100
	Total	69	100	
	Missing	4		
	Total	73		
TCM	None	4	5	5
	Less than 25%	14	16	21
	25-75%	23	27	48
	More than 75%	25	29	78
	All	19	22	100
	Total	85	100	
	Missing	11		
	Total	96		
Combined	Less than 25%	10	29	29
	25-75%	11	32	62
	More than 75%	8	24	85
	All	5	15	100
	Total	34	100	
	Missing	8		
	Total	42		

Appendix-E.18: Section E: Miscellaneous Q25 - Kruskal Wallis

Component	Allocated style	N	Mean Rank	Chi-Square	p
Cupping-local	Medical	69	72	35.4	< 0.001
	TCM	87	109		
	Combined	35	110		
	Total	191			
Cupping-distal	Medical	69	73	31.1	< 0.001
	TCM	87	109		
	Combined	35	109		
	Total	191			
Heat lamp-local	Medical	69	60	63.2	< 0.001
	TCM	86	122		
	Combined	35	100		
	Total	190			
Heat lamp-distal	Medical	68	69	41.1	< 0.001
	TCM	86	113		
	Combined	35	101		
	Total	189			
Massage	Medical	69	70	31.1	< 0.001
	TCM	87	118		
	Combined	35	94		
	Total	191			
TENS	Medical	69	101	4.1	0.129
	TCM	85	94		
	Combined	34	82		
	Total	188			

df = 2 Non significant results shaded $p < 0.05$

Appendix-E.19: Section E: Advice Q26 - Kruskal Wallis

Component	Allocated style	N	Mean Rank	Chi-Square	p
Dietary advice	Medical	69	72	23.2	< 0.001
	TCM	86	106		
	Combined	36	119		
	Total	191			
Exercise advice	Medical	69	117	18.3	< 0.001
	TCM	86	82		
	Com	36	88		
	Total	191			
Advise the knee should be kept warm	Medical	69	68	28.9	< 0.001
	TCM	85	113		
	Combined	34	102		
	Total	188			

Appendix E.20: Additional searches for previous surveys

Medline, CINAHL complete, AMED, PsycINFO - 1st January 2018

Search History/Alerts

Print Search History | Retrieve Searches | Retrieve Alerts | Save Searches / Alerts

Select / deselect all | Search with AND | Search with OR | Delete Searches | Refresh Search Results

	Search ID#	Search Terms	Search Options	Actions
☐	S5	S1 AND S2 AND S3 AND S4	**Search modes** - Find all my search terms	View Results (294) | View Details | Edit
☐	S4	acupuncturist OR practitioner	**Expanders** - Apply equivalent subjects; Apply related words; Also search within the full text of the articles **Search modes** - Find all my search terms	View Results (1,178,618) | View Details | Edit
☐	S3	osteoarthritis OR pain OR gonarthritis OR gonarthrosis	**Expanders** - Apply equivalent subjects; Apply related words; Also search within the full text of the articles **Search modes** - Find all my search terms	View Results (2,330,447) | View Details | Edit
☐	S2	survey OR questionnaire	**Expanders** - Apply equivalent subjects; Apply related words; Also search within the full text of the articles **Search modes** - Find all my search terms	View Results (4,500,225) | View Details | Edit
☐	S1	acupuncture	**Expanders** - Apply equivalent subjects; Apply related words; Also search within the full text of the articles **Search modes** - Find all my search terms	View Results (88,537) | View Details | Edit

Subscribed to by Library Services, at London South Bank University

Scopus Searches - 1st of January 2018	
("practitioner survey" **) AND** acupuncture **AND** pain	12
("practitioner survey" **) AND** acupuncture **AND** osteoarthritis	3
("practitioner survey" **) AND** acupuncture **AND** knee	2
("acupuncturist survey" **) AND** acupuncture **AND** knee	0
("acupuncturist survey") **AND** acupuncture **AND** osteoarthritis	0
("acupuncturist survey" **) AND** acupuncture **AND** pain	0
("acupuncturist survey" **) AND** acupuncture **AND** osteoarthritis	0
(*"acupuncturist survey"*) **AND** *acupuncture*	0
("practitioner survey") AND acupuncture	24
(*"acupuncturist survey"*) **AND** *acupuncture*	0
delphi **AND** *acupuncture*	503
(*"practitioner interview"*) **AND** *acupuncture*	1
(*"acupuncturist interview"*) **AND** *acupuncture*	0

Appendix F: Pilot Study

Appendix F Table of Contents

Appendix F.1: Ethics confirmation (Pilot study)

London South Bank University

[redacted]

Ref: UREC 1562

Ian Appleyard

[redacted]

Wednesday 20 January 2016

Dear Ian

RE: Acupuncture and moxibustion in practice for the treatment of osteoarthritis OA of the knee: Pilot Study

Thank you for submitting this proposal and for your response to the reviewers' comments.

I am pleased to inform you that Full Chair's Approval has been given by Vice Chair, Rachel Taylor, on behalf of the University Research Ethics Committee.

I wish you every success with your research.

