

Research article critique

by Jill McDowell

Acupuncture for migraine prophylaxis: a randomized controlled trial⁽¹⁾

Ying Li MD PhD, Hui Zheng MD PhD, Claudia M. Witt MD MBA, Stephanie Roll PhD, Shu-guang Yu MD, Jie Yan MD, Guo-jie Sun MD, Ling Zhao MD, Wen-jing Huang MD, Xiao-rong Chang MD, Hong-xing Zhang MD PhD, De-jun Wang MD, Lei Lan MD, Ran Zou MD, Fan-rong Liang MD

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Introduction

Headaches have been described as the most common complaint known to man.⁽²⁾ The prevalence of migraine headaches (with and without aura) have been reported between 5-20% in the world's adult population.^(3, 4) The financial costs of migraines (treatment, medication, time off work) have been estimated at 27 billion Euro per year in Europe alone.⁽³⁾ Understandably researchers are seeking more cost effective treatments of this condition and over 40% of chronic headache patients are now also seeking non-drug related therapy via complementary and alternative medicine means since 2006.⁽⁵⁾

In this study the authors performed a single blinded, randomized controlled trial over 20 months, around 9 hospitals in China. Patients were recruited via hospital clinic, television and newspaper advertisements. Patients received 20 sessions of electro-acupuncture (EA) via either one of three Traditional Chinese Medicine (TCM) based acupuncture point prescriptions or via sham acupuncture points over four weeks. Outcomes were measured by headache diary over the following four weeks. The author's specific research interest was obtaining data on acupuncture point specificity for migraine prophylaxis, with the clinical outcome measure of 'number of days with headaches' from a headache diary. Secondary outcomes were measured with a Migraine Specific Quality of Life Questionnaire (MSQL) at baseline, 4, 8 and 16 weeks.

No significant differences in days with migraine were found between the three TCM groups at the end of the 8th week on headache diary review but mild clinical changes were measured by questionnaire at week 16. Acupuncture was more effective than sham acupuncture as measured by MSQL Questionnaire.

Research methodology

The screening criteria of the trial were comprehensive to ensure a relatively homogeneous group and to reduce the bias of utilizing a volunteer group for trialing. Screening criteria included meeting the International Headache Classifications criteria for migraines with or without aura,⁽³⁾ being aged between 18-65 years of age, with onset of migraines before 50 years of age. Volunteers had to experience acute migraines at least twice a month for over a year for the three months prior to the trial. They also had to agree to taking a headache diary and abstaining from prophylactic migraine medicine for the month before the trial. Patients were excluded if they were unable to give informed consent or they had headaches of organic origin.

International Headache Society Criteria for migraine

5 or more episodic headaches lasting 4-72 hrs with:

Any 2 of:

unilateral
throbbing
worsened by movement
moderate or severe

+

Any 1 of:

nausea or vomiting
photophobia and
phonophobia

2

It seems to be the trend to pre-publish trial designs and protocol before a study is commenced and Ying et al quote themselves in the randomization and intervention section of their article. This has a degree of “hassle factor” for the reader, as a second search is required for another article, in this case:

Li Y, Liang F, Yu S, et al. Randomized controlled trial to treat migraine with acupuncture: design and protocol. *Trials* 2008;9:57.

Needles were alternated from left to right sides per treatment and de qi was elicited in all non-sham cases. Eight needles were retained at classical points for 30 minutes in the treatment groups and 4 needles were retained for 30 minutes at non-acupuncture points in the sham group. EA was applied to all needles – even the sham group with a HANS stimulator, 2/100Hz, 0.1mA to 1.0mA. Current was not run from “point to point” but to a 13mm “auxiliary” needle which pierced the skin 2mm lateral to the true acupuncture or sham point.

Points are included below for interest.

Treatment group 1

Waiguan (TE5), Yanglingquan (GB34), Qiuxu (GB40), Fengchi (GB20) are punctured by filiform needles unilaterally. Waiguan (TE5) is punctured perpendicularly 0.5–1 cun. Yanglingquan (GB34) is punctured perpendicularly 1–1.5 cun. Qiuxu (GB40) is punctured perpendicularly 0.5–0.8 cun. Fengchi (GB20) is punctured obliquely 0.8–1.2 cun, the tip of needle towards the tip of the nose.

Treatment group 2

Luxi (TE19), Sanyangluo (TE8), Xiyangguan (GB33), Diwuhui (GB42) are punctured by filiform needles unilaterally. Luxi (TE19) is punctured transversely 0.3–0.5 cun. Sanyangluo (TE8) is punctured perpendicularly 0.5–1 cun. Xiyangguan (GB33) is punctured perpendicularly 1–1.5 cun. Diwuhui (GB42) is punctured perpendicularly 0.5–0.8 cun.

Treatment group 3

Touwei (ST8), Pianli (LI6), Zusanli (ST36), Chongyang (ST42) are punctured by filiform needles unilaterally. Touwei (ST8) is punctured transversely 0.5–1.0 cun. Pianli (LI6) is punctured perpendicularly 0.3–0.5 cun. Zusanli (ST36) is punctured perpendicularly 1–2 cun. Chongyang (ST42) is punctured perpendicularly 0.3–0.5 cun, avoid needling the artery.

