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## **As Acupressure Decreases Pain, Acupuncture May Improve Some Aspects of Quality of Life for women with Primary Dysmenorrhea: A Systematic Review with Meta-Analysis**

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**Conflict of Interest:** None declared.

### **ABSTRACT**

Primary dysmenorrhea is the most common gynecological symptom reported by women and constitutes a high health, social and economic burden. Chemotherapies with their attendant side effects have not yielded satisfactory outcomes. Alternative non-pharmacological interventions, including acupuncture and acupressure, have been advocated, but evidence regarding their beneficial effect is inconclusive. This study sought to obtain evidence for the effectiveness of acupuncture and acupressure interventions. Twelve electronic databases were searched by using the menstrual pain intensity and quality of life as primary and secondary outcomes, respectively, with the PEDro guideline for quality appraisal. Data unsuitable for a meta-analysis were reported as descriptive data. The search yielded 38 citations, from which 8 studies were systematically reviewed, 4 of the 8 being eligible for meta-analysis. The systematic review showed moderate methodological quality with a mean of 6.1 out of 10 on the PEDro quality scale. Acupressure showed evidence of pain relief while acupuncture improved both the mental and the physical components of quality of life. In conclusion, physiotherapists should consider using acupuncture and acupressure to treat primary dysmenorrhea, but a need exists for higher quality, randomized, blinded, sham-controlled trials with adequate sample sizes to establish clearly the effects of these modalities.

**KEYWORDS**

acupuncture;

Acupressure;

Acupoints;

menstrual pain;

quality of life

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## 1. Background of study

Dysmenorrhea constitutes a high health, social and economic burden. Primary dysmenorrhea defined as painful menstruation without pelvic pathology usually develops 1 or 2 years after menarche, mainly afflicting young women, but may persist in females as old as 40 years of age [1]. The incidence of primary dysmenorrhea is as high as 80% for women in their teens and early 20s, with half of these women experiencing loss of time from school or work [2-5]. The condition is so common that many women do not report it during medical reviews [6, 7]. Absenteeism from school or work at least once due to the symptoms of primary dysmenorrhea has been reported to occur in one-third to one-half of all women, with 5% to 14% of the absenteeism occurring frequently [8]. Dysmenorrhea is a common cause of reduced quality of life in women [9, 10].

Many women with primary dysmenorrhea do not respond to the primary choice of therapy, nonsteroidal anti-inflammatory drugs (NSAIDs) or oral contraceptives, with some showing contraindications. Consequently, alternative non-pharmacological interventions, including acupressure and acupuncture, have been advocated as a major non-medical intervention for the relief of pain [11, 12]. Previous studies have indicated that acupressure at the SP6 point may be considered a noninvasive method for alleviating discomfort associated with primary dysmenorrhea, with its effects persisting for as long as two hours after treatment [13, 14]. Acupressure is thought to stimulate the regulatory systems and to activate a variety of endocrine and neurological mechanisms, which, in turn, stimulate a variety of physiological functions toward homeostasis [15]. Also, some evidence indicates that acupuncture is effective in treating primary dysmenorrhea [16-21], but that evidence was largely based on one small, randomized,

controlled trial (RCT). Two more recent sham acupuncture RCTs failed to show evidence of pain reduction [22, 23].

Although a few reviews of acupuncture and/or acupressure for the treatment of primary dysmenorrhea are currently available, those reviews have several limitations. One [24] included only one trial of acupuncture, and another [25] included two acupuncture and two acupressure trials. A third systematic review [26] evaluated acupuncture-related therapies, including moxibustion and acupressure treatment. Additionally, none of those reviews reported data on quality of life, which is a very important factor for women with primary dysmenorrhea.

The evidence regarding the main issue of how the different interventions are beneficial to women suffering from primary dysmenorrhea is conflicting. One of the major challenges for stakeholders in the subject of primary dysmenorrhea with respect to acupuncture and acupuncture therapies has been the subjective nature of the symptoms' presentations coupled with the heterogeneity of the different protocols and acupoints utilized. As a result, evidence of pain relieve has been somewhat contradictory at best, with much of the research being of low methodological quality. Therefore, a systematic review with a meta-analysis to identify robust evidence from numerous trials is warranted so that quality evidence can be put forward for the use or not of these modalities for pain relief and quality-of-life improvement in individuals with primary dysmenorrheal.