Yours sincerely,

N Mitchell

Nicola Mitchell

Secretary, LSBU Research Ethics Committee

cc:

Prof Shushma Patel, Chair, LSBU Research Ethics Committee

Appendix F.2: Recruitment checklists

London South Bank University

Study Contact Number 07

Warm needle acupuncture vs. needle acupuncture
A pilot study

Recruitment Checklists

1. Initial Contact Checklist
2. Preliminary Assessment Checklist
3. Enrolment Checklist

Confidential

Study Contact Number 07

1. Initial Contact Checklist

Date of first contact	/ / day/month/year
Phone or email	
Details	
Family Name	
Given Name	
Telephone	
Mobile	
Email	
Address	
Postcode	
Require Large Print?	

Form	Sent [date]	Email	Paper
Patient information booklet			
Study consent form			
Given opportunity to ask questions	Yes	No	

Any issues or follow up action required?

Assessor [Print Name] _____

Signature _____

Study Contact Number 07

2. Preliminary Assessment Checklist

Preliminary eligibility assessment	Met	Unmet
Age > 50 years		
On a scale of 1-10 how bad is your knee pain? 10 is as bad as it could be. (Criteria > 3)		
Knee pain for more than 6 months		
Ability to speak English		

Exclusion Criteria	Present	Absent
A systemic disease of the musculoskeletal system		
Bone tumour, bone tumour like lesions or metastasis		
Bone fracture in the lower extremities during the last three months		
Acute infection or osteonecrosis in the knee joint		
Recent sprain injury to the knee joint		
Surgery of the afflicted extremity during the last six months or planned surgery		
Ongoing cortico-steroid therapy or cortisone injections in the past six weeks		
Taking anti-coagualant medication		
Coagulopathy		
Other pain conditions which compels the patient to take analgesics for more than three days during the last four weeks		
Addiction to analgesics, opiate or other drugs		
Acupuncture treatment in the past 3 months		
Dermatological disease within the acupuncture area impairing acupuncture treatment		
Pregnant or breast-feeding patients		
Inability to follow instructions or understand the consent form (insufficient command of language, dementia)		
Participation in another clinical study		
Ongoing legal proceedings concerning degree of disability		

Study Contact Number 07

Checklist		
Is the individual interested in taking part in the study?	Yes	No
Is there are reasonable expectation that the individual will meet the eligibility criteria?	Yes	No
If yes to both of the above questions, has the individual been asked to bring in a list of their current medication and make a note of usage?	Yes	No
Does the individual appear to understand the objectives, potential benefits, risks and inconveniences of the study?	Yes	No
Has the individual been told they are free to withdraw at anytime?	Yes	No
Appointment for enrolment interview		
Date		
Time		
Location		

Are there any issues of concern arising from eligibility criteria?	Yes	No
If yes, describe the action taken		

Assessor [Print Name] _____

Signature _____

Date (DD/MM/YYYY): / /

Study Contact Number 07

Enrolment Checklist

Inclusion criteria

Table 1: Eligibility criteria	Met	Unmet
Age > 50 years		
Stiffness < 30 minutes		
Crepitus		
Bony Tenderness		
Bony enlargement		
No palpable warmth		
At least 3 of the above 6		
Ability to speak English		
Signed consent form		

WOMAC score _____

Study Contact Number 07

Table 2: Exclusion Criteria	Present	Absent
A systemic disease of the musculoskeletal system		
Bone tumour, bone tumour like lesions or metastasis		
Bone fracture in the lower extremities during the last three months		
Acute infection or osteonecrosis in the knee joint		
Recent sprain injury to the knee joint		
Surgery of the afflicted extremity during the last six months or planned surgery		
Ongoing cortico-steroid therapy or cortisone injections in the past six weeks		
Taking anti-coagualant medication		
Coagulopathy		
Other pain conditions which compels the patient to take analgesics for more than three days during the last four weeks		
Addiction to analgesics, opiate or other drugs		
Acupuncture treatment in the past 6 months		
Dermatological disease within the acupuncture area impairing acupuncture treatment		
Pregnant or breast-feeding patients		
Inability to follow instructions or understand the consent form (insufficient command of language, dementia)		
Participation in another clinical study		
Ongoing legal proceedings concerning degree of disability		

Study Contact Number 07

To confirm	Eligible	Excluded
Patient Consent Form		
Table 1: Eligibility Criteria		
WOMAC		
Table 2: Exclusion Criteria		

Are there any issues of concern arising from eligibility criteria? Yes No
If yes, describe the action taken

If applicable enter the Trial Entrant Number here

Confirm Study Contact Spreadsheet has been updated Yes / No

Assessor [Print Name] _____

Signature _____

Date (DD/MM/YYYY): / /

Appendix F.3: Consent form (Pilot study)

Study Contact Number 22

London South Bank University

CONSENT FORM

Acupuncture and moxibustion in practice for the treatment of osteoarthritis (OA) of the knee: Pilot study

