

Osteoarthritis and Chinese Medicine: An Overview of Theories and Evidence

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Abstract

Osteoarthritis (OA) has been treated with Chinese medicine (CM) for hundreds of years, albeit under the auspices of other clinical descriptors understood within the field of CM. This paper provides an overview of how OA is typically understood and treated within CM. OA has typically fallen under the clinical descriptor of 'bi syndrome' (painful obstruction syndrome). As theory continues to develop, however, new ideas are emerging regarding its pathogenesis that have consequences for treatment - that OA should be considered as a combination of 'wei syndrome' and bi syndrome. The therapeutic thrust of herbal medicine and acupuncture thus shifts from a focus on the Kidney zang to the Liver zang, and consequently different kinds of herbs are chosen within medicinal formulas. The majority of clinical studies into the efficacy of acupuncture and Chinese herbal medicine in the treatment of knee OA have methodological shortcomings, although there is some evidence that acupuncture may be useful in alleviating pain and improving joint function. More studies that are scientifically rigorous are required in this field.

Introduction

Osteoarthritis (OA) is a common disorder of synovial joints characterised by the degeneration of articular cartilage, new bone formation at the joint margins (osteophytosis), variable degrees of mild synovitis and, in severe cases, narrowing of the joint space and changes in the subchondral bone (Dieppe et al., 2005). OA has become a major cause of morbidity, limitation of activity and health care utilisation, especially in elderly patients (Felson et al., 2000a). The goal of management in Western medicine (WM) is pain control and improvement in function and health-related quality of life (Felson et al., 2000a). Non-steroidal anti-inflammatory drugs (NSAIDs) are the most widely prescribed pharmacological medications, which are associated with serious side-effects including bleeding and perforating gastric ulcers. Cyclooxygenase-2 (COX-2) inhibitors have been associated with increased risk of cardiovascular disease such as myocardial infarction (Hippisley-Cox et al., 2005; Hudson et al., 2005; Jüni et al., 2005). There is a need for alternative approaches to treatment.

OA has been treated with Chinese medicine (CM) for hundreds of years, albeit under the auspices of other clinical descriptors understood within the field of CM. With the call for various forms of complementary and alternative medicine to become evidence-based, there is an imperative to demonstrate efficacy using scientific methods. This paper explains how OA is understood in CM, including its aetiology, pathogenesis and treatment. An emerging theory about the classification and pathogenesis of OA is

discussed, which has consequences for treatment. Finally, we explore the scientific evidence base of acupuncture and Chinese herbal medicine (CHM) in the treatment of OA of the knee.

How is OA typically understood in Chinese medicine?

The term 'osteoarthritis' did not exist in ancient Chinese medical texts, although there were descriptions of diseases that were very similar in terms of clinical characteristics. In general, OA is usually categorised as 'bi syndrome' (painful obstruction syndrome), and more specifically, 'bi syndrome of bone'. In modern texts, the term 'bi syndrome' describes conditions of pain, soreness or numbness of muscles, tendons and joints as a result of invasion of external pathogenic wind, cold and/or dampness (Maciocia, 1994; Ni, 1995). However, the term 'bi' is an ancient concept with broad meaning. In the *Huang Di Nei Jing Su Wen* (Yellow Emperor's Inner Classic Plain Questions), one of the key ancient texts of Chinese medicine that is likely to have been compiled during the Han Dynasty, the word 'bi' translates as 'blockage' (Unschuld, 2003). Unschuld (2003) explains how within the *Su Wen* there is evidence of several changes in conceptualisation of the concept of 'bi', from a more basic reference to mechanical blockage of the urethra, to its conceptualisation as a disease caused by excessive wind, cold and/or dampness. In modern CM, 'bi' is now used to describe a disease, a set of signs and symptoms, or a term in pathology (Unschuld, 2003). With respect to bi as a disease name, this is further specified in terms of the predominant

pathogenic factor/qi involved, for example 'wind block', or the location of pathology, for example 'bone block' or 'Liver block'.

Since pathological changes associated with bi syndrome usually occur in joints and muscles, pain associated with OA typically occurs with joint usage and/or stiffness of less than 30 minutes duration (Hochberg et al., 1995; White, 2006). Other symptoms and signs of bi syndrome include joint disability and/or oedema and numbness (Zhang et al., 1985). In mild cases, there may be pain in the limbs and joints that becomes more pronounced with changes in the weather and, in severe cases, more pronounced soreness and pain, deformities and decreased range of movement (Aung et al., 2006). However, some patients with radiologic evidence of OA have no symptoms (Felson et al., 2000b). Lack of pain in some OA sufferers is not inconsistent with descriptions of 'bi' in the *Su Wen* of blocks affecting the bones, sinews, vessels, flesh and skin that do not cause pain (Unschuld, 2003).

In the two official clinical guidelines from the People's Republic of China, OA and degenerative arthrosis are both classified as 'bi syndrome of bone' (China State Administration of Traditional Chinese Medicine, 1994; China State Bureau of Technical Supervision, 1997). However, other conditions such as rheumatoid arthritis may also be classified under bi syndrome. Thus there is no exclusive and direct one-to-one correspondence of OA with bi syndrome.

Aetiology, pathogenesis and treatment of OA

OA has generally been considered to be a type of bi syndrome caused by depletion of the Kidney and Liver zang, which invites invasion of exogenous pathogenic factors. Such invasion obstructs the channels, leading to impaired qi and blood circulation and, consequently, pain. In the majority of cases, the external causes of bi syndrome are a combination of three pathogens: wind, cold and dampness (Zhang et al., 1985). Impairment of the transformation of body fluids over long periods (due to Spleen depletion) leads to stagnation of non-substantial phlegm. Blood and phlegm stagnation become secondary pathogenic factors that accumulate in the joints and further exacerbate the problem (Xiao, 2004), with phlegm condensing to form bone growths (Maciocia, 1994).

The Kidney has traditionally been considered the primary organ involved in the development of bi syndrome, with the Liver secondary (Jiang et al., 2001). There are logical reasons for this within CM theory. The Kidney is said to dominate bones. The Kidney essence (jing) (a vital substance responsible for the formation of bone, growth and development) declines with age, which causes the qi of the organs to become depleted, the bones to become frail, tendons to stiffen and consequently movement to become impaired (Ni, 1995). Osteophytes - outgrowths of bone - are often associated with OA. The Liver is said

to store blood and control the sinews (tendons, cartilages and ligaments) through its nourishing and moistening functions. Kidney yin is the foundation of Liver yin and blood. The Spleen is also involved by virtue of its actions of controlling the muscles and limbs, and transforming and transporting fluids and qi. Spleen depletion can lead to deficiency of qi and blood (since the Spleen produces qi), further reinforcing deficiency of Kidney jing and Liver blood. In addition, the Spleen is easily affected by external dampness (Ni, 1995).