## **2. Methods and methods**

This research is a systematic review of the literature with a meta-analysis. A systematic review of the literature was conducted to identify the outcomes and the quality of various research trials on acupuncture and acupressure interventions for a reduction of pain and an improvement in the

quality of life for females suffering from primary dysmenorrhea pain. This study was approved by the Health Research and Ethics Committee, University of Nigeria Teaching Hospital, Ituku Ozalla Enugu, Nigeria.

A comprehensive search was conducted online to identify all relevant publications on acupuncture and acupressure interventions for the management of pain and quality of life for females with primary dysmenorrhea. Allied health, health-related, health science and medical databases, including Ovid Medline, Cochrane library, Science Direct, PubMed, Scopus, PEDro, Web of Science, CINAHL, MANTIS, SCIENCE DIRECT, SCOPUS, PsycINFO, Ovid Medline, AMED and EMBASE, were used. The search was performed by using the following key indexing terms independently: acupuncture, acupressure, acupoints, physiotherapy, primary dysmenorrhea, quality of life, and physical intervention. Also, the search strategy described in Ref. 27 was employed. A Google search and a hand search of the reference lists of existing articles was conducted to find papers that did not appear in the main databases. The search covered literature from 1970 to April 2014.

Studies with their main focus on the efficacy, effectiveness, or effect of acupuncture and acupressure interventions using different acupoints for the management of primary dysmenorrhea were included, as were studies on the quality of life of females with primary dysmenorrhea. Only studies utilizing human females of reproductive age were included. Studies were limited to peer-reviewed journals and conference proceedings. All study abstracts meeting these broad criteria were initially included. When the decision could not be made based on the title and the abstract of the paper, the authors were contacted for any missing data, and the full text of the paper was included for further decision. Case reports and clinical opinions were excluded. The decision to include data based on the inclusion criteria was independently made

by the authors. When a difference of opinion occurred, consensus was reached on inclusion or exclusion by discussion and reflection. A third party was called upon in the event of disagreement. Selection of trials was also based on the criteria described in the similar systematic review in Ref. 28.

The following inclusion criteria determine eligibility for inclusion in this review: primary dysmenorrhea (pain affecting daily activity or with a high baseline score  $\geq 3$  on the visual analogue scale (VAS) or an equivalent tool), primary dysmenorrhea in the majority ( $> 50\%$ ) of menstrual cycles, primary dysmenorrhea for at least one day of menses, subjects were of reproductive age, and quality of life was an outcome measure. Trials that met any of the following criteria were not included in the review: irregular or infrequent menstrual cycles (usually outside of the typical range of 21 to 35 days) and use of an intra-uterine contraceptive device (IUD) or oral contraceptive pills (OCP).

The first author trained the second author who acted as the principal reviewer. The first author acted as the second reviewer to extract data from the included papers. Training sections included clarification of all data items and required elements of the quality appraisal tool. Standardization of the procedure was required for consistency in the method of data extraction used by the reviewers. To this end, before data extraction began, a trial was conducted on two similar, but unrelated, papers, and the result was discussed. A third party – a senior faculty member – was consulted when the first and the second author disagreed. The senior faculty member's opinion stimulated further discussion to arrive at a consensus. This data extraction method (double data extraction) has been shown to have a lower rate of error than simple data extraction [29]. Pooling of data was undertaken where adequate homogeneity of results existed. Discrepancies were resolved by discussion. For each included trial, data were extracted regarding



the participants (age range, eligibility criteria), the nature of the interventions, and the outcomes specified above. The data extraction form contained descriptive characteristics (see Table 1) and a quality appraisal tool. Data were extracted based on the elements of this form, which were related to the research questions and the aims of this systematic review.