Please circle Yes or No

I have read the Participant Information Sheet for this study (Version 1 23 Dec 2015) and have been given a copy to keep. I have had the opportunity to discuss the details and ask questions about this information.	Yes	No
The researcher has explained the nature and purpose of the research and I believe that I understand what is being proposed.	Yes	No
I understand that my personal involvement and my particular data from this study will remain strictly confidential.	Yes	No
I have been informed about what the data collected in this investigation will be used for, to whom it may be disclosed, and how long it will be retained.	Yes	No
I have been informed that I will be interviewed about my experiences of being in the trial.	Yes	No
I understand that my anonymised quotes (I will not be identifiable from any quotes) maybe used in publications/ presentations.	Yes	No
I have been informed that the interview will be audio recorded.	Yes	No
I understand that I will be able to continue any current medication use or therapy.	Yes	No
I consent not to start any other new therapy during the course of the study, unless necessary on medical grounds on the advice of my GP or consultant. If I do start a new therapy I will inform the researcher.	Yes	No
I understand that I am free to withdraw from the study at any time, without giving a reason for withdrawing.	Yes	No
I hereby fully and freely consent to participate in the study.	Yes	No
May we contact your GP to inform them that you are taking part in this study? (This does not affect your eligibility to take part in the study)	Yes	No

1 of 2

Study Contact Number 22

Participant's Name: (Block Capitals) ……

Participant's Signature: …… Date: ……

As the Researcher responsible for this investigation I confirm that I have explained to the participant named above the nature and purpose of the research to be undertaken.

Researcher's Name: ……

Researchers's Signature: ……

Date: ……

Appendix F.4: Baseline data form

Study Contact Number XX

London South Bank University

Warm needle acupuncture vs. needle acupuncture
A pilot study

Form 1a: Baseline data Summary - Check

Trial Entrant Number

Step 1 WOMAC

Womac	
Pain	
Stiffness	
Physical Function	
Combined	

If participant meets the WOMAC inclusion criteria:
➡ **Write Trial Entrant Number into box provided on the cover page.**
➡ **Continue to collect the data.**

If participant does NOT meet the inclusion criteria:
➡ **Write X into the box provided on the cover page**

Data Check List	Tick ✓
WOMAC	
SF-36	
Medication	
BMI	
Expectation data	
OA confirmation letter	

Study Contact Number XX

Expectation Questions

a) How effective do you consider acupuncture to be in general?	
very effective	
effective	
slightly effective	
not effective	
don't know	

b) What do you personally expect from the acupuncture treatment you will receive?	
cure	
clear improvement	
slightly improvement	
no improvement	
don't know	

c) Do you think the warm needle acupuncture will be more effective than needle acupuncture for your knees?	
much more effective	
more effective	
slightly more effective	
not more effective	
don't know	

SF 36	
Physical Functioning	
Role functioning/physical	
Role functioning/mental	
Energy/fatigue	
Emotional Well-being	
Social functioning	
Pain	
General Health	
Health change	

Medication	Dose	Frequency	7 day total

Body Mass Index	
Height (m)	
Weight (kg)	
BMI	

Appendix F.5: Patient notes

Trial Entrant Number XX

London South Bank University

Warm needle acupuncture vs. needle acupuncture
A pilot study

Form 2: Patient Notes

Trial Entrant Number

XX

Contents

Trial Entrant Number XX

Patient Consent

Title: ……

Surname: ……

Forename(s): ……

As a patient you have a right to understand the treatment you receive, to choose at all stages whether or not to receive the treatment and to know that confidentiality will be maintained by the clinic and those providing your care.

I understand that I consent to an appropriate examination and treatment with acupuncture and moxibustion, notwithstanding my right to withdraw this consent at any time.

Signature:…… Date:……

Trial Entrant Number XX

Personal Details

Date of Birth	Day	Month	Year
Gender			
Occupation			
Address			
Post Code			
Telephone			
Mobile			
Email			

We need to keep the name and address of your GP for our records. However, if we feel we need to contact your GP we will ask your permission in advance. In general we recommend that you inform your GP that you are having acupuncture.

Name of G.P.	
Address	
Post Code	
Telephone	

Trial Entrant Number XX

Initial Consultation

Knee pain: Standard questions				
How long have you suffered from knee pain?		Years		Months
Which knee is affected?	Left	Right	Both	
What is the pain like?				
Where on the knee do you feel pain?				
What makes the knee worse?				
What makes the knee better?				
When is the knee worse/ better?				
Can you describe the development of the knee pain?				
Is the knee better for warmth?	Yes	No	Not sure	
Is the knee better if it is cooled?	Yes	No	Not sure	
Is the knee worse in damp weather?	Yes	No	Not sure	
What do you think caused your knee pain?				

Further information

Knee: Inspection		
Does the knee appear swollen?	Yes	No
Does the skin around the knee appear red?	Yes	No
Is there any deformity of the bones?	Yes	No
Which areas are tender on palpation? Left knee		
Which areas are tender on palpation? Right knee		

Further information

Trial Entrant Number XX

General Health Questions			
Problems with….	Yes	No	Brief details
Headaches			
Eyes			
Ears			
Nose			
Digestion			
Bowels			
Thirst			
Urination			
Sweat			
Sleep			
Palpitations			
Energy levels			
Emotions/stress/ mood			
Pain (Apart from knee)			
Back pain			
Breathing			
Menstruation			

Trial Entrant Number XX

Tongue

Pulse

Past medical history

Further information

Trial Entrant Number XX

Pattern Differentiation

Knee Pain Differentiation	Tick only one
Qi and Blood Stagnation	
Damp Bi Syndrome	
Cold Damp Bi Syndrome	
Cold Bi Syndrome	
Bony Bi Syndrome	