The treatment strategy for OA logically follows the diagnosis and understanding of its pathogenesis. General treatment principles give consideration to the 'ben' or root cause of a condition and the 'biao' or branch (which relates more to the symptoms and signs). Bi syndrome is considered to be a condition where the root is deficient (deficient Kidney jing and Liver blood), allowing invasion of pathogenic factors and contributing to the pathogenic development of blood and phlegm stagnation. The branch, on the other hand, is often excessive (referring to qi/blood/phlegm stagnation and invasion of external pathogenic factors that cause painful obstruction). As a consequence of this understanding of the pathogenesis of the condition, the treatment strategy of CM has traditionally been to tonify the Kidney and Liver, nourish qi and blood, expel wind-cold, remove dampness, promote blood circulation and remove obstruction from the channels and collaterals.

The majority of CHM formulas used to treat OA follow this basic pattern identification, and emphasise tonifying the Kidney and Liver, promoting blood circulation, expelling wind and resolving dampness (Li, 2003). Some herbal formulas emphasise invigorating the Spleen where there are inflamed, degenerative joints (Cao et al., 2006). Typically, most CHM formulas focus on a specific stage of the disease process, thereby addressing only part of the pathogenic process (Liu et al., 2004c). Proprietary CHMs in the form of pills have been found to be the most common form used for OA (Liu et al., 2005). One survey (Liu et al., 2005) found that herbs with the actions of dispersing exogenous wind and dampness, tonifying blood and activating blood circulation were found to be the most common components of proprietary forms of CHMs for OA; over 50 per cent of the herbs in these formulas were pungent, sweet and bitter in terms of taste, and warm in terms of temperature. External application of CHM primarily addresses symptoms rather than underlying causes (as internal CHM does) (Wu et al., 2006a). Fumigation-washing therapy, plaster or ointment applications and ionotherapy with CHM are the most common external therapies used in Chinese clinics. An investigation of 87 different external-use formulas for OA found that herbs with the actions of dispelling wind-dampness and eliminating blood stagnation were those used most commonly, and that 73 per cent of the

most commonly prescribed herbs were warm in nature (Yao et al., 2005). In Chinese hospitals, intra-articular injection of CHM into the knee cavity has been applied as a form of therapy (Zhang et al., 2005); few studies have investigated its effectiveness, however, and of these many are methodologically flawed (Wan et al., 2006).

Acupuncture has been widely used for treatment of OA of the knee and chronic knee pain (Kwon et al., 2006; White et al., 2007a), and, at least in China, commonly in conjunction with other techniques including electronic stimulation (electro-acupuncture) (Lao et al., 2003; Li et al., 2008a; Wu, 1998; Wu et al., 2008), moxibustion, electrical heat lamps and other special electromagnetic therapeutic apparatus (Cai & Huang, 2004; Lin & Liang, 2005; Wang & He, 2007), acupoint injection, cupping, physical exercise and herbal medicine (oral, external and/or ionotherapy methods) (Bao et al., 2007; Lao et al., 2003; Li et al., 2008a; Wu, 1998; Wu et al., 2008). The technique of 'warm needling' is the most popular treatment modality for OA (Le, 2001; Li et al., 2006; Lin et al., 2004; Wu et al., 2006), in keeping with the idea that OA is due to Kidney deficiency and invasion of cold and damp (Yang et al., 2007). Laser therapy is also used for OA treatment in China (Xi et al., 2008).

Arguments about the classification of OA and emerging theories

The main reason for classifying OA as bi syndrome centres on the key symptom of pain. It is not difficult to understand the reasoning behind the primacy of the Kidney in the pathogenesis of OA, given the previously outlined theoretical rationale. However, some researchers have argued that OA should be categorised as a disease of the sinews rather than 'bi syndrome of bone' (Cao et al., 2006). The arguments for this include the fact that pathogenic changes of OA occur in articular cartilage and the tissue around joints - which are classified as 'sinews' in CM and considered to be an extension of the Liver. In addition, the knees are known as the 'Palace of the Tendons' (Ni, 1995). Inability to bend or straighten a joint properly, or overcompensation in order to do so is a sign of tendon degeneration (Ni, 1995). Consideration of the function of Liver blood suggests a potential pathomechanism: if Liver blood is deficient the sinews will lack moistening and nourishment, which may cause contraction, spasm, impaired flexion, numbness of the limbs, tingling and muscle cramps. In addition, if there is stasis of Liver blood, the sinews will lack suppleness and the person may experience stiffness, rigidity and pain of the joints (Maciocia, 2005).

A relatively recent emergent theory is that OA should be considered a combination of wei syndrome and bi syndrome, with wei syndrome considered the fundamental disorder and bi syndrome secondary. Thus greater emphasis is placed on the role of the Liver

in the pathogenesis of OA, rather than the Kidney. A key proponent of this theory is Professor Shi Yinyu of Shanghai Shuguang Hospital, whose clinical experience has provided supporting anecdotal evidence (Shi et al., 1994). Wei syndrome is defined as progressive weakening or degeneration of the limbs caused by a deficiency of qi, blood, body fluids and/or jing. It manifests as flaccidity of the sinews or muscles and, in severe cases, loss of voluntary movement of the limbs (Shi et al., 1994). The following quote from Chapter 44 of the *Su Wen* clearly links the notion of blockage (described in other parts of the *Su Wen* in relation to bi syndrome) and muscle flaccidity, a key symptom of wei syndrome:

'When someone is submerged in dampness, [because] his work has to do with water, and if some [dampness] stays [in the body], or when someone's place of living is damp, and his muscles and the flesh are soggy, a block [develops together with] numbness. This develops into flesh limpness' (Unschuld, 2003: p.215).

Signs and symptoms of OA in the initial stage are indicative of 'painful obstruction' (bi syndrome), although the clinical manifestation of advanced OA is atrophy of the muscles of the limbs (from lack of use) - a major feature of wei syndrome - along with muscle weakness. Other symptoms such as numbness may be shared by both bi syndrome and wei syndrome. According to CM theory, by fifty-six years the Liver energy weakens causing the tendons to stiffen (Ni, 1995). Chapter one of the *Su Wen* states that the Kidney qi begins to decline over the age of 40 years (Ni, 1995). Indeed, the Kidney jing and Liver blood are understood to have a common source. Therefore the decline in function of the Liver and Kidney with increasing age, as described in CM theory, is in keeping with the epidemiology of OA: that approximately 40 per cent of adults over 70 years old are affected by OA of knee, 80 per cent of whom have limitations of movement and 25 per cent of whom cannot perform the major daily activities of living (Crepaldi et al., 2003). For these reasons, it has been argued by some that OA should be considered a combination of bi syndrome and wei syndrome (Guo et al., 2003; Shi et al., 1994).