The quality of a paper was assessed by using the PEDro quality appraisal tool. Answers to the quality appraisal items were defined as Yes, No, Not applicable or Unclear. A score of one was given for each yes answer, and a score of zero was given for each no, unclear, or not applicable (N/A) answer. The overall score for each study was reported as a tally of all yes answers out of 10. Scores of individual items from the critical appraisal tool were added to present a total score.

[Insert Table 1 about here]

### 3. Results

The initial searches identified a number of potentially relevant papers. The flow of papers through the process of assessment of eligibility is approximately represented, along with the reasons for exclusion at each stage of the process, in Fig. 1. When data were not reported in a format that allowed inclusion in the review, the authors of the study were contacted. Where data could not be included in a suitable format, the paper was excluded.

[Insert Fig. 1 about here]

In total, the 8 included studies contributed data on 1221 participants. However, only 4 trials (contributing data on participants) met the criteria for inclusion in the meta-analysis. The quality appraisal of the included trials, including trials with research from 1985 to April 2014, is presented in Tables 1 and 2 while the level/grade of evidence for each outcome is presented in Table 3. The methodological quality of the included trials ranged from low to high, with a mean

PEDro score of 6.1 out of 10. Four trials were methodologically high-quality trials with scores  $\geq$  7. The individual PEDro items satisfied by almost all the trials were random allocation, groups similar at baseline, concealed allocation, < 15% dropout rate, and reports of between group differences.

[Insert Tables 2 and 3 about here]

The completeness of outcome data for each outcome was adequately described in all the studies included in the meta-analysis. No other limitations, such as stopping early or use of invalidated outcome measures, were identified in any of the included studies. Summaries of the findings and evidence profiles are presented in Tables 1 to 3. The overall grades of the evidence obtained for the outcomes of both acupressure and acupuncture trials were above 'moderate'.

The sample sizes contributed by the included trials ranged from 35 to 649. The mean ages of the participants in the included trials ranged from 14 to 40 years. Three trials compared an acupuncture group to a control group [13, 30, 31]; one trial compared the effects of acupressure at different acupoints [32]; one trial compared the effect of acupressure at two acupoints to a control [33]; one trial compared the relative efficacies of acupressure, ibuprofen and a placebo [10]; and one trial compared the effect of acupressure to that of nitric oxide [34].

All trials included the measured pain intensity/severity as an outcome measure, with five trials using the VAS, two trials using the numeric pain rating scale, three trials using McGill's questionnaire, one trial using a verbal multidimensional scoring system, and one trial using a menstrual distress questionnaire. Two trials also assessed the quality of life of the participants by using the short form of the Health Related Quality of Life questionnaire (HR-QoL, SF-36).

Of the eight studies included in the systematic review, four were excluded from the meta-analysis. Those 4 studies [32-34] were excluded because they did not meet the inclusion criteria for the meta-analysis, which are randomized trials with control or placebo groups, pain outcome measures convertible to the VAS, and quality of life outcome measures. Two authors [35-36] did not respond to emails sent to them for clarification, so their studies were not included in either the systematic review [35] or the meta-analysis [36].

Four trials on acupressure and four studies on acupuncture were included in the descriptive characteristics presented in Tables 1 and 2, respectively. A total of 1221 participants with ages ranging 14 to 40 years were recorded. The outcome measures included were the score on the VAS, answers on the Health Related Quality of Life questionnaire and on the short form of McGill's questionnaire, and the scores on the verbal multidimensional scale and the numeric rating scale. Data pooled from two trials compared the effect of acupuncture to sham acupuncture, and the meta-analysis of the weighted mean difference showed no statistical significance, as presented in Fig. 2. Two trials, as shown in Fig. 3, compared the analgesic effect of acupressure with sham acupressure as a control. The trials were methodologically high quality with high-grade evidence. The results showed statistical significance.

[Insert Figs. 2 and 3 about here]

Figure 4 presents the results of two trials that compared the effect of acupuncture on the physical component of the quality of life. The results indicated that acupuncture significantly improved the physical component of quality of life of women with primary dysmenorrhea. Figure 5 shows the meta-analysis of the two trials that compared the effect of acupuncture on the mental component of the quality of life of women with primary dysmenorrhea. The results

indicated that acupuncture significantly improved the mental component of the quality of life (favored the control group B).

