

Current Research and Clinical Applications

Acupuncture as an Adjunct to Exercise-based Physiotherapy Does not Improve the Pain of Knee Osteoarthritis

Shu-Feng Zhou* PhD

Division of Chinese Medicine, RMIT University

Charlie Changli Xue PhD

Division of Chinese Medicine, RMIT University

Osteoarthritis is the most likely underlying reason for knee pain in 70% of community-dwelling adults aged 50 or more.¹ A recent summary of systematic reviews by Smidt et al.² has concluded that exercise therapy, such as strengthening, stretching, and functional exercises, is effective for patients with knee osteoarthritis compared with no treatment. The chronic use of oral non-steroidal inflammatory drugs is discouraged because of their potential gastrointestinal side effects. A recent randomised, multi-centred and placebo-controlled clinical study by Foster et al.³ indicates that the addition of acupuncture to a course of advice and exercise for knee osteoarthritis delivered by physiotherapists provides no additional improvement in pain. This study recruited 352 adult patients aged 50 or more with a clinical diagnosis of knee osteoarthritis from 37 physiotherapy centres accepting primary care patients referred from general practitioners within the Midlands and Cheshire regions of the United Kingdom between November 2003 and October 2005. The patients were randomised to receive advice and exercise only ($n = 116$), advice and exercise plus true acupuncture ($n = 117$), or advice and exercise plus non-penetrating acupuncture ($n = 119$).

The acupuncture protocol was based on the concept of adequacy of

treatment, survey results, a consensus workshop and recommendations from traditional Chinese protocols.⁴ For each individualised treatment session, six and ten acupuncture points from 16 commonly used local and distal points were selected. Local points were SP9 *Yinglingquan*, SP10 *Xuehai*, ST34 *Liangqiu*, ST35 *Dubi*, ST36 *Zusanli*, Ex-LE5 *Xiyan*, GB34 *Yanglingquan* and trigger points. Distal points included LI4 *Hegu*, TE5 *Waiguan*, SP6 *Sanyinjiao*, LR3 *Taichong*, ST44 *Neiting*, KI3 *Taixi*, BL60 *Kunlun* and GB41 *Zulinqi*. Sterilised disposable steel needles (30×0.3 mm) were used; the depth of insertion was 5–25 mm, depending on the points selected. Needles were manipulated to achieve the Deqi sensation (e.g. aching, warm or tingling sensation) and the therapists recorded the sensations in patients. The protocol permitted 25 to 35 minutes between insertion of the last needle and stopping treatment. The therapists revisited and manipulated the needles as appropriate. If the Deqi sensation was no longer present, the therapists were expected to use stronger manipulation, either rotation or thrust-and-withdraw techniques, to elicit it. Moxibustion, cupping, herbs or electroacupuncture were not allowed. The non-penetrating acupuncture was delivered through needles with a blunt tip. The shaft of these needles collapses into the handle,

creating an illusion of insertion. They meet the recommendations for acceptable controls for acupuncture research.⁵ No attempt was made to elicit the Deqi sensation but participants were told they may experience sensations and to report what they felt. Researchers who collected, entered and analysed data were unaware of treatment allocation. By necessity the physiotherapists delivering the interventions were not blind to allocation.

The primary outcome observed was change in scores on the Western Ontario and McMaster Universities osteoarthritis index pain subscale (Likert 3.0)⁶ at six months. Secondary outcomes included function, pain intensity and unpleasantness of pain at weeks 2 and 6, and months 6 and 12. The researcher recorded the number of patients in each group that achieved a clinically significant response according to criteria from the outcome measures in the Rheumatology and Osteoarthritis Research Society international initiative (OMERACT-OARSI). Side effects of treatment, adverse events and use of co-interventions were also recorded.⁷

The follow-up rate at month 6 was 94% and the baseline pain score was 9.2 ± 3.8 . At six months, the reductions in pain score of patients receiving advice and exercise only, advice and exercise plus

* Correspondent author; e-mail: shufeng.zhou@rmit.edu.au

true acupuncture, and advice and exercise plus non-penetrating acupuncture were 2.28 ± 3.8 , 2.32 ± 3.6 , and 2.53 ± 4.2 , respectively. Mean differences in change scores between advice and exercise alone and each acupuncture group were 0.08 (95% confidence interval = -1.0 to 0.9) for advice and exercise plus true acupuncture and 0.25 (-0.8 to 1.3) for advice and exercise plus non-penetrating acupuncture ($p > 0.05$, by χ^2 test). Similarly, non-significant differences were observed at other follow-up points. However, there were small, statistically significant improvements in pain intensity and unpleasantness at weeks 2 and 6 for true acupuncture and at all follow-up points for non-penetrating acupuncture compared with advice and exercise alone. No adverse events occurred in the advice and exercise group or in the advice and exercise plus non-penetrating acupuncture group. Five adverse events were reported for participants receiving true acupuncture (pain, sleepiness, fainting, nausea and swelling around the treated knee).