Underlying Pattern Differentiation	Tick if applicable
Kidney Yang Xu	
Kidney Yin Xu	
Kidney Jing Xu	
State other patterns differentiations	

Main Pattern	Signs and symptoms
Minor Pattern	

Trial Entrant Number XX

Treatments

Treatment 1						Date / /		
Consultation Notes/ Adverse events								
Point	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**
Nei Xiyan			GB 34			LIV 8		
ST 35			GB 33			LIV 7		
ST 36			SP 9			Heding		
ST 34			SP 10			Ahshi		
Ahshi points, Location, Moxa								
Acupuncturist								
Is warm needle acupuncture appropriate?						Yes	No	

Treatment 2						Date / /		
Consultation Notes/ Adverse events								
Point	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**
Nei Xiyan			GB 34			LIV 8		
ST 35			GB 33			LIV 7		
ST 36			SP 9			Heding		
ST 34			SP 10			Ahshi		
Ahshi points, Location, Moxa								
Acupuncturist								
Is warm needle acupuncture appropriate?						Yes	No	

Trial Entrant Number XX

Treatment 3						**Date** / /		
Consultation Notes/ Adverse events								
Point	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**
Nei Xiyan			GB 34			LIV 8		
ST 35			GB 33			LIV 7		
ST 36			SP 9			Heding		
ST 34			SP 10			Ahshi		
Ahshi points, Location, Moxa								
Acupuncturist								
Is warm needle acupuncture appropriate?						Yes	No	

Trial Entrant Number XX

Treatment 4 Expectation Question

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

Treatment 4	Date / /							
Consultation Notes/ Adverse events								
Point	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**
Nei Xiyan			GB 34			LIV 8		
ST 35			GB 33			LIV 7		
ST 36			SP 9			Heding		
ST 34			SP 10			Ahshi		
Ahshi points, Location, Moxa								
Acupuncturist								
Is warm needle acupuncture appropriate?						Yes	No	

Trial Entrant Number XX

Treatment 7						Date / /		
Consultation Notes/ Adverse events								
Point	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**
Nei Xiyan			GB 34			LIV 8		
ST 35			GB 33			LIV 7		
ST 36			SP 9			Heding		
ST 34			SP 10			Ahshi		
Ahshi points, Location, Moxa								
Acupuncturist								
Is warm needle acupuncture appropriate?						Yes	No	

Treatment 8						Date / /		
Consultation Notes/ Adverse events								
Point	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**
Nei Xiyan			GB 34			LIV 8		
ST 35			GB 33			LIV 7		
ST 36			SP 9			Heding		
ST 34			SP 10			Ahshi		
Ahshi points, Location, Moxa								
Acupuncturist								
Is warm needle acupuncture appropriate?						Yes	No	

Trial Entrant Number XX

Treatment 9						**Date**	/ /	
Consultation Notes/ Adverse events								
Point	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**
Nei Xiyan			GB 34			LIV 8		
ST 35			GB 33			LIV 7		
ST 36			SP 9			Heding		
ST 34			SP 10			Ahshi		
Ahshi points, Location, Moxa								
Acupuncturist								
Is warm needle acupuncture appropriate?						Yes	No	

Treatment 10						**Date**	/ /	
Consultation Notes/ Adverse events								
Point	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**
Nei Xiyan			GB 34			LIV 8		
ST 35			GB 33			LIV 7		
ST 36			SP 9			Heding		
ST 34			SP 10			Ahshi		
Ahshi points, Location, Moxa								
Acupuncturist								
Is warm needle acupuncture appropriate?						Yes	No	

Trial Entrant Number XX

Treatment 11						**Date**	/ /	
Consultation Notes/ Adverse events								
Point	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**
Nei Xiyan			GB 34			LIV 8		
ST 35			GB 33			LIV 7		
ST 36			SP 9			Heding		
ST 34			SP 10			Ahshi		
Ahshi points, Location, Moxa								
Acupuncturist								
Is warm needle acupuncture appropriate?						Yes	No	

Treatment 12						**Date**	/ /	
Consultation Notes/ Adverse events								
Point	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**	**Point**	**Needle**	**Moxa**
Nei Xiyan			GB 34			LIV 8		
ST 35			GB 33			LIV 7		
ST 36			SP 9			Heding		
ST 34			SP 10			Ahshi		
Ahshi points, Location, Moxa								
Acupuncturist								
Is warm needle acupuncture appropriate?						Yes	No	

Appendix F.6: Mid-point data

Trial Entrant Number 06

London South Bank University

Warm needle acupuncture vs. needle acupuncture
A pilot study

Form 3: Mid-point data

Trial Entrant Number 06

Form 3a - Mid point data Summary - Check 1

Trial Entrant Number 06

Womac	
Pain	
Stiffness	
Physical Function	
Combined	

SF 36	
Physical Functioning	
Role functioning/physical	
Role functioning/mental	
Energy/fatigue	
Emotional Well-being	
Social functioning	
Pain	
General Health	
Health change	

Medication	Dose	Frequency	7 day total

Trial Entrant Number 06

Safety

Have you experienced any side effects or adverse events because of the acupuncture?

