

## Meta Analysis the Effectiveness of Acupuncture vs Sham Acupuncture on Low Back Pain

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### ABSTRACT

**Background:** Low Back Pain is pain, aches and pains that occur in the lower back area and can be local pain or radicular pain. Acupuncture is a non-pharmacological therapy that can be used as an option to treat low back pain. This study aims to examine the effectiveness of acupuncture and sham acupuncture on reducing pain in cases of low back pain.

**Subjects and Method:** Meta-analysis was carried out with PICO as follows: The population in this study were patients with low back pain with an age range of 20-95 years. Intervention in the form of acupuncture therapy. Comparison in the form of sham acupuncture. Outcome in the form of pain scale. A meta-analysis study was applied to this study with electronic data sources Clinical Key, Google Scholar, MEDLINE/PubMed, Science Direct, Scopus, and Springer. The article used is a full-text article with a Randomized Control Trial (RCT) study design. There are 9 articles used in this study. Articles were analyzed using the Review Manager 5.3 application. The results of this study aim to determine the Standardized Mean difference (SMD) and the heterogeneity of the research sample.

**Results:** The heterogeneity in the results of this study was  $I^2=79\%$ ;  $p < 0.001$ , so it was analyzed by Random Effects Model (REM). Acupuncture was more effective in reducing pain than sham/placebo acupuncture, with a statistical significance of (SMD -0.59; 95% CI = -0.88 to -0.30;  $p < 0.001$ ).

**Conclusion:** Acupuncture is more effective than sham/placebo acupuncture in reducing pain scale in cases of low back pain.

**Keywords:** Acupuncture, Sham Acupuncture, Low Back Pain

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### Cite this as:

Nugraha NA, Murti B, Prasetya H (2021). Meta Analysis the Effectiveness of Acupuncture vs Sham Acupuncture on Low Back Pain. *Indones J Med.* 06(03): 336-346. <https://doi.org/10.26911/theijmed.2021.06.03.11>.



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### BACKGROUND

Nowadays health problems are increasingly complex, especially in the case of pain. So if the right steps or treatment are not taken immediately, it will have an impact on the slowing down of the healing process. Pain is a sensory and emotional experience that does not unpleasant consequences of actual

or potential tissue damage. Pain arises as a form of sensory response after receiving a painful stimulus. Pain can be caused by tissue damage in the body as a result of an injury, accident, or medical action such as surgery (Ratnasari, 2013).

Low back pain is pain that is often

experienced by students, workers, to professional athlete. Low Back Pain can be caused by various musculoskeletal diseases, psychological disorders and wrong mobilization (Duthey, 2013). Low Back Pain is pain, aches and pains that occur in the lower waist area and can be local pain or radicular pain (Meliala, 2003). The pain felt by someone who has low back pain occurs in the lumbosacral area, can also be referred to other areas (Sulaeman and Tresna, 2015). Low back pain generally involves the muscles, nerves, and spine. In addition, the movement of the spine itself is very complex and the structure will produce a unique pattern of pain.

Low Back Pain can have an impact on decreasing human productivity significantly, 50-80% causing the inability of workers to work optimally so that they are not productive. The Global Burden of Disease Study estimates that Low Back Pain is in the top 10 diseases included in Disability-adjusted life years (DALY) in the world (Hurwitz et al, 2018).

The prevalence of age-standardized low back pain globally was 8.20% (95% UI: 7.31-9.10%) in 1990, and this decreased to 7.50% (95% UI: 6.75-8.27%) in 2017. The prevalence is higher in women compared to men. For women, it was 8.86% (95% UI: 7.90-9.82%) in 1990 and 8.01% (95% UI: 7.22-8.84%) in 2017, while for men the prevalence was 7.47% (95% UI: 6.67-8.31%) in 1990 and 6.94% (95% UI: 6.24-7.67%) in 2017. The estimated number of sufferers of low back pain was 377.5 million in 1990, and increased to 577.0 million in 2017, due to increased sizeable population globally from 1990 to 2017 (Wu et al, 2017).

Management of low back pain needs to be done to reduce pain. Management can be done by pharmacological and non-pharmacological. Pharmacological management is

by administering analgesic drugs. Meanwhile, non-pharmacological pain management is very diverse, including hypnosis, physiotherapy, massage, and acupuncture (Andarmoyo, 2013).