[Insert Figs 4 and 5 about here]

#### 4. Discussion

This systematic review was able to identify and review several studies on acupressure and acupuncture with an aim to find possible statistically significant reductions in pain severity and other menstrual symptoms. Currently, available data suggest that most of the trials on acupuncture and acupressure report fewer side effects, and acupuncture and acupressure are preferred to pharmacological treatment or herbal medicine for the reduction of pain associated with primary dysmenorrhea.

The meta-analysis of acupuncture and acupressure was done differently with sham-controlled trials. Comparisons of the results of the meta-analysis for the different interventions revealed an interesting pattern with acupressure having more statistical significance than acupuncture. Results from the meta-analysis of acupuncture versus sham-control indicated no statistical significance. This interesting pattern implies that acupuncture can be used to treat primary dysmenorrhea. Although one study recorded a significant positive effect of acupuncture, that effect was only on the quality of life. This suggests that the effect of acupuncture may not always be attributable to relief of pain due to primary dysmenorrhea, but may be attributable to some of other symptoms of primary dysmenorrhea, including improvement in the physical and the mental components of the quality of life. This pattern of results is in contrast to that of the systematic review by Cho *et al.* [28]. Their study indicated that acupuncture was associated with a significant reduction in pain.

The relevance of the different acupoints used in the studies is difficult to interpret. The same results for acupuncture trials were obtained when different acupoints were used. Smith *et al.* [7] used a total of seven acupoints, but the inability of Witt *et al.* [30] to control the use of additional conventional treatments even with high follow-up rates is questionable based on the results of the study. In all, generally, acupuncture is thought to alleviate pain, though not menstrual pain, in all cases, but the issue of its being cost effective compared to other interventions is still questionable because only two studies in our review reported an improve quality of life.

This study had several limitations. The studies satisfying the inclusion criteria were clinically and methodologically heterogeneous with respect to the severity of pain, the participants, the different types and techniques of intervention used in similar trials, the control groups employed, and the outcomes examined. The follow-up length and the timing of outcome assessment also varied, as did the treatment schedule and frequency. In addition, a possible publication bias cannot be definitely excluded for this review as the majority of the trials reported were those readily available from journals and authors; also, the majority of those included indicated positive effects of the interventions used to treat primary dysmenorrhea. Another possible limitation was the paucity of data on interventions with similar techniques. This made drawing definite conclusions on interventions involving few similar trials impossible.

#### **4. Conclusion**

This study involved three reviewers who dependently and independently performed study selection, quality assessment, and data extraction and management. Several interventions indicated statistical significance. Insights into the efficacies of the interventions were identified in correlation to themselves and with one another. The systematic review highlighted promising evidence in the form of studies done to establish the effectiveness of acupuncture and

acupressure in the management of primary dysmenorrhea. However, the results were limited and had methodological flaws. The review and the meta-analysis indicated that acupressure significantly reduced the pain associated with primary dysmenorrhea and that acupuncture improved both the physical and the mental components of quality of life. The magnitude of these effects may or may not be clinically worthwhile, but as the costs and the risks of these interventions is low, these results may be clinically useful.

## **5. Recommendation**

Further research is merited as the quality of the trials and the reporting of the trial methodologies reviewed in this study were on average moderate; further higher-quality trials are needed to assess the effectiveness of acupuncture and acupressure for the management of menstrual pain. If the quality of the trial design, the level of performance, and the degree of reporting of clinical trials are to be improved, future researchers should follow the basic guidelines for reporting clinical trials, such as the PEDro guideline, which provides specific guidelines for clinical trials.

Further research should also be patient blind and assessor blind against a sham control intervention in order to allow for the placebo effect. The research should also include a sufficient sample size and employ validated outcome measures of clinical effectiveness. The quality of life of the participants should also be included as an outcome of interest in future research.

For future systematic reviews or meta-analyses of this sort, authors and journals should make studies available for researchers to work with, especially when researchers cannot gain access to the papers for obvious reasons. Authors should also establish correspondence with researchers so that more works can be included in reviews of this sort.