CLINICAL RELEVANCE

Patients with knee osteoarthritis prefer non-pharmacological options for pain relief and often choose complementary medicine approaches.⁸ Acupuncture is one of the most popular options. However, clinical trials of acupuncture have been criticised for small sample sizes, inadequate blinding and lack of credible sham controls and long-term follow-up. Systematic reviews have concluded that acupuncture is more effective than placebo for osteoarthritis of the knee.^{4,9-11} However, data on the benefits of adding acupuncture to other treatments, such as physiotherapy, for this population remain scant. In the present study by Smidt et al.,² acupuncture delivered by physiotherapists as part of an integrated package of health care with advice and exercise, for older adults with osteoarthritis of the knee, provided no additional improvement in pain scores compared with advice and exercise alone measured on the Western Ontario and

McMaster Universities osteoarthritis index at six and twelve months. This makes it different in several important aspects from those in previous trials of acupuncture for knee osteoarthritis which compared true acupuncture with sham acupuncture (including off-point needling),¹² ongoing stable medication,¹³ waiting-list controls^{14,15} or education alone.¹⁶

Smidt et al.² used fewer treatment sessions: six acupuncture treatments compared with 10–24 in previous studies.¹²⁻¹⁵ The participants with a clinical diagnosis of knee osteoarthritis in this study are the patients seen in primary care, rather than those with a confirmed radiological diagnosis only, as used in other trials. Importantly, they used the credible acupuncture control of non-penetrating acupuncture at the same points as the true acupuncture rather than minimal depth needling at predefined distant non-acupuncture points. There is much debate within the acupuncture literature about the validity of sham acupuncture,¹⁷ and given that a considerable proportion of participants in the non-penetrating acupuncture group reported sensations fitting the normal descriptions of Deqi, this intervention cannot be considered inert.

However, as the authors have pointed out, a potential limitation of this trial lies in its use of fewer treatment sessions than in previous studies of acupuncture practice, such as those from the United States¹⁶ and Germany.^{15,18} Nevertheless, the acupuncture protocols were developed to fit within current physiotherapy practice in the United Kingdom and the protocols met the minimum criteria for adequacy of acupuncture.

CONCLUSIONS

The current study indicated that true acupuncture did not show any greater therapeutic benefit than a credible control procedure in patients with knee osteoarthritis; acupuncture was safe, with

few, minor adverse events; acupuncture provided no additional improvement in pain scores compared with a course of six sessions of physiotherapy-led advice and exercise. Small benefits in pain intensity and unpleasantness were observed in both acupuncture groups, making it unlikely that this was due to acupuncture needling effects, manual stimulation throughout treatment, and elicitation of the Deqi sensation. Further studies are warranted to investigate the underlying mechanisms of acupuncture, particularly the role of expectancy effects.

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Acupuncture for Persistent Allergic Rhinitis

Chris Zaslowski PhD

University of Technology, Sydney

This Australian study¹ was a randomised, single-blind, sham-controlled (sham needling) trial that investigated the effect of acupuncture on persistent allergic rhinitis (PAR). Eighty participants were randomised to either group and given 16 sessions of either acupuncture or invasive sham acupuncture (nearby non-acupoint sites with shallow needling). The primary acupoints used were LI20 *Yingxiang*, Ex-HN3 *Yintang* (midway between the medial eyebrows) and GB20 *Fengchi*. In addition, Chinese medicine pattern differentiation was used to provide secondary acupoints: LI4 *Hegu* for Lung Qi deficiency, ST36 *Zusanli* for Spleen Qi deficiency and CV6 *Qibai* for Kidney Qi deficiency patterns. Needle manipulation involving rotation (either supplementation or reduction) was applied and repeated at 10 minutes and prior to withdrawal of the needles. The primary outcome measure was self-assessed symptoms scores for nasal obstruction, sneezing, nasal itch and nasal discharge (rhinorrhoea). A secondary outcome measure was use of PAR relief medication.

Following eight weeks (two sessions per week) of treatment, results showed that the verum acupuncture resulted in a statistically significant reduction in the combined mean score of the nasal symptoms compared to the sham treatment at both the completion of the study and at follow-up of 12 weeks when compared to the sham acupuncture group. There was a significant reduction in use of PAR relief medication compared to baseline (within group comparison) at completion and at 12 weeks follow-up. This, however, was not significant when compared to the sham group (between-group comparison). Reported events included minor discomfort at the needling sites for 11 verum and eight sham acupuncture participants.

CLINICAL SUMMARY

Sixteen sessions (two sessions per week) of needling should be administered to the acupoints LI20 *Yingxiang*, Ex-HN3 *Yintang* and GB20 *Fengchi*. Pattern differentiation should be used to determine whether Lung, Spleen or Kidney Qi deficiency patterns are

present and the use of LI4 *Hegu*, ST36 *Zusanli* and CV6 *Qibai* be administered if appropriate. Needle manipulation should be applied three times during the 25-minute treatment session. Patients should expect a decrease in symptoms such as nasal obstruction, sneezing and nasal itch with a greater reduction in nasal discharge (rhinorrhoea). These effects become apparent after eight sessions (at week 4). Patients may need to return for further treatment after a period of three months. Patients should also be informed that there may be some discomfort associated with the needling at some acupoint sites and that they may expect a reduction in the use of their PAR relief medication

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