Concealment

Do you think you are receiving warm needle acupuncture or needle acupuncture?

Circle:

Warm needle **Needle acupuncture**

Trial Entrant Number 06

Data Check List	Tick ✓
WOMAC	
SF-36	
Medication	
Safety Question	
Group Allocation Question	
Qualitative Study	

Assessor [Print Name] _____

Signature _____ **Date**

Appendix F.7: End of treatment data

Trial Entrant Number 24

London South Bank University

Warm needle acupuncture vs. needle acupuncture
A pilot study

Form 4a: End of treatment data Summary - Check

Trial Entrant Number 24

Trial Entrant Number 24

Womac	
Pain	
Stiffness	
Physical Function	
Combined	

SF 36	
Physical Functioning	
Role functioning/physical	
Role functioning/mental	
Energy/fatigue	
Emotional Well-being	
Social functioning	
Pain	
General Health	
Health change	

Medication	Dose	Frequency	7 day total

Trial Entrant Number 24

Safety

Have you experienced any side effects or adverse events because of the acupuncture?

Concealment

Do you think you received warm needle acupuncture or needle acupuncture?

Circle:

Warm needle **Needle acupuncture**

Trial Entrant Number 24

Data Check List	Tick ✓
WOMAC	
SF-36	
Medication	
Safety Question	
Group Allocation Question	

Assessor [Print Name] _____

Signature _____ **Date**

Appendix F.8: Follow-up data

Trial Entrant Number 19

London South Bank University

Warm needle acupuncture vs. needle acupuncture
A pilot study

Form 5a: Follow up data
Summary-Check

Trial Entrant Number 19

Trial Entrant Number 19

Womac	
Pain	
Stiffness	
Physical Function	
Combined	

SF 36	
Physical Functioning	
Role functioning/physical	
Role functioning/mental	
Energy/fatigue	
Emotional Well-being	
Social functioning	
Pain	
General Health	
Health change	

Medication	Dose	Frequency	7 day total

Trial Entrant Number 19

Safety

Have you experienced any side effects or adverse events because of the acupuncture?

Data Check List	Tick ✓
WOMAC	
SF-36	
Medication	
Safety Question	

Assessor [Print Name] _____

Signature _____ **Date**

Appendix F.9: Interview schedule (Pilot study)

Interview schedule: participants

Thank you for agreeing to be interviewed. As you know you are taking part in a study investigating acupuncture for OA of the knee. I would like to hear about your experiences of the trial and the treatment you have been receiving.

The trial process:

Recruitment:
Please tell me about your experience of hearing about the study and the process of becoming a participant?

Prompts

- When you first heard about the study what were your initial thoughts?
- Why did you decide to take part in the study?
- What attracted you to the study? Was there anything that put you off?
- Could you tell me what you think about the recruitment process?
- How did the information you receive prepare you for being part of the trial?
- Is there anything you would add?/Was it easy to understand?
- How easy did you feel it was to ask questions?

Outcome measures
Please tell me about the questionnaires you needed to complete?

Prompts

- How did you find filling in those questionnaires?
- Do you think you benefitted at all from filling out the questionnaires? Were they interesting?/ Were they difficult?
- Did you find filling out the questionnaires took too much time, about right, or less time than you expected?
- Were there any changes that you experienced that the questionnaires did not cover?
- Do you think there was anything else we should have asked?

The trial as a whole

- What do feel about the study as whole? What were the good things, the problems or bad experiences?
- Were there any surprises?
- Is there anything you feel that should be changed?
- Could sum up your experience of being in this study in a sentence?

Needle sensations:

These questions are asked in order to understand what sensations you felt during and immediately after acupuncture. We want to know if there were any differences in experience between the two groups.

Prompts

- What kind of sensations do you feel around the needles?
- Do you feel sensations elsewhere in your body?
- How long do the sensations last?
- How do you feel immediately after you have had acupuncture?
- How do feel about having acupuncture needles inserted?

Treatment process

These questions are being asked in order to understand
Previous experience of acupuncture influences perceptions about the study
Whether or not additional outcome measures should be included
Collect information regarding expectations which may be useful in refining the questions related to expectation
Acceptability of warm needle acupuncture
If participants found the process convincing
Practitioner participant relationship

- Could tell me what you think about acupuncture?
- Could you tell me about any past experience you have had of acupuncture before being in this study?
- Do you think the acupuncture you receive in this trial is different from the treatment you would get if you had acupuncture privately? If it was different in what way was it different?
- What were your expectations about having acupuncture

- Can you tell me about the practitioners the acupuncturist and the assistant?
- How did you get on with them?

- Did you feel it was difficult to get to the appointments?
- Do you think ideally it would have been better to have treatment more often, less often or do you think it was about right?
- In what ways did acupuncture disrupt your routine?

Is there anything else you want to say about acupuncture and your experience of acupuncture?

Wider benefits or harms:

- Have you noticed any changes in your life since starting acupuncture?
- And do you think the acupuncture had any effect on your general wellbeing, on like your mental state?
- You noticed any negative effects from having acupuncture?