## Acknowledgement

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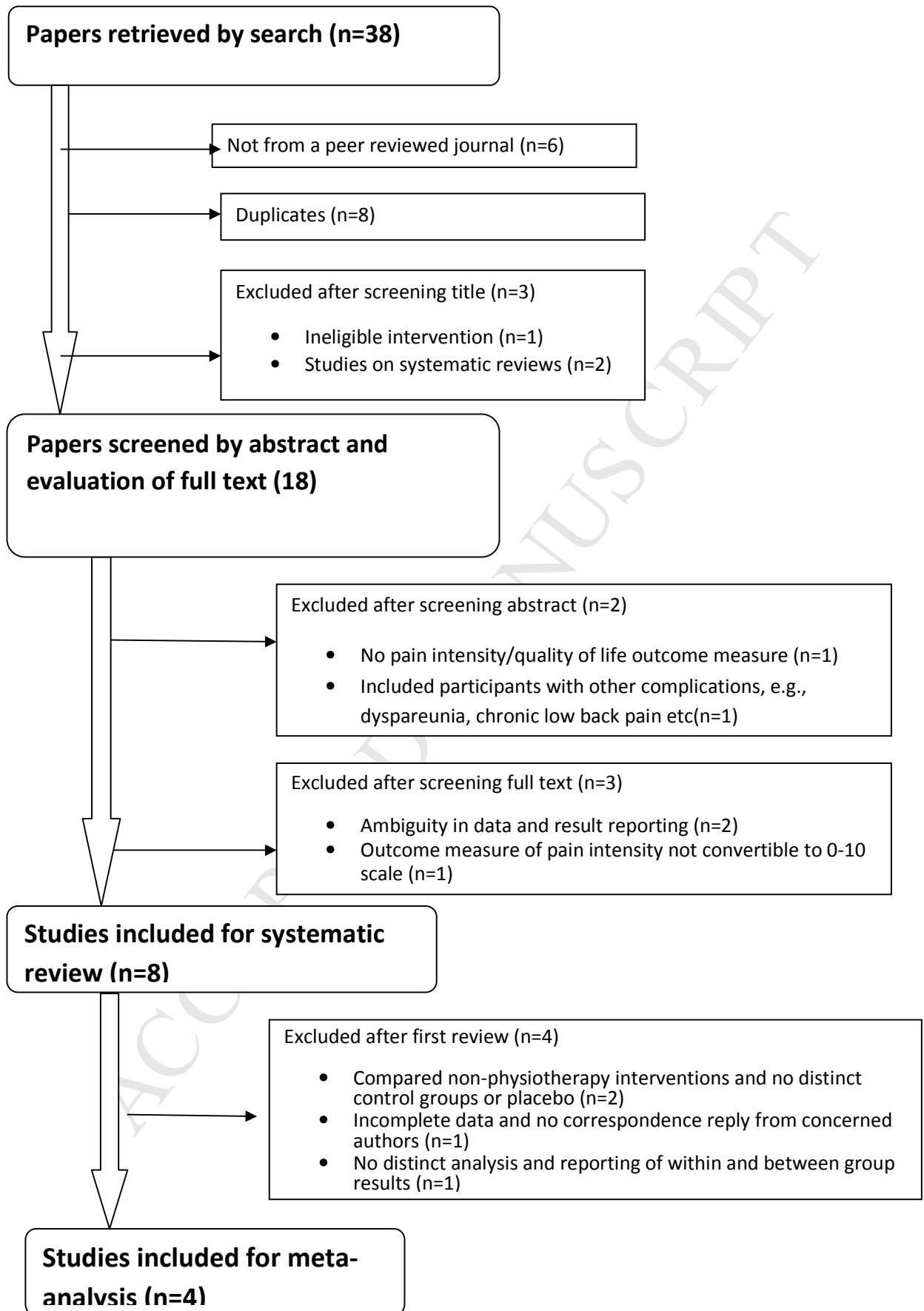
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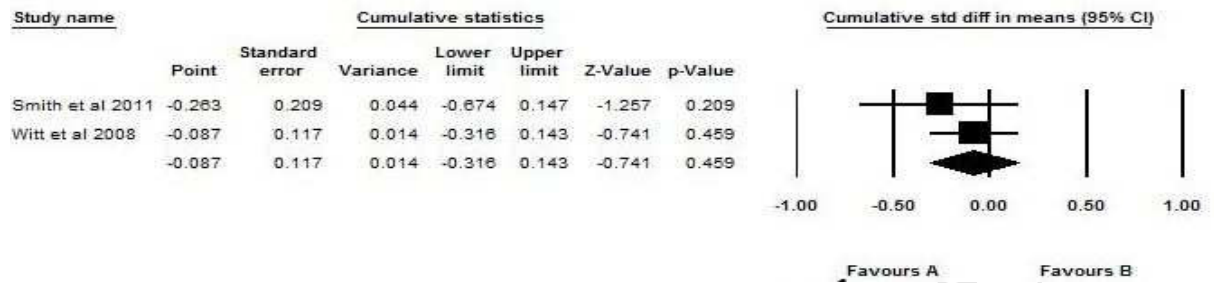