Acupuncture is a non-pharmacological therapy that can reduce the degree of low back pain. Acupuncture is widely used in many countries on the Asian continent and over time it is increasingly being used in Western countries (Shergis et al., 2016). Acupuncture is a medical therapy by inserting a special needle (filiform needle) at acupuncture points that have been mapped on the human body. Needle insertion at acupuncture points has a local effect through the axon (nerve fiber), releasing neuropeptides and increasing blood flow at the puncture site (White, 2017).

Acupuncture can be used for therapy for low back pain, besides that acupuncture is quite safe if it is done by a professionally trained person because it has few side effects and can reduce pain (Carolyn, 2014). Acupuncture has been widely used as a method for treating low back pain. According to the literature, it is concluded that acupuncture has an effect on reducing pain and improving functional in low back pain (Shin et al., 2011). Based on the research of Fuentes et al., 2020 confirmed the effectiveness of acupuncture on low back pain. Acupuncture is an effective treatment for low back pain, even when compared to other interventions (sham acupuncture, usual care, or no treatment) (Fuentes et al., 2020).

## SUBJECTS AND METHOD

### A. Study Design

This was a systematic review and meta-analysis involving various appropriate electronic journal databases including: Clinical Key, Google Scholar, MEDLINE/PubMed,

ProQuest, Science Direct, Scopus, and Springer Link. The literature search was conducted using the following keywords: “acupuncture”, “low back pain”, “randomized controlled trial”, “acupuncture for low back pain, low back pain and randomized controlled trial, acupuncture and randomized controlled trial, acupuncture and visual analog scale, acupuncture and non-specific low back pain, acupuncture and placebo acupuncture, low back pain and sham acupuncture”.

### **B. Inclusion Criteria**

1. Full paper with Randomized Controlled Trial (RCT) research method
2. The article has an appropriate title and is related to the effectiveness of acupuncture against low back pain
3. Articles published in English and/or Indonesian
4. Include the results of the study in the form of the number of respondents, the mean value and the value of standard deviation (SD)
5. Research subjects in the age range of 20-95 years
6. Intervention in the control group in the form of sham / placebo acupuncture
7. Intervention on research subjects in the form of acupuncture

### **C. Exclusion Criteria**

1. Research conducted with non-RCT studies.
2. The article is not full text
3. Articles published after 1996
4. Articles published other than English.

### **D. Operational Definition of Variable**

Acupuncture is an intervention by inserting a special needle (filiform needle) at acupuncture points that have been mapped on the human body. Sham Acupuncture is an intervention by inserting the original acupuncture needle but inserted shallowly so

that it does not hit the acupuncture point or using different acupuncture points, where these points have very different functions and uses. Low Back Pain Low back pain is a condition with discomfort or acute pain in the fifth and sacral (L5-S1) lumbar segments. This pain can be local pain, radicular pain, or both

### **E. Instrument**

Published articles obtained from various databases of appropriate electronic journals include: Clinical Key, Google Scholar, MEDLINE/PubMed, Science Direct, Scopus. This research was conducted for 30 days (14 October 2021 - 14 November 2021) by searching for and selecting research results from various races, ethnicities and locations in the world.

### **F. Data Analysis**

This research was conducted using secondary data in the form of data from the results of previous studies and data processing was carried out using the Review Manager (RevMan 5.3).