Appendix F.10: Participant information booklet (Pilot study)

London South Bank University

Participant Information Booklet

The title of the Research Project is:

Warm needle acupuncture vs. needle acupuncture

A pilot study

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

Ian Appleyard MBAcC

What is the purpose of the study?

There is evidence that acupuncture is an effective treatment for osteoarthritis of the knee. In the future we wish to compare two different styles of acupuncture using a randomised controlled trial to find out which style is best. The purpose of this small study is to support the development of the randomised controlled trial.

Why have I been chosen?

The reason you have been asked to take part in this study is because you are an adult with osteoarthritis of the knee.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will be involved?

You are being asked to take part in a small study. If you agree to take part then you will be allocated to one of two groups. The group you are allocated to will be decided randomly, as if by tossing a coin. Both groups will receive a course of acupuncture treatment. Both groups will have a full consultation and be treated by an acupuncturist who is fully trained.

The difference between the two groups is the additional use of moxibustion in one group. Moxibustion is a method traditionally used by acupuncturists to warm specific acupuncture points or parts of the body. Burning an herb called moxa does the warming. In English moxa is called mugwort (artemis vulgaris).

In one group a smokeless moxa cone will be placed on the handle of the needle and lit. This is known as ‘warm needle acupuncture’. In the other group although the moxa cone will be placed on the needle but it will not be lit.

What should I expect?

- Apart from the moxibustion the treatment for both groups will be the same.
- Needles will be inserted around both knees and will remain in place for approximately 25 minutes.
- Approximately 8-12 acupuncture needles will be used in total.
- You will be treated whilst sitting in a chair. This enables the acupuncturist to easily insert the needles into the relevant acupuncture points.
- A screen will be placed in front of you after the needles have been inserted to prevent you from seeing whether or not the moxa has been lit.
- You will receive up to 12 treatments over an 8-week period.

At each appointment the acupuncturist will conduct a consultation with you, as they would in normal practice. This will involve questions about your general health and your knees in particular. Once the needles have been inserted the acupuncturist will leave the room and an assistant will enter the room. A screen will be placed in front of you to prevent you seeing your knees. It is important that neither you nor the acupuncturist knows which group you are in.

During the treatment the assistant will ask you from time to time whether or not you feel comfortable. They will ask you whether the moxa feels hot. If you feel uncomfortable and wish to stop the treatment the assistant will remove the needles. However, they **will not confirm** whether or not you were having warm needle acupuncture or needle acupuncture.

You may continue to use any current medications or other therapies. However, please do not start a new therapy during the course of the study unless asked to do so by your doctor. If you do start a new therapy please tell the researcher.

What will I feel?

When the needles are inserted you may feel a dull ache or a tingling sensation around the point. There may also be a sensation of warmth. Please note that **even if the moxa is not being used** you may still feel sensations of warmth.

What information will be required?

The acupuncturist will conduct a consultation with you as they would in normal practice. This will involve questions about your general health as well as your knees.

You will also be required to complete questionnaires that are designed to help us understand how well you are responding to treatment. These questionnaire will assess your knee pain and general well being. You will also be asked a few short questions about your feelings about acupuncture and whether you experience any side effects or adverse events

The questionnaires need to be completed on four separate occasions. At the beginning, and then after four weeks, eight weeks and 16 weeks.

Interviews

This is a pilot study. The purpose of a pilot study can be described as a practice run. We want to make sure all our procedures work well before going on to run a larger randomised controlled trial (RCT). Therefore we will interview you to listen to understand what you thought and felt about being in the trial and the treatment you received. The interviews will usually take place when you come to treatment in the fourth week. If this is not convenient we may arrange a different time or conduct the interview by telephone. The interview will take approximately 45 minutes. The interviews will be audio recorded. Once the interviews have been typed up the audio recording will be destroyed. Direct quotes from these interviews maybe use in publications and presentations. However you will not be identifiable as all quotes will be anonymised.

Are there any risks?

Both groups will receive a treatment that is commonly given by acupuncturists in the UK, China and worldwide. Acupuncture has been shown to be safe. The most common side effect is slight bruising around the site of the needle; this occurs in about 6% of patients who have a course of acupuncture. Some patients may feel dizzy; this is uncommon and occurs in a about 0.2% of patients. These adverse events are short term and do not typically require further treatment.

What are the possible benefits of taking part?

There is evidence that acupuncture is an effective treatment for osteoarthritis of the knee. Therefore you may experience a reduction in the pain and stiffness of your knees.

Will my taking part in this study be kept confidential?

All information collected from you during the course of the research will be kept strictly confidential. The notes will be kept in a locked filing cabinet within the university. The data will be stored on a password-protected computer at LSBU until 2023. The notes and data will then be deleted/destroyed. Any information that is shared with others (e.g. in reports and publications) will have your name and address removed so that you cannot be recognised from it.

London South Bank University Research Ethics Committee has reviewed and approved this Research Proposal.