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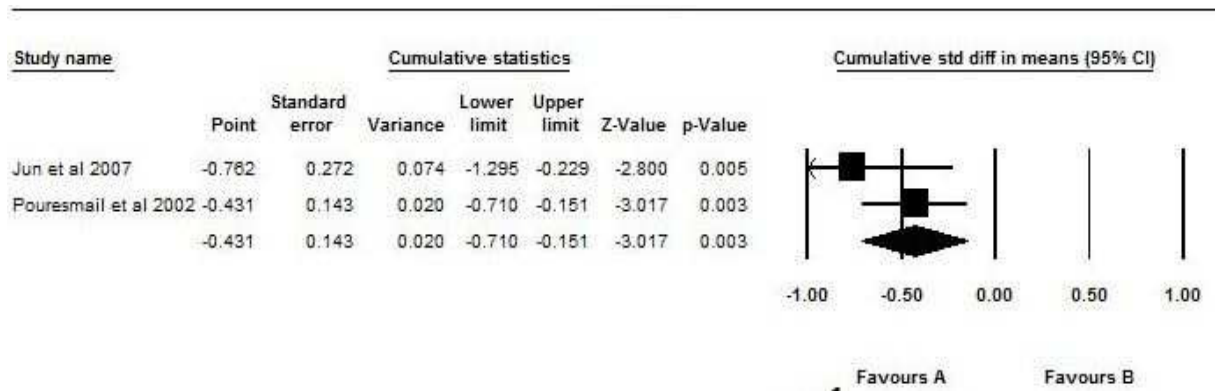


**Figure 1** Flow of studies through the review.

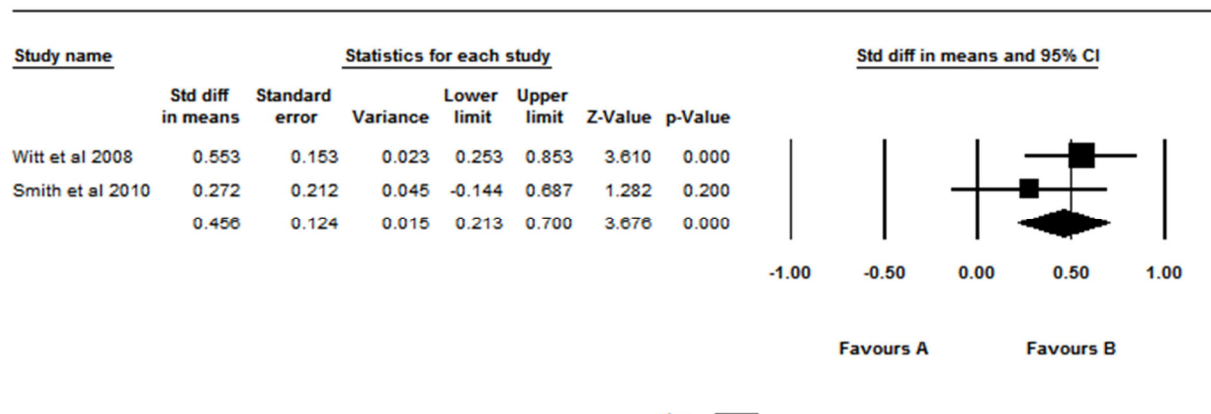
## Meta-analysis of the effects of intervention using different modalities