This has important consequences in terms of treatment, particularly in relation to the kinds of herbs included in medicinal formulas. The treatment principles that follow this reasoning emphasise soothing and nourishing the Liver (in particular the Liver blood), soothing the sinews and eliminating exogenous pathogenic factors (Cao et al., 2006). Other authors such as Guo et al. (2002) support the notion that in a chronic disease such as OA, comprehensive treatment strategies are required, and suggest that treatment strategies should encompass tonifying the Kidney, soothing the Liver, invigorating the Spleen and removing blood and phlegm stasis. Thus if

the Liver is the key organ, CHM formulas need to have a greater emphasis on nourishing Liver blood than on tonifying the Kidney, with the pungent and drying herbs typically found in bi syndrome formulas being replaced by mild and nourishing herbs (Liu, 1999; Shi et al., 1994). Histopathology studies in animals have demonstrated improved outcomes when CHMs that nourish and soothe the Liver are used, particularly in synovitis, in comparison to CHMs that did not treat the Liver (Shen et al., 1995; Wang et al., 1998).

The scientific evidence base of Chinese medicine in OA treatment

In comparison with rheumatoid arthritis, OA has historically not been a priority area for research (Birrell, 2004). Studies of CAM have found that CAM is cost-effective and can reduce the burden of OA (Herman et al., 2005), which was estimated as costing Australia AUD\$1090 million in 2001 (Segal et al., 2004).

To understand the scientific evidence base for the treatment of OA with CM we conducted a literature search of clinical studies that investigated the efficacy of acupuncture and CHM in treating OA of the knee, a common location for OA. The literature search used two key databases: the English language database PubMed (including Medline) and the large Chinese database www.cqvip.com. Both were searched thoroughly between April 2007 and August 2007. Search terms used included: 'osteoarthritis', 'Chinese medicine', 'acupuncture', 'herbal medicine', 'RCT', 'knee' and 'double-blind'.

The Jadad Scale, a research tool used to assess the quality of randomised controlled trials (RCTs) in pain research (on a scale of zero to five) (Jadad et al., 1996) was applied to the studies identified. The Jadad Scale has been found to be reliable in a number of different settings (Clark et al., 1999; Moher et al., 1996; Olivo et al., 2008), although like many scales used to assess methodological quality, it has limitations. For example, it is not particularly suitable for assessing studies of treatment interventions such as manual therapy or exercise therapies, since double-blinding is unlikely to be a feature of such studies. There is no assessment tool that is specifically suitable for CAM research requirements (Katrak et al., 2004).

Results: Chinese herbal medicine

An Australian study found that as many as 40 per cent of OA sufferers used CAM (Zochling et al., 2004). A systematic review indicated that the incidence of adverse effects associated with the herbal medicine treatment of OA appeared to be low, and that herbal medicine may offer a much-needed alternative for individuals with long-term chronic OA (Long et al., 2001). Herbal medicines are also commonly used for rheumatic conditions (Setty et al., 2005).

There were 35 clinical trials identified that investigated

the efficacy of CHM treatment of OA of the knee (Bian et al., 2005; Cao et al., 2004b; Chen, 1995; Chen et al., 2005; Dang et al., 2003; Du et al., 2005; Fan, 2006; Ge et al., 2002; Guo, 2006; He et al., 2005; Hu et al., 2001; Jiang, 2005; Le et al., 2004; Li et al., 2003; Li et al., 2005; Liu, 1995; Liu et al., 2004a; Liu et al., 2004b; Qi et al., 2005; Ruan et al., 2005; Shi et al., 1994; Tang et al., 2003; Wang et al., 2004; Wu et al., 2001; Xiao et al., 2005; Xie, 2005; Yang et al., 2003; Zhang et al., 2000; Zheng et al., 2004; Zheng et al., 2006a; Zheng et al., 2006b; Zhong et al., 2006; Zhou et al., 2006; Zhou, 2003; Zhu et al., 2002). The majority of these were published in Chinese. Ten are set out in Table 1 as examples [online version only]. Other articles published in English relate to studies of single herbs (or single herb extracts) or Ayurvedic medicine, and are not guided by pattern differentiation (Kang et al., 2005), and were therefore not included.

In general, the majority of Chinese studies suffered from methodological shortcomings, a finding similar to the conclusion of another survey conducted on the quality of RCTs reported in Chinese journals (Wang et al., 2007a). Only two studies published in Chinese were explicitly double-blinded and randomised (Cao et al., 2004b; Ge et al., 2002). Methodological problems include not using reliable diagnostic criteria, inappropriate study design and/or inappropriate statistical analysis (Cao et al., 2006; Li, 2003). The Jadad scores for the majority of the studies are low: mean 1.0 (std. deviation 0.9), range zero to four. Comparability across studies is difficult due to the range of diagnostic and treatment assessment criteria used. Many Chinese researchers are not familiar with the classification criteria for OA that are commonly accepted and used in Western countries. The criterion of the American College of Rheumatology is most widely known in China (Hochberg et al., 1995). Lack of rigour in clinical trials in general has been recognised as a problem in China, and measures to counteract this have consequently been introduced. For example, the State Food and Drug Administration's Clinical Research Guidelines of New Chinese Medicine (Zheng, 2002) and the State Administration of Traditional Chinese Medicine's Criteria of Diagnosis and Therapeutic Effect of Disease and Syndromes in Traditional Chinese Medicine (The State Administration of Traditional Chinese Medicine, 1994) have been published in order to guide conduct of clinical trials.

Results: acupuncture

Limited scientific evidence from RCTs suggests that acupuncture is useful for pain control and can improve physical dysfunction associated with knee OA (Selfe et al., 2008). However, many studies have methodological shortcomings, including lack of randomisation and blinding, lack of an adequate placebo control and lack of use of validated assessment tools (Li et al., 2007).