## **RESULTS**

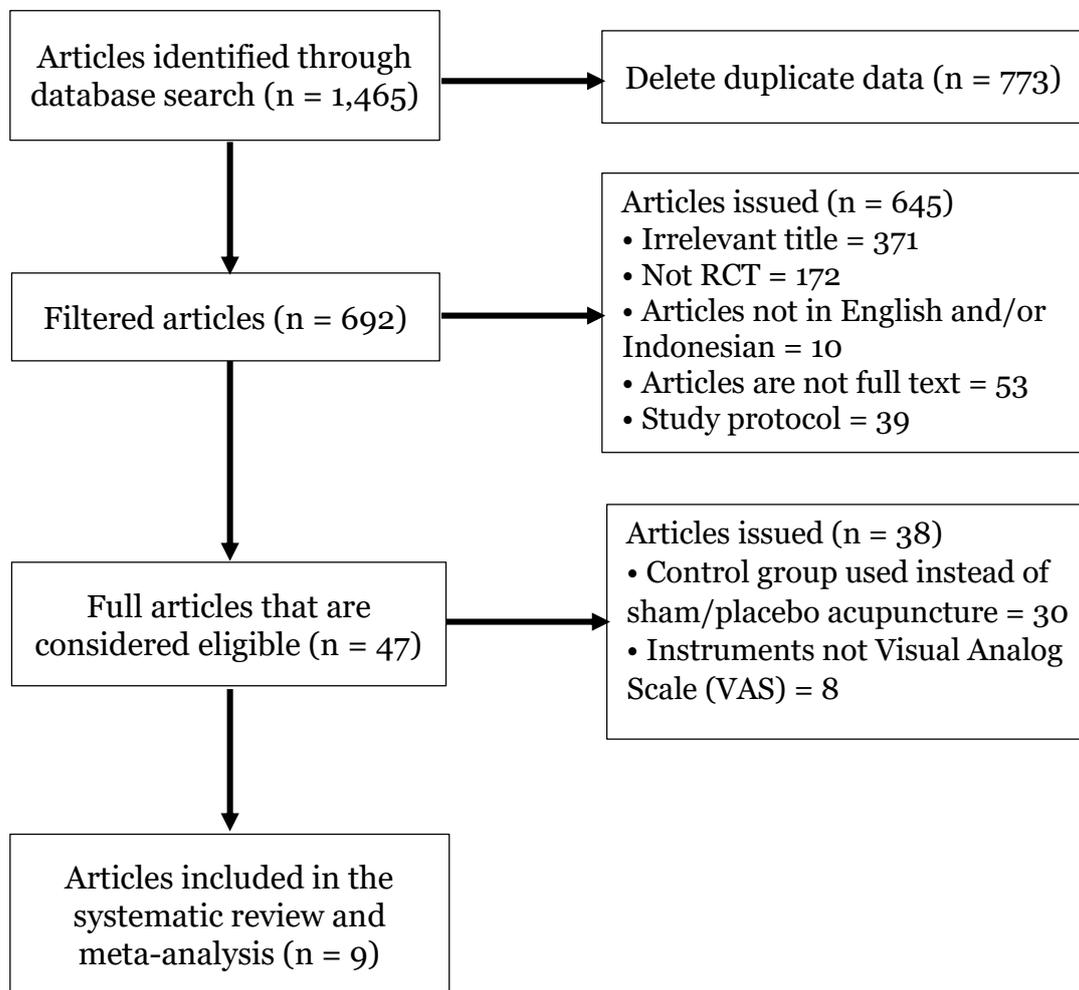
The article selection process is carried out using the Mendeley desktop application. In the initial article search process, 1465 articles were obtained from 5 electronic database sources, namely Clinical Key, Google Scholar, MEDLINE/PubMed, Science Direct, Scopus, and Springer.

The results obtained after the selection process found the same 773 articles, so that the duplicate articles were deleted. A total of 692 articles were obtained after the deletion process, but among those articles there were still 645 articles that were excluded because they did not meet the inclusion criteria

The next stage of screening of 47 existing articles, there were 38 articles that were not suitable because they did not meet

the inclusion criteria and 9 articles were obtained which were the final results of article selection which were included in the

systematic review and meta-analysis process.