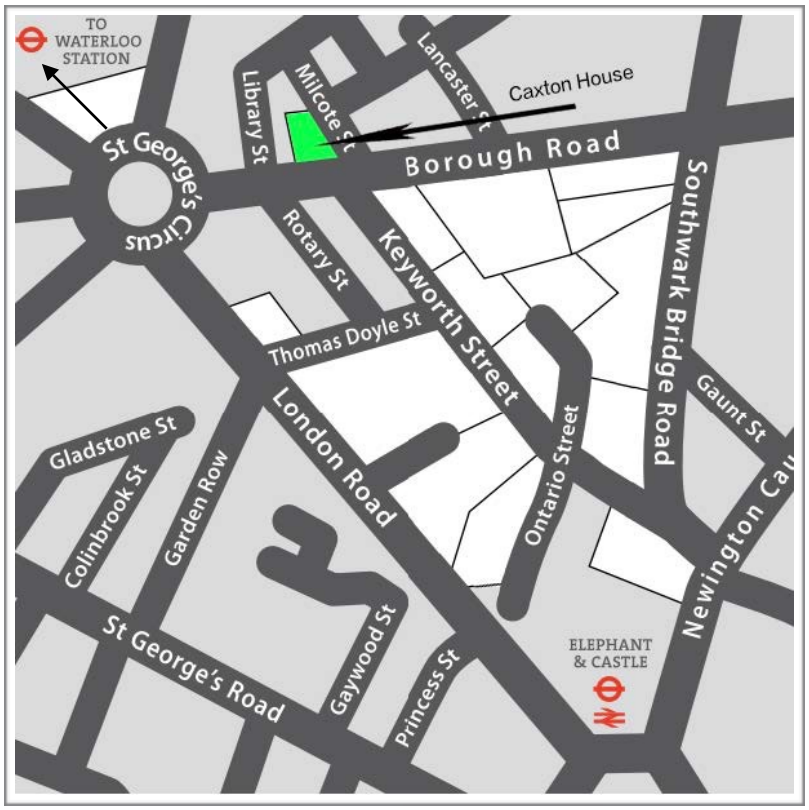
What if something goes wrong?

If the you wish to make a complaint about the conduct of the study could you please contact-

Chair of the University Research Ethics Committee
London South Bank University
103 Borough Road
SE 1 0AA
Email: ethics@lsbu.ac.uk

If you require further information please don't hesitate to contact me

Ian Appleyard
School of Health and Social Care
London South Bank University
103 Borough Road
SE 1 0AA
Tel 020 7815 8014
Email: appleyai@lsbu.ac.uk



The entrance to the acupuncture clinic in Caxton house is from Borough Road

LSBU campus is well served by London Underground. The nearest Tube station is Elephant & Castle, which is on both the Bakerloo and Northern lines.

A large number of buses travel to and connect in the Elephant and Castle area from across London.

Appendix F.11: Expectations and end-point pain - Fisher's exact test

Expectations and end-point pain - Fisher's exact test

How effective do you consider acupuncture in general?			
	Low	High	**Fisher Sig**
Non-responder	2	3	1.00
Responder	5	4	
What do you personally expect from the acupuncture treatment you will receive?			
	Low	High	**Fisher Sig**
Non-responder	4	5	1.00
Responder	3	2	
Do you think warm needle acupuncture will be more effective than needle acupuncture for your knees?			
	Low	High	**Fisher Sig**
Non-responder	4	3	1.00
Responder	3	4	
How confident do you feel that this treatment can alleviate your knee pain?			
	Low	High	**Fisher Sig**
Non-responder	3	4	0.56
Responder	1	6	

2 sided significance

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Appendix-F.12.a: WOMAC Paired t-tests: Baseline vs. mid-point (week 4)

Group	Dimension	Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Warm n=8	Pain	1.28	1.29	0.46	0.20	2.35	2.79	7	0.027
	Stiffness	1.75	2.96	1.05	-0.73	4.23	1.67	7	0.139
	Function	1.74	1.52	0.54	0.46	3.01	3.23	7	0.015
	Global	1.59	1.73	0.61	0.14	3.04	2.59	7	0.036
Needle n=6	Pain	2.07	1.94	0.79	0.03	4.10	2.61	5	0.048
	Stiffness	1.00	4.05	1.65	-3.25	5.25	0.60	5	0.572
	Function	0.71	1.75	0.71	-1.13	2.55	1.00	5	0.365
	Global	1.26	2.28	0.93	-1.13	3.65	1.35	5	0.234
All n=14	Pain	1.61	1.58	0.42	0.70	2.53	3.81	13	0.002
	Stiffness	1.43	3.34	0.89	-0.50	3.36	1.60	13	0.134
	Function	1.30	1.65	0.44	0.35	2.25	2.95	13	0.011
	Global	1.45	1.91	0.51	0.34	2.55	2.84	13	0.014

Appendix-F.12.b: WOMAC Paired t-tests: Baseline vs. end of treatment (week 8)

Group	Dimension	Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Warm n=8	Pain	1.55	2.53	0.90	-0.57	3.67	1.73	7	0.127
	Stiffness	1.88	3.76	1.33	-1.27	5.02	1.41	7	0.201
	Function	2.39	2.85	1.01	0.00	4.78	2.37	7	0.050
	Global	1.94	2.95	1.04	-0.53	4.41	1.86	7	0.106
Needle n=6	Pain	3.56	2.36	0.96	1.08	6.04	3.69	5	0.014
	Stiffness	3.08	2.65	1.08	0.30	5.87	2.85	5	0.036
	Function	1.94	2.33	0.95	-0.51	4.39	2.04	5	0.097
	Global	2.86	2.31	0.94	0.43	5.29	3.03	5	0.029
All n=14	Pain	2.41	2.58	0.69	0.92	3.90	3.50	13	0.004
	Stiffness	2.39	3.27	0.87	0.50	4.28	2.74	13	0.017
	Function	2.20	2.56	0.68	0.72	3.67	3.22	13	0.007
	Global	2.33	2.64	0.71	0.81	3.86	3.31	13	0.006