Our literature search revealed 33 clinical trials that

have investigated the efficacy of acupuncture in the treatment of OA of the knee (Berman et al., 2004; Berman et al., 1999; Bi, 2006; Cai et al., 2004; Fu et al., 2007; Gu et al., 2008; Huang, 2002; Jia et al., 2005; Lao et al., 2003; Le, 2001; Li et al., 2006; Li et al., 2008a; Li et al., 2002; Li et al., 2008b; Lin et al., 2004; Lin et al., 2005; Qiu et al., 2002; Sangdee et al., 2002; Scharf et al., 2006; Song et al., 2001; Sun et al., 2008; Tao et al., 2003; Vas et al., 2006; Wang et al., 2007b; Witt et al., 2005; Wu, 1998; Wu et al., 2006b; Wu et al., 2008; Xi et al., 2008; Xu, 2008; Zhang et al., 2004; Zhang et al., 2001 and Zhao, 2007). The details of ten of these are set out in Table 2 to illustrate the types of studies conducted [online version only]. Twenty-seven of the studies were conducted in China, all of which found that acupuncture was effective. Several assessed multiple treatment modalities, making it difficult to reach any conclusions about the efficacy of acupuncture itself. Some studies utilised different treatment periods within the study. Several used unreferenced treatment assessment criteria and did not use accepted OA diagnostic criteria. Very few reported safety or compliance data. The majority did not give any description of blinding, so that the reader cannot be sure that this occurred. The Jadad scores for the majority of the 33 studies are low: mean 1.7 (std. deviation 1.1, range zero to five).

There were six studies conducted in Western countries, five of which supported the contention that acupuncture is significantly more effective in relieving pain and improving knee function in OA sufferers in comparison with either placebo or other active intervention (Berman et al., 2004; Berman et al., 1999; Sangdee et al., 2002; Vas et al., 2006; Witt et al., 2005). One clinical trial found that the effect of acupuncture for pain relief decreased over a 12-month follow-up period in comparison to a control group which received superficial needling (Witt et al., 2005). The one RCT (Scharf et al., 2006) that found that acupuncture was no better than placebo but better than conservative therapy might be criticised for imperfect blinding and the sham acupuncture procedure used as a control. It is well recognised within the field of acupuncture research that one of the difficulties of research is the identification of an appropriate placebo control (White et al., 2007b).

Systematic reviews and meta-analyses are equivocal with respect to the efficacy of acupuncture. One meta-analysis concluded that the clinical improvements due to acupuncture may be due to placebo or expectation effects (Manheimer et al., 2007). Another systematic review found acupuncture superior to sham (placebo) acupuncture for treating chronic knee pain in both the short and longer term (White et al., 2006). Systematic reviews of acupuncture

studies in OA indicate that there were no associated adverse events (Manheimer et al., 2007; White et al., 2006; Yamashita et al., 2006) and that acupuncture is a relatively cost-effective therapy for OA patients (White & Kawakita, 2006; Witt et al., 2006).

The most commonly used acupoints in clinical trials include: Dubi ST-35, Zusanli ST-36, Yanglingquan GB-34, Yinlingquan SP-9 and Neixiyan MN-LE-16 (Li et al., 2007; Selfe & Taylor, 2008).

Only one study published in English has investigated the efficacy of moxibustion therapy in OA (Vas et al., 2004), and reported that 75 per cent of patients gained moderate clinical improvements - with patients consuming less analgesics and anti-inflammatory drugs during the trial. However, moxibustion treatment was combined with electro-acupuncture and auricular therapy and there was no control group or randomisation. Chinese studies of moxibustion found that moxibustion significantly improved symptoms of OA in comparison with controls (Fu et al., 2007; Huang, 2002; Li et al., 2008a; Li et al., 2002; Sun et al., 2008), although these studies have methodological problems and caution needs to be taken in interpreting their findings.

Future research: investigating new theories in CM

The relatively new hypothesis that OA should be considered to be a combination of wei syndrome and bi syndrome has some support clinically (Cao et al., 2004b; Shi et al., 1994) and in animal studies (Cao et al., 2004a; Shen et al., 1995; Wang et al., 1998), although more rigorous clinical evidence is needed. In order to investigate this new hypothesis further, a parallel design, placebo-controlled RCT investigating the efficacy of a CHM in the treatment of OA of the knee started in Australia in 2009 by Victoria University and Nucleus Network (Baker Medical Research Institute). The CHM under investigation has been designed with a strategic focus on treating OA as a combination of wei syndrome and bi syndrome.

Conclusion

How OA is understood and treated in CM is vastly different to Western medicine, which is unsurprising given the very different paradigms of these two systems of medicine. OA is usually categorised as bi syndrome, although an emerging theory suggests that OA should be considered as a combination of wei syndrome and bi syndrome. This theory has some support clinically and in animal studies, and a theoretical case may be made to rationalise it. However, it has not been established scientifically. Further studies are needed in order to develop a greater evidence base for the treatment of OA with

CM, and in particular, to explore emerging theories and treatment strategies. One such study is currently underway in Australia. ■

Please note that for reasons of space the tables and references for this article will only appear in the online version.

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Table 1: Clinical studies of the Chinese herbal medicine treatment of OA of the knee