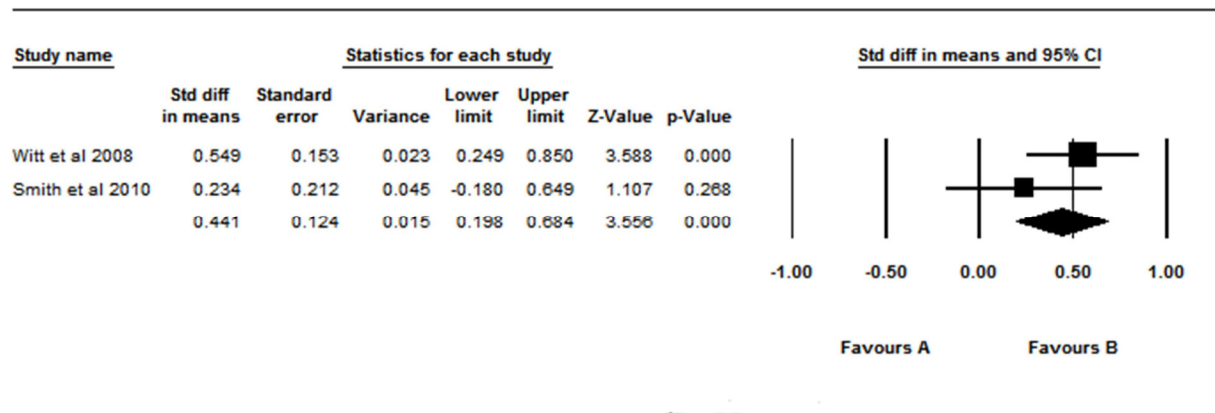
**Figure 2** Forest plot of weighted mean differences (95% CI) for pain intensity for acupuncture versus sham.



**Figure 3** Forest plot of weighted mean differences (95% CI) for pain severity for acupressure versus sham.



**Figure 4** Forest plot of weighted mean differences (95% CI) for the physical component of the quality of life for acupuncture versus sham.



**Figure 5** Forest plot of the weighted mean differences (95% CI) for the mental component of the quality of life for acupuncture versus sham.

**Table 1 Descriptive characteristics of studies on acupressure.**

Study	Design	Participants' Characteristics	Intervention	Control	Outcome Measures
1) Gharloghi <i>et al.</i> 2012	RCT	n = 42 (Exp = 21 and Con = 21) Age = 18 – 30 yrs McGill scale (Moderate to severe)	Group I -> Acupressure at SP6 Group II -> Acupressure at SP8 parts	No control group	Pain severity: McGill scale (0-10), systemic symptoms: VMSS (0-3) (Verbal multidimensional scoring system)
2) Wang <i>et al.</i> 2009	RCT	n = 71 (Exp = 36 and Con = 35) Age = 18 - 28 yrs (Exp = 22.3 (2.4) and Con = 22.6 (2.6)) DQ = Exp = 609 (1.11) Con = 6.29 (1.75) No. Exp = 0.353 (0.12) Con = 0.340 (0.16)	Auricular acupressure by seed pressure method on liver (Co12), kidney (C10) and endocrine (CO18) acupoints.	Plain adhesive patch with no seed at some acupoints	Pain" MDQs (short form) (1-100), blood levels of nitric oxide by using ELISA kit & reader
3) Jun <i>et al.</i> 2007	Pre & Post-test design	n = 58 (Exp = 30 and con = 28) Age = 22 yrs (2.65) VAS: Exp = 5.30± 1.31 Con = 5.14 ± 0.84 Skin temp CV 2 acupoint: Exp. 34.09± 0.93 Con. 34.03±0.76 CV 12 acupoint: Exp. 33.81±1.30 Con. 33.86±0.83 Exp = 34	Acupressure at SP6 site of both legs with strong vertical pressure applied	Acupressure at some sites without any pressure applied	Pain: VAS (0-10), skin temperature, strip skin temperature
4) Pouresmail <i>et al.</i> 2002	RCT	n = 216 Age = 14 – 18 yrs VAS: Acupressure group -> 6.11 ± 1.509 Ibuprofen group - > 6.009 ± 1.65 Placebo group - > 6.4375 ± 1.527	Group I -> Acupressure Group II -> Ibuprofen (9 tablets (400 mg) for 3 days starting 24 hrs before the onset of the menstrual period		Severity of pain, VAS (0-10)