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Appendix-F.12.c: WOMAC Paired t-tests: Baseline vs. follow-up (week 16)

Group	Dimension	Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Warm n=8	Pain	2.68	1.58	0.56	1.36	3.99	4.79	7	0.002
	Stiffness	3.13	3.02	1.07	0.60	5.65	2.93	7	0.022
	Function	2.70	2.91	1.03	0.27	5.13	2.62	7	0.034
	Global	2.83	2.43	0.86	0.80	4.86	3.30	7	0.013
Needle n=6	Pain	2.73	2.35	0.96	0.27	5.20	2.85	5	0.036
	Stiffness	2.58	3.47	1.42	-1.06	6.22	1.82	5	0.128
	Function	2.04	2.12	0.86	-0.18	4.26	2.36	5	0.065
	Global	2.45	2.35	0.96	-0.01	4.92	2.56	5	0.051
All n=14	Pain	2.70	1.86	0.50	1.63	3.77	5.43	13	< 0.001
	Stiffness	2.89	3.10	0.83	1.10	4.68	3.49	13	0.004
	Function	2.42	2.53	0.68	0.96	3.88	3.58	13	0.003
	Global	2.67	2.31	0.62	1.34	4.00	4.33	13	0.001

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Appendix-F.12.d: WOMAC Paired t-tests: Mid-point (week 4) vs. end of treatment (week 8) & vs. follow-up (week 16)

Time point	Dimension	Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Week 8	Pain	0.80	1.76	0.47	-0.22	1.81	1.69	13	0.115
	Stiffness	0.96	2.57	0.69	-0.52	2.45	1.40	13	0.183
	Function	0.90	1.71	0.46	-0.09	1.89	1.97	13	0.070
	Global	0.89	1.87	0.50	-0.19	1.97	1.77	13	0.100
Week 16	Pain	1.09	1.40	0.37	0.28	1.90	2.90	13	0.012
	Stiffness	1.46	2.85	0.76	-0.18	3.11	1.92	13	0.077
	Function	1.12	1.81	0.48	0.07	2.17	2.31	13	0.038
	Global	1.22	1.83	0.49	0.17	2.28	2.50	13	0.026

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Appendix-F13: RAND-36 (v1.0) Paired t-tests: Baseline vs. mid-point/ end of treatment/follow-up (weeks 4/8/16)

Time point	Dimension	Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Week 4	PHC	3.84	7.16	1.91	-0.30	7.97	2.00	13	0.066
	MHC	4.09	9.79	2.62	-1.57	9.74	1.56	13	0.142
Week 8	PHC	5.41	8.18	2.19	0.68	10.13	2.47	13	0.028
	MHC	3.64	13.94	3.73	-4.41	11.69	0.98	13	0.346
Week 16	PHC	4.70	8.36	2.23	-0.12	9.53	2.10	13	0.055
	MHC	4.91	14.13	3.78	-3.25	13.07	1.30	13	0.216

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Appendix-F.14: Independent t-tests: Change from baseline in WOMAC sub-scale - inter group comparison

Time point	Sub-scale	Levene's Test for Equality of Variances		t-test for Equality of Means					
		F	Sig.	t	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
								Lower	Upper
Mid-point	Pain	1.73	0.213	-0.92	0.376	-0.79	0.86	-2.67	1.08
	Stiffness	0.30	0.593	0.40	0.695	0.75	1.87	-3.32	4.82
	Function	0.33	0.577	1.17	0.265	1.03	0.88	-0.88	2.93
End of treatment	Pain	0.04	0.854	-1.51	0.157	-2.01	1.33	-4.91	0.89
	Stiffness	0.46	0.509	-0.67	0.516	-1.21	1.81	-5.14	2.72
	Function	0.20	0.662	0.31	0.760	0.45	1.43	-2.67	3.57
Follow-up	Pain	1.44	0.253	-0.06	0.956	-0.06	1.05	-2.34	2.22
	Stiffness	0.14	0.711	0.31	0.760	0.54	1.74	-3.24	4.33
	Function	0.49	0.497	0.47	0.647	0.66	1.41	-2.41	3.73

df = 12

Appendix-F15: Independent t-test: PHC and MHC at baseline

Composite scale		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
PHC	Equal variances assumed	8.887	0.011	-0.29	12	0.773	-1.12	3.80	-9.39	7.15
	Equal variances not assumed			-0.33	10.490	0.752	-1.12	3.44	-8.74	6.50
MHC	Equal variances assumed	.067	0.800	-2.13	12	0.055	-11.31	5.32	-22.91	0.28
	Equal variances not assumed			-2.23	12.000	0.046	-11.31	5.08	-22.37	-0.26