Ref.	Sample size and no. of dropouts	Mean age (yrs)	Sex ratio (M : F)	Power calculation	Study design	Study intervention / control treatment	Diagnostic criteria	Concomitant medication recorded	Compliance assessed	Safety monitoring	Outcome measures	Results	Jadad score
(Tang et al., 2003)	60 (treatment group n=30, control group n=30). No information of dropouts.	63.5	28 : 32	No information.	Parallel design. No description of randomisation.& blinding. 4 week treatment period.	Treatment group: <i>Gu Yan Ding</i> decoction oral administration plus external application 1 package per day (Pu Gu Zhi 12g, Gu Sui Bu 12g, Niu Xi 12g, Hong Hua 5g, Huang Qi 20g, Mu Gua 15g). Control group: acetaminophen 0.9g t.i.d. p.o. (oral administration only).	ACR 1986 and TCM syndrome differentiation (Kidney and Liver deficiency accompanied by Blood stagnation).	No information.	No information.	No information.	① Activities of Daily Living Scale of the Knee (ADLS). ② Serum estradiol level test.	Within group analysis: <i>Gu Yan Ding</i> significantly increased the scores of symptoms, activity function and overall scores of ADLS (p<0.01). Between groups analysis: significant improvement in total score on ADLS in <i>Gu Yan Ding</i> group (P<0.05).	0
(Zheng et al., 2004)	60 (treatment group only, no control group). 6 dropouts; 3 excluded in screening.	55.4	Female only.	No information.	Open label trial. No description of randomisation or blinding. 1 month treatment period.	Treatment group: <i>Gu Shu Kang</i> granules (Yin Yang Huo, Shu Di Huang, Huang Qi, Dan Shen, Gu Sui Bu) made by Healthstar Medical Development Co. Beijing.	ACR 1991 and TCM syndrome differentiation (Kidney deficiency).	No information.	No information.	No information.	① Activities of Daily Living Scale of the Knee (ADLS). ② Serum estradiol level test.	Within group analysis: <i>Gu Shu Kang</i> significantly reduced pain and improved scores of knee functional assessment (p<0.01). Serum estradiol level rose after treatment (p<0.05).	1
(Ruan et al., 2005)	120 (TCM group n=30; estradiol group n=30; TCM + estradiol group n=30; non-treatment group n=30). No drop-out patients.	52±5 (treatment groups). 54±5 (non-treatment group).	Female only.	No information.	Parallel study design. RCT, but no description of randomisation. Single blind (assessor blinded). 12 week treatment period.	Treatment group: <i>Qiang Gu</i> capsules (flavone of rhizoma drynariae produced by Beijing Qihuang Pharmaceutical Factory). Control group medication: estradiol 0.5-1.5mg q.d. p.o. (individualised dosage used in the trial).	ACR 1995	No information.	No information.	Yes. No adverse events found.	① Effective range of the motion of knee.	Improvement found in all 3 treatment groups (p<0.01). TCM + estradiol group significantly improved motion range compared with other groups (p<0.01), but estradiol group had similar effect to TCM group.	2
(Shi et al., 1994).	262 (Treatment group n=50; TCM control group n=24; Fenbid control group n=188). No information of dropouts.	No information.	95 :167	No information.	Parallel study design (3 groups). No information of randomisation & blinding. 4 week treatment period.	Treatment group: <i>Yang Xue Ruan Jian</i> Decoction (Bai Shao, Mu Li, Qin Jiao, Gan Cao; manufacturer name not given) 70 ml per day. TCM control group: Tonify Kidney and Strengthen Bone Decoction, 70 ml per day. Western medicine control group: Fenbid (ibuprofen): no dosage description given.	ACR (no citation of publication year).	No information.	No information.	No information.	① Author-created OA scale scores (referred to articles of Lequesne MG et al & Goldberg VM et al).	Significant difference between treatment group and Fenbid control group for an OA score improvement of ≥10' (p<0.05). Highly significant difference between treatment group and Fenbid group (p<0.01) for an OA score improvement of ≥20. Significant difference between treatment group and TCM control group in terms of OA scores (p<0.05).	0
(Cao et al., 2004)	120 (first trial: treatment group n=30, control group n=30; second trial: treatment group n= 30, control group n=30). No drop-outs.	First trial: 58±7 (treatment group); 59±9 (control group). Second trial: 64±9 (treatment group); 62±9 (control group).	First trial 21:39 Second trial 19:41	Yes.	First trial: parallel study design, double blind RCT. Second trial: parallel design, no blinding, RCT 4 weeks treatment period (for each trial).	Treatment group medication: <i>Yang Xue Ruan Jian</i> Capsule (Bai Shao, Mu Li, Qin Jiao, Gan Cao) 1.05g t.i.d. p.o. TCM control: <i>Kang Gu Zhi Zeng Sheng</i> capsule (1.75g t.i.d. p.o.). Western medicine control: Glucosamine (0.75g t.i.d. p.o.).	ACR 1986	Yes, but no detailed description given.	Yes, but no detailed description given.	Yes. 4 adverse events in the treatment group in the first trial; no adverse event in the second trial.	① WOMAC index. ② Visual Analogue Scale.	Analgesic function of <i>Yang Xue Ruan Jian</i> Capsule became apparent during weeks 2- 4, and WOMAC scores of the treatment group decreased after 4 weeks therapy (p<0.05). Therapeutic effectiveness was similar across all three groups (p<0.05).	4
(Ge et al., 2002)	200 (treatment group n=100, control group n=100). No drop-outs.	55.87 ± 7.64 (treatment group) & 54.13 ± 7.16 (control group).	57:143	No information.	Parallel design double-blind RCT, but no description of randomisation. 1 month treatment period.	Treatment group: compound <i>Du Zhong Jian Gu</i> (DZJG) granules (Du Zhong, Xu Duan, Niu Xi, Dang Gui etc. 12g q.d. p.o.). Control: <i>Zhuang Gu Guan Jie</i> pill 6g b.i.d. p.o.). Treatment group: real DZJG plus sham control medicine. Control group: sham DZJG plus real control medicine.	Clinical Research Guidelines of New Chinese Medicine - Edition 3 (China) and TCM syndrome differentiation (deficiency of Kidney and Liver, with Blood stagnation).	No information.	No information.	Yes. No trial related adverse event found except for some digestive discomfort (no detailed information).	① Joint function scale scores based on Clinical Research Guidelines of New Chinese Medicine - Edition 3 (China).	Compound DZJG was superior to the control group for total effective rate (p<0.01) and TCM signs (p<0.01). Within group analysis: both herbal medicines associated with improved symptoms(p<0.01). Between groups analysis: no significant difference between two groups (p>0.05). Better response in DZJG group in patients with mild OA compared with moderate or severe OA.	3