Control group

In the medial arm on the anterior border of the insertion of the deltoid muscle at the junction of deltoid and biceps muscles [12], is punctured perpendicularly 0.5–1 cun. The edge of tibia 1 to 2 cm lateral to the Zusanli (ST36) horizontally [13], is punctured perpendicularly 0.5–1

cun. Half between the tip of the elbow and the axilla [14], is punctured perpendicularly 0.5–1 cun. Ulnar side, half between epicondylus medialis of the humerus and ulnar side of the wrist [14], is punctured perpendicularly 0.5–1 cun. All non-acupoints are punctured by filiform needles unilaterally.

Statistical analysis

One hundred and twenty patients were allocated to the four trial groups (480 in total) to allow for dropouts and a 90% power of statistical significance of a reduction in headaches of 1.6 days migraines per month. My question is whether 1.6 headache days is significant for people averaging 5.5-6.3 days of migraines per month? Even in the best case scenario (and without spectacularly complicated math) reducing someone from 5.5 to 3.9 days per month is only an improvement of 29%. Doesn't even a placebo have a 34% chance of success? I lacked the motivation to investigate *p* values any further after this!

On the PEDro scale 7 of 11 criterion were satisfied in this trial, however in this case it did not guarantee that there was evidence that the treatment described was clinically useful.

Confounding issues

A key issue for me is the trial's use of sham acupuncture as a control. Sham acupuncture is not an inert intervention. The skin is pierced; the mediators of healing, the humoral and immune systems respond, and DNIC pain pathways are activated. It has also been proven that a positive expectation of treatment can positively affect a patient's neurochemistry and therefore overall response.⁽⁶⁾ The authors conclusion is confusing - that the influence of acupuncture for migraine prophylaxis is only "minor" is based on the treatment groups outcome at 16 weeks not in comparison to sham acupuncture as the research design would expect the reader to surmise. This reduces the clarity of the trial. One would assume the practitioner is not currently in a quandary deciding on whether to offer sham or true acupuncture at their practice! The use of a "no treatment" control would be more valuable – perhaps to prove that acupuncture has greater than "minor" effect on migraine prophylaxis compared to no treatment at all.

Interestingly when randomizing and obtaining informed consent the patients were told they would receive acupuncture based on either one of three TCM methods or "modern acupuncture theory". I think calling sham acupuncture "modern acupuncture theory" is stretching the truth somewhat! The authors argued that electro-acupuncture is common in China and the use on sham acupuncture points was done in order to "reduce the chance of unblinding".

No references were cited to support the use of "auxiliary" needles as an electrotherapy technique and no mention of polarity was mentioned so the technique may not be fully reproducible from the protocol published. Previous reading of Han's work would have suggested the use of a spinal segmental pairing of electrodes. The use of a non-validated technique lessens the readers ability to draw conclusions from the trial.

Whether this treatment could be applicable to the New Zealand population is debatable. Twenty treatments of EA over 4 weeks would possibly challenge even the staunchest of regular "willing" acupuncture patients and current private consultation fees (even at my modest practice rate) would cost over \$980. With only "clinically minor" effects observed it would also be a 'hard sell' if the practitioner can only extrapolate potential improvements to their patient over a four to eight week window post treatment. The trial would definitely be strengthened by longer-term follow up than 8 weeks.

Comparisons are made to only two other studies in the discussion, which is disappointingly superficial. The author's conclusion is also over simplistic. Their research did not prove that "acupuncture appeared to have a

clinically minor effect for migraine". It proved that a unique and as yet to be validated EA method appeared to have a clinically minor effect for migraine at 8 weeks post stimulation as established by a self reporting questionnaire. The authors do however acknowledge the limitations of their study, primarily the short follow up period, self reporting, non blinding of physicians performing the acupuncture, non specific effects of the intervention and difficulty with generalization to the western population (due to the high frequency of treatment and a small number of acupuncture points used). I would challenge the "small" number of needles used – the addition of 8 auxiliary needles for the TCM groups would bring the total up to 16, high numbers for a western population.

Summary

Ying et al. admirably tried a large-scale trial to find the best EA point selection for migraine prophylaxis but failed to deliver clinical relevance for the acupuncture practitioner in my opinion. This is surprising with Li's previous experience in research into the management of acute migraine attacks⁽⁷⁾ and Witt's extensive research portfolio including reviews on cost effectiveness of acupuncture interventions for headache.⁽⁸⁻¹⁵⁾ The results of this trial should be considered with caution and may not apply to New Zealand Practitioners.

Jillian McDowell
PAANZ tutor

MNZSP, Dip. Phys., Reg. Physio Acup., Post Grad. Cert. Sports Med., Dip. M.T., Cred. M.D.T., Cred. Mulligan Concept, MNZCP (Acupuncture), MNZCP (Manipulation), MPhty, MCTA

Prohealth Physiotherapy
124 Kelvin Street
Invercargill
New Zealand
Phone 0064 3 2189052
Fax 0064 3 2141950
www.prohealthphysio.co.nz

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