Exp = Experimental group; Con = Control group.

**Table 2** Descriptive characteristics of studies on acupuncture.

Study	Design	Participants Characteristics	Intervention	Control	Outcome Measures
1) Smith <i>et al.</i> 2011	RCT	n =90 (Exp = 46 and Con = 44) Age = 14 – 25 yrs (Exp = 19.5 (2.9) and Con = 18.9 (3.2)) VAS $\geq$ 6	Acupuncture (De qi Sensation)	Sham acupuncture	Pair Intensity VAS (0-10) McGill questionnaire Duration of pain (Hrs)
2) Kiran <i>et al.</i> 2013	RCT	n = 35 (Group I = 24 and Group II = 14) Age: 15 – 40 yrs (Group I > 21.0 $\pm$ 5.1, Group II > 20.6 $\pm$ 2.4) VAS: Group I > 23.0 $\pm$ 11.9 and Group II > 24.6 $\pm$ 10.6 Exp = 30 Con = 30	Group I - NSAID (naproxen sodium, 550 mg) Group II - acupuncture treatment	No control group	VAS (0-10)
3) Shi <i>et al.</i> 2014	RCT	n = 60 (Sp6 acupuncture group = 23, GB 39 control group = 26, non acupoint control group = 11) Duration of pain = 83.2 $\pm$ 40.7 months VAS = 64.8 $\pm$ 16.8	Group I - SP6 acupuncture	Group II - GB39 acupuncture Group II - non-acupuncture (sham)	Pain intensity VAS (0-10))
4) Witt <i>et al.</i> 2008	Quasi-RCT	n = 649 (acupuncture = 101, control = 100, non-randomized acupuncture = 448) age = 36.1 $\pm$ 7.1 yrs no baseline scores	Group I - immediate acupuncture Rx Group II (non-randomized) also received immediate treatment.	Control group – delayed acupuncture treatment	Pain intensity NRS (0-10) Quality of life Cost effectiveness

Exp = Experimental group; Con = Control group.



**Table 3** PEDro quality appraisal of studies on acupuncture and acupressure.

Study Name of Author	Random Allocation	Concealed Allocation	Groups Similar at Baseline	Participant Blinding	Therapist Blinding	Assessor Blinding	<15% Dropout	Intention to Treat Analysis	Between Group Difference	Point Estimate & Variability Reported	Total 0-10
1) Smith <i>et al.</i> 2011	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	9
2) Gharloghi <i>et al.</i> 2012	Y	N	Y	N	N	N	N	N	Y	Y	5
3) Wang <i>et al.</i> 2009	Y	Y	Y	N	Y	Y	Y	N	Y	N	7
4) Jun <i>et al.</i> 2007	N	Y	Y	N	N	Y	Y	Y	Y	Y	7
5) Wu <i>et al.</i> 2012											
6) Kiran <i>et al.</i> 2013	Y	N	Y	N	N	N	Y	N	Y	N	4
7) Shi <i>et al.</i> 2014	Y	N	Y	N	Y	Y	Y	N	Y	Y	7
9) Witt <i>et al.</i> 2008	Y	N	N	N	N	N	Y	Y	Y	Y	5
10) Pouresmail <i>et al.</i> 2002	Y	Y	Y	N	N	N	Y	N	Y	N	5