Ref.	Sample size and no. of dropouts	Mean age (yrs)	Sex ratio (M : F)	Power calculation	Study design	Study intervention / control treatment	Diagnostic criteria	Concomitant medication recorded	Compliance assessed	Safety monitoring	Outcome measures	Results	Jadad score
(Wang et al., 2004)	400 (treatment group n=300, control group n=100). No drop-outs.	Treatment group: ≤ 50yrs (n=69), 51-60yrs (n=131), 61-70yrs (n=100).	78:222 (treatment group). No information on control group.	No information.	RCT, but no information of randomisation & blinding. 1 month treatment. Period.	Treatment group: compound <i>Du Zhong Jian Gu</i> granules (DZJG granules) (Du Zhong, Xu Duan, Niu Xi, Dang Gui etc. produced by Tianjin Lisheng Pharmaceutical Co.Ltd.) 12g q.d. p.o.). Control group medication: <i>Zhuang Gu Guan Jie</i> pill 6g b.i.d p.o.	Clinical Research Guidelines of New Chinese Medicine - Edition 3 (China) & TCM syndrome differentiation (Kidney and Liver deficiency with Blood stagnation).	No information.	No information.	Yes. 3 patients reported digestive discomfort.	① Joint function scale scores based on Clinical Research Guidelines of New Chinese Medicine - Edition 3 (China).	Compound DZJG was superior to the control group for total effective rate (p<0.01), time to respond (p<0.01) and in terms of TCM signs (p<0.01). Within groups analysis: improvement in symptoms compared with pre-treatment in both treatment group and control group (p<0.01).	2
(Zhang et al., 2000)	100 (treatment group only). No information on dropouts.	57.2 ± 6.8	38 : 62	No information.	Open label study. 6 week treatment period.	Treatment group: <i>Zhui Feng Tou Gu</i> (ZFTG) pill (Zhi Chuan Wu, Bai Zhi, Xiang Fu, Bai Zhu, Chuan Xiong, Dang Gui, Ru Xiang, Mo Yao, Qin Jiao, Qiang Huo, Tian Ma, Gan Cao, Guangzhou Jing Xiu Tang Pharmaceutical Company Ltd) 6g t.i.d. p.o.	ACR (no citation of publication year) & Clinical Criteria of TCM Syndrome Differentiation (Shanghai Health Bureau, 1998) including 3 patterns.	Yes.	No information.	Yes. No adverse events being reported.	① Clinical efficacy based on Clinical Efficacy Criteria of TCM Syndrome Differentiation (Shanghai)*.	ZFTG pill improved clinical symptoms (p<0.01).	0
(Jiang, 2005)	150 (treatment group n=80, control group n=70). No information of dropouts.	62.41 ± 6.11 (treatment group). 63.62 ± 5.31 (control group).	28 : 52 (treatment group). 24 : 46 (control group).	No information.	Parallel design, RCT but no detailed information of randomisation. No blinding. 3 month treatment period.	Treatment group: Individualised CHM decoction according to TCM syndrome differentiation. Control group: sulindac (150mg bid po) + glucosamine sulphate (500mg q.d. p.o.).	Clinical Research Guidelines of New Chinese Medicine (China 2002).	No information.	No information.	No information.	① Clinical efficacy based on Clinical Efficacy Criteria of Clinical Research Guidelines of New Chinese Medicine (China).	TCM decoction significantly superior to control medication in reduction of clinical symptom scores (p<0.01).	1
(Zhou et al., 2006)	60 (Treatment group n=29; control group n=26). 1 drop-out in treatment group, 4 drop-outs in control group.	56.90 ± 7.09 (treatment group). 57.73 ± 7.44 (control group).	10 : 19 (treatment group) 8 : 18 (control group).	No information.	Parallel design, RCT, but no detailed information on randomisation & no information of blinding. 6 week treatment period.	Treatment group: <i>Guan Jie Kang</i> (GJK) tablet (Shu Di Huang, Niu Xi, Du Zhong, Gou Qi Zi, Dan Shen, Hong Hua, Mu Xiang, Bu Gu Zhi etc.) 23.68g t.i.d. p.o. Control group medication: Celecoxib 200mg q.d. p.o.	ACR1995; TCM syndrome differentiation (based on ranking symptoms, no pattern assessed).	Yes, no detailed information.	No information.	No information.	① Author-created TCM symptom Scale developed from WOMAC index and Lesquene knee osteoarthritis index.	Clinical improvement after treatment within both treatment and control groups (p<0.01). GJK tablet had the same therapeutic effectiveness as Celecoxib (p>0.05) with respect to the TCM symptom scale. GJK tablet was more effective than Celecoxib in altering TCM signs and symptoms (p<0.01).	2

Key: ACR: American College of Rheumatology; TCM: traditional Chinese medicine; CHM: Chinese herbal medicine; * Clinical efficacy criteria of TCM Syndrome Differentiation (Shanghai) is an official standard that includes disease definition, diagnosis criteria, treatment standards and assessment criteria; p.o.: by mouth; q.d.: per day; t.i.d.: three times daily

Table 2: Studies of the acupuncture treatment of OA

Reference	Sample size and no. of drop-outs	Study design	Power calculation	Study intervention / control treatment	Diagnostic criteria	Safety monitoring	Outcome assessment	Results	Jadad score
(Berman et al., 1999)	Total participants n=73. Treatment group n=37 (7 drop-outs). Control group n=36 (8 drop-outs).	Partial crossover design. Randomised. Assessors blinded. 8 week treatment period, 4 week follow-up.	Yes	Treatment group: Needling at Yanglingquan GB-34, Yinlingquan SP-9, Zusanli ST-36, Dubi ST-35, Xiyan (EX-LE5, Xuanzhong GB-39, Sanyinjiao SP-6, Taixi KID-3; Electrodes connected between Dubi ST-35 and Xiyan EX-LE5. 2 sessions weekly for 8 weeks. Control group: Standard care (conventional oral drugs).	ACR criteria 1996	Yes. No side-effects reported by participants.	① WOMAC index ② Lequesne scale	① ② significant difference between treatment group and control group for all outcomes scores (p < 0.001).	3
(Sangdee et al., 2002)	Total participants n=193. Acupuncture treatment group n= 48 (2 drop-outs). Combined treatment group n=49 (3 drop-outs). Comparison Diclofenac group n=49. Control (placebo) group n=47 (2 drop-outs)	Parallel design. Single-blind (patient blinded). Randomised. Placebo-controlled (sham). 4 week treatment period, 2 month follow-up.	No information	Treatment groups: Electro- acupuncture (EA) group: EA at Dubi ST-35, EX-LE4, Xialian L.I.-8 and trigger point. Electro-acupuncture: electrodes connected between Dubi ST-35 and Neixiyan (EX-LE4); another pair between Xialian LI-8 and trigger point. 3 sessions weekly for 4 weeks. Diclofenac comparison group: Diclofenac tablet plus placebo EA Combined treatment group: Diclofenac tablet plus EA. Control (placebo) group: placebo tablet plus placebo EA (performed by attaching patch electrodes to the same acupoints).	ACR criteria 1995	Yes. 7 patients reported adverse effects (across the three groups).	① Amount of paracetamol tablets taken per week. ② 50 feet walk time. ③ Pain VAS. ④ WOMAC. ⑤ Lequesne functional index. ⑥ Physician Global Assessment and Patient Global Assessment (patient final opinion of change).	① No statistical significance in amount of paracetamol taken between the four groups. ② No statistical significance between the four groups. ③ Mean changes in pain VAS significantly greater in EA group compared with both the placebo group and the Diclofenac comparison group (p < 0.05). ④ Combined treatment group: greater change in WOMAC pain index compared with placebo group (p <0.05). ⑤ Significantly greater change in Lequesne’s functional index in EA group compared with placebo group (p <0.05). ⑥ Physician global assessments in EA group were greatest at week 4 (p <0.05). Patient Global Assessment (final opinion of change): no significant difference in no. of patients with overall opinion of ‘much better’ between the 4 groups.	3
(Berman et al., 2004)	Total participants n=570. Real acupuncture group n=190 (44 drop-outs). Control sham acupuncture group n=191 (50 drop-outs). Control education group n=189 (81 drop-outs).	Parallel design. Randomised. Placebo-controlled (sham). Patient and assessors blinded. 26 weeks treatment period, no follow-up.	Yes	Treatment group (real acupuncture): Needling on Yanglingquan GB-34, Yinlingquan SP-9, Zusanli ST-36, Dubi ST-35, Xiyan EX-LE5, Kunlun BL-60, Xuanzhong GB-39, Sanyinjiao SP-6, Taixi KID-3, electroacupuncture on Xiyan EX-LE5 only; plus 2 sham acupuncture points on abdomen (tapped plastic guide tube on surface of skin). 2 sessions weekly for the first 8 weeks, 1 session weekly for the following 2 weeks, and 1 session fortnightly for the next 4 weeks, then 1 session per month for the remaining 12 weeks. Control sham acupuncture group: real needling on 2 sham points on abdomen and sham acupuncture on the same real points. Control education group: 6 two- hour sessions of education with additional follow-up educational materials mailed periodically during the study.	Author defined these but no reference to particular standard (criteria: age 50 years or older, diagnosis of OA of knee, radiographic evidence of at least 1 osteophyte at tibiofemoral joint (Kellgren-Lawrence grade ≥ 2), moderate or greater clinically-significant knee pain on most days during the past month and willingness to be randomly assigned).	Yes. 26 adverse events were reported, none were due to acupuncture treatment; no significant difference between groups.	① WOMAC pain index ② WOMAC function index ③ SF-36 ④ Patient global assessment ⑤ 6 minutes walk	① At end of 26 weeks, significantly greater decrease in WOMAC pain index in real acupuncture group compared with sham acupuncture (p<0.01). Significantly smaller change in WOMAC pain index in education group compared with sham acupuncture group (p < 0.01). ② At 26 weeks, significantly greater decrease in the WOMAC function score in the real acupuncture group compared with sham acupuncture group (p < 0.01); significantly smaller decrease in the WOMAC function scale in education group compared with sham acupuncture group (p<0.01). ③ No significant difference between real and sham acupuncture groups for SF-36 physical health score. ④ No significant difference between real acupuncture and sham acupuncture groups ⑤ No significant difference between real and sham acupuncture groups.	
(Witt et al., 2005)	Total participants n=294. Acupuncture group n=149 (3 drop-outs). Minimal acupuncture group n=75 (4 drop-outs). Waiting list group n=70.	Parallel design. Randomised. Single-blind. Placebo-controlled. 8 week treatment periods, follow-up at week 26 and week 52.	Yes	Treatment group: Needling on 6 local points from Liangqiu ST-34, Dubi ST-35, Zusanli ST-36, Yinlingquan SP-9, Xuehai SP-10, Weizhong BL-40, Yingu KID-10, Xiyangguan GB-33, Yanglingquan GB-34, Xialian L.I.-8 and 2 distant points from Gongsun SP-4, Shangqiu SP-5, Sanyinjiao SP-6, Jiache ST-6, Pishu BL-20, Chengshan BL-57, Feiyang BL-58, Kunlun BL-60, Shenmai BL-62 and Taixi KID-3. 2 sessions weekly in the first 4 weeks and 1 session weekly in the following 4 weeks. Control minimal acupuncture group: superficial acupuncture on distant non-acupuncture points. Control waiting list group: true acupuncture treatment from week 9.	ACR criteria (year not reported).	Yes. 9 adverse events (3 in treatment group, 2 in control minimal acupuncture group, 4 in control waiting list group). Total 40 side effects reported (24 in treatment group, 16 in minimal acupuncture group).	① WOMAC Index	① Treatment group: WOMAC index was significantly lower after treatment in comparison to minimal acupuncture group and waiting list group after 8 weeks (p <0.01), but no significant difference after 26 and 52 weeks between treatment group and minimal acupuncture group.	3

Reference	Sample size and no. of drop-outs	Study design	Power calculation	Study intervention / control treatment	Diagnostic criteria	Safety monitoring	Outcome assessment	Results	Jadad score
(Vas et al., 2006)	Total participants n=97 participants (9 drop-outs). Acupuncture group n=48. Control group n=49.	Parallel design. Randomised. Controlled. Single blind (patients blinded). 12 weeks treatment period, one month follow-up.	Yes	Treatment group (acupuncture): Needling conducted on Zusanli ST-36 plus pairs of acupoints: Yanglingquan GB-34 and Yinlingquan SP-9; Dubi ST-35 and Nei Xiyuan EX-LE4; EA applied plus Diclofenac tablet (1 tablet every 8 hours). 1 session weekly for 12 weeks. Control group: Streitberger ring (a kind of sham acupuncture with no piercing of the skin, using an adhesive plaster) plus Diclofenac tablet (1 tablet every 8 hours).	Author-defined but no reference given.	Yes, but no data reported.	① WOMAC Index (Likert version). ② Pain VAS.	① & ② the treatment group: significantly greater decreases in index scores than control group (p <0.01).	3
(Scharf et al., 2006)	Total participants n=1039 (32 excluded, 22 drop-outs). True acupuncture group n=326. Sham acupuncture group n=365. Conventional therapy group n=316.	Parallel design. Randomised. Controlled. Patients were blinded to whether they received real acupuncture or sham acupuncture (however, 16 in the treatment group and 17 in the sham acupuncture group realised what treatment they received). 6 weeks treatment period, follow-up at week 26; no Diclofenac from week 24.	Yes	Treatment group (real acupuncture): Needling at Liangqiu ST-34, Zusanli ST-36, Xiyuan EX-LE5, Yinlingquan SP-9, Xuehai SP-10, Yanglingquan GB-34 with optional 1-4 ashi points and 1-2 of 16 defined distal acupoints (based on TCM differentiation); plus 6 sessions physiotherapy and diclofenac as-needed (no Diclofenac in weeks 24-26). 10 sessions in 6 weeks. Sham acupuncture group: 6 sessions physiotherapy plus shallow needling of non-acupuncture points and Diclofenac as required. Conventional therapy group: 6 sessions of physiotherapy plus Diclofenac 150mg/d or rofecoxib 25 mg/d.	ACR 1995	Yes 515 adverse events reported (179 in the treatment group, 177 in the sham acupuncture group and 159 in the conventional therapy group). The most frequently reported were arthralgia, bone pain, haematoma, back pain and joint lock.	① WOMAC index ② SF-12 physical subscale ③ SF-12 mental subscale ④ Patient global assessment	① ② ④ Real acupuncture group had significantly greater reduction in scores than conventional therapy group. Sham acupuncture group had significantly greater reductions in ①, ②, and ④ compared with conventional therapy group (p <0.0001), but there was no statistical difference between real acupuncture and sham acupuncture groups (p=0.48). ③ No statistical difference amongst three groups.	3
(Wu et al., 2008)	Total participants n=40. Treatment group n=20. Control group n=20. No information of dropouts.	Parallel design. Randomised (randomly divided into two groups) but no information on procedure. No information of blinding. 1 month treatment period, no follow-up.	No information.	Treatment group: Needling on He Ding EX-LE2, Nei Xiyuan EX-LE4, Xiyuan EX-LE5, Yinlingquan SP-9, Xuehai SP-10, Jimen SP-11, Liangqiu ST-34, Zusanli ST-36, Electrostimulation applied at Nei Xiyuan EX-LE4, Xiyuan EX-LE5 and Xuehai SP-10 and Jimen SP-11. 3 sessions weekly for 4 weeks. Control group: Diclofenac 25mg, t.i.d. for 1 month.	ACR 1986	No information	① Lysholm scores (higher score indicated improvement in clinical symptoms and functioning).	Lysholm scores significantly greater after the treatment period in the treatment group compared with the control group (p <0.05). Within groups analysis: significant increase in the Lysholm score at the end of the study period compared with baseline in both groups (p<0.01).	1
(Tao et al., 2003)	Total of 116 knees. Treatment group n=60. Control group n=56. No information of dropouts.	Parallel design. Randomised (randomly divided into two groups) but no information on procedure. No information of blinding. 1 session every other day (10 sessions total).	No information.	Treatment group: Needling at Guanyuan REN-4, Zhongwan REN-12, Quepen ST-12, Huaroumen ST-24, Daheng SP-15 and abdominal extra points, accompanied by warming needling at Dubi ST-35, He Ding EX-LE2, Nei Xi Yan Ex-LE4, Xiyangguan GB-33, Yanglingquan GB-34, plus leg lift exercises. Control group: Warming needling on Dubi ST-35, HeDing EX-LE2, Nei Xi Yan EX-LE 4, Xiyangguan GB-33 and Yanglingquan GB-34 with optional needling of additional acupoints (no exercise).	ACR (no year reported), no exclusion criteria.	No information.	Researchers created own index based on symptoms and knee function.	Within groups analysis: Index score was significantly lower at the end of the treatment period compared with baseline in both groups (lower score represents a more favourable outcome) (p <0.01). Between groups analysis: decrease in index score was significantly greater in the treatment group compared with the control group (p<0.05).	1
(Li et al., 2008)	Total participants n=60 (104 knees). Treatment group n=30 (54 knees). Control group n=30 (50 knees). No information of dropouts.	Parallel design. Randomised (randomly divided into two groups) but no information on randomisation procedure. Single blind study. 1 session everyday (10 sessions in total).	No information.	Treatment group: Needling on Liangqiu ST-34, Dubi ST-35, Zusanli ST-36, Nei Xiyuan EX-LE4, Yinlingquan SP-9, Yanglingquan GB-34 and ashi points, EA applied, plus moxibustion at Shenque REN-8 (moxa box). 1 session everyday for 10 sessions. Control group: Same as treatment group except sham moxibustion applied (sham moxibustion = applied tin foil and asbestos sheet between the skin and the moxa to prevent heat reaching skin).	ACR 1995	No information	① Pain VAS ② Functional score of knee (function)	Within groups analysis: ① ② scores were significantly increased (better clinical functions) after treatment compared with baseline for both groups (p <0.01). Between groups analysis: significantly greater improvements in ① and ② scores in treatment group compared with control group (p<0.01), but no statistically significant difference in pain VAS between groups at 1 month follow-up.	1

Reference	Sample size and no. of drop-outs	Study design	Power calculation	Study intervention / control treatment	Diagnostic criteria	Safety monitoring	Outcome assessment	Results	Jadad score
(Lao et al., 2003)	Total participants n=138. Treatment group n=85. Control group n=53. No information of dropouts.	Parallel design. Randomisation (randomly divided into two groups). No blinding description. 1 month treatment period, assessment at 1 month follow-up.	No information.	Treatment group: Warming needling at Yinlingquan SP-9, Xuehai SP-10, Liangqiu ST-34, Zusanli ST-36, Nei Xiyang EX-LE4, Xiyang EX-LE5 & distal points according to TCM syndrome differentiation, then electro-stimulation (no information of which acupoints used). Also oral herbal medicine (modified <i>Du Huo Ji Sheng Tang</i>), 3 bags per week for 4 weeks. 1 session everyday, 10 sessions total Control group: indomethacin 25mg t.i.d. and Diclofenac 500mg b.i.d. for 1 month.	Criteria of the Medical Committee of Chinese People Liberation Army	No information	① Clinical efficacy (based on ranking of clinical symptoms and joint function, referred to ACR criteria).	① Significant difference between groups after treatment (p <0.01): clinical efficacy higher in the treatment group than the control group.	1
(Li et al., 2006)	Total participants n=120. Warm needling group n=60 (2 drop-outs). Needling group n=60 (4 drop-outs).	Parallel design. Randomised (randomisation table). No information of blinding. Treatment period 15 days overall. No follow-up.	No information	Treatment group: warming needling at Guanyuan REN-4, Jizhong DU-6, Xiyang EX-LE5, Zusanli ST-36, Yanglingquan GB-34. 14 treatments in total (1 treatment per day for 7 days then one day rest, then 1 treatment per day for another 7 days). Control group: Same acupoints as treatment group but needling only. Treatment protocol as above (14 treatments in total).	ACR 1991	No information.	① Lequesne scale. ② clinical efficacy (based on the score change on the Lequesne scale).	① ② Scores of Lequesne scale significantly lower in the treatment group compared to control group after treatment (p <0.05).	3
(Lin et al., 2005)	Total participants n=65. Treatment group n=35. Control group n=30. No information of dropouts.	Parallel design. Randomised (using procedure of drawing straws technique). No information on blinding. Treatment period 40 days. No follow-up.	(33)	Treatment group: Electro-warming needling on Nei Xiyang EX-LE4, Dubei ST-35, Yanglingquan GB-34 and Yinlingquan SP-9. 1 session every other day, 20 sessions in total. Control group: same acupoints but needling only. 1 session every other day, 20 sessions total.	ACR 1986	No information.	① Clinical efficacy (based on ranking of clinical symptoms and joint function; referred to a paper in the Chinese literature)	① Treatment group: significantly greater clinical efficacy following treatment compared with control group (p<0.01).	2

Key: ACR: American College of Rheumatology; WOMAC Western Ontario & McMaster Universities Osteoarthritis Index; EA: electroacupuncture; VAS visual analogue scale.