**Figure 1** Flow chart of the article review process

**Table 1. PICO (Population, Intervention, Comparison and Outcome) for each study**

No	Author	P (Population)	I (Intervention)	C (Comparison)	O (Outcome)
1	Leibing <i>et al.</i> , (2002)	Research subjects who have been diagnosed by a doctor with low back pain > 6 months (n=131)	Acupuncture at points GV 3, GV 4, SP 6 BL 23, BL 25, BL 40, BL 60, GB 30, and GB 34	Sham acupuncture	Visual analog scale
2	Molsberger <i>et al.</i> , (2002)	Research subjects with low back pain > 2 months and visual analog scale > 5 cm (n=186)	Acupuncture at points BL 23, BL 25, BL 40, BL 60, GB 30, and GB 34	Sham acupuncture	Visual analog scale
3	Inoue <i>et al.</i> , (2006)	Research subjects with low back pain who have consulted at the Center for Acupuncture and Moxibustion, Meiji University (n=31)	Acupuncture at local points (BL 20, BL 21, BL 22, BL 23)	Sham acupuncture	Visual analog scale dan Schober test
4	Itoh <i>et al.</i> , (2006)	Research subjects with low back pain Research subjects who have been diagnosed by a doctor with low back pain > 6 months (n=26)	Acupuncture on trigger points	Sham acupuncture	Visual analog scale
5	Haake <i>et al.</i> , (2007)	Research subjects with visual analog scale < 7 cm (n=1162)	Acupuncture at local points	Sham acupuncture and conventional therapy	Visual analog scale
6	Kennedy <i>et al.</i> , (2008)	Study subjects with low back pain who were registered at the Physiotherapy clinic > 2 months (n=48)	Acupuncture at points GV 3, GV 4, BL 23, BL 25, BL 29, BL 30, BL 31, BL 34, BL 40, BL 60	Sham acupuncture and Physiotherapy	Visual analog scale dan Roland and Morris Disability Questionnaire
7	Vas <i>et al.</i> , (2012)	Research subjects who have been diagnosed by a doctor with low back pain > 6 months (n=275)	Acupuncture on trigger points	Sham acupuncture	Visual analog scale
8	Cho <i>et al.</i> , (2013)	Research subjects who have been diagnosed by a doctor with low back pain > 3 months (n=130)	Acupuncture at local points	Sham acupuncture	Visual analog scale
9	Hasegawa <i>et al.</i> , (2013)	Research subjects with low back pain > 2 months	Acupuncture with the Yamamoto New Scalp Acupuncture technique	Sham acupuncture	Visual analog scale

**Tabel 2. Research Quality Assessment (Critical Appraisal)**

Research Item	Publication								
	Leibing <i>et al.</i> , (2002)	Molsberger <i>et al.</i> , (2002)	Inoue <i>et al.</i> , (2006)	Itoh <i>et al.</i> , (2006)	Haake <i>et al.</i> , (2007)	Kennedy <i>et al.</i> , (2008)	Vas <i>et al.</i> , (2012)	Cho <i>et al.</i> , (2013)	Hasegawa <i>et al.</i> , (2013)
Relevance of goals and problems	1	1	1	1	1	1	1	1	1
Relevance of methods and problems	1	1	1	1	1	1	1	1	1
Sufficient sample	1	1	1	1	1	1	1	1	1
Sample validity	1	1	1	1	1	1	1	1	1
Comparable cases and controls	1	1	1	1	1	1	1	1	1
No bias	0	1	1	1	1	1	1	1	1
Information data search	1	1	1	1	1	1	1	1	1
Analysis of relevant and valid data	1	1	1	1	1	1	1	1	1
Relevance Effect Size	1	1	1	1	1	1	1	1	1
95% CI reporting	1	1	1	1	1	1	1	1	1
Confounding factors reported	1	1	1	1	1	1	1	1	1
Total	11	12	12	12	12	12	12	12	12

Note:

Yes = 1

No = 0

There are 9 randomized controlled trial (RCT) studies as a source of research, a systematic review and meta-analysis of the effectiveness of acupuncture and sham acupuncture in cases of low back pain in this study. An overview of the PICO (Population, Intervention, Comparison, Outcome) of the 9 articles used in the meta-analysis study in this study can be seen in Table 1

The interpretation of the results of the meta-analysis of 9 primary research articles in this study can be seen in the forest plot

image (Figure 4.3). Based on the results of the analysis using RevMan 5.3 software, it is known that there is high heterogeneity between one experiment and another ( $I^2 = 79\%$ ;  $P < 0.001$ ), so the Random Effect Model (REM) was used. Acupuncture therapy was able to reduce the degree of low back pain with a Standardized Mean Difference (SMD) of 0.59 compared to false acupuncture (SMD= 0.59; 95% CI = -0.88 to -0.30;  $p < 0.001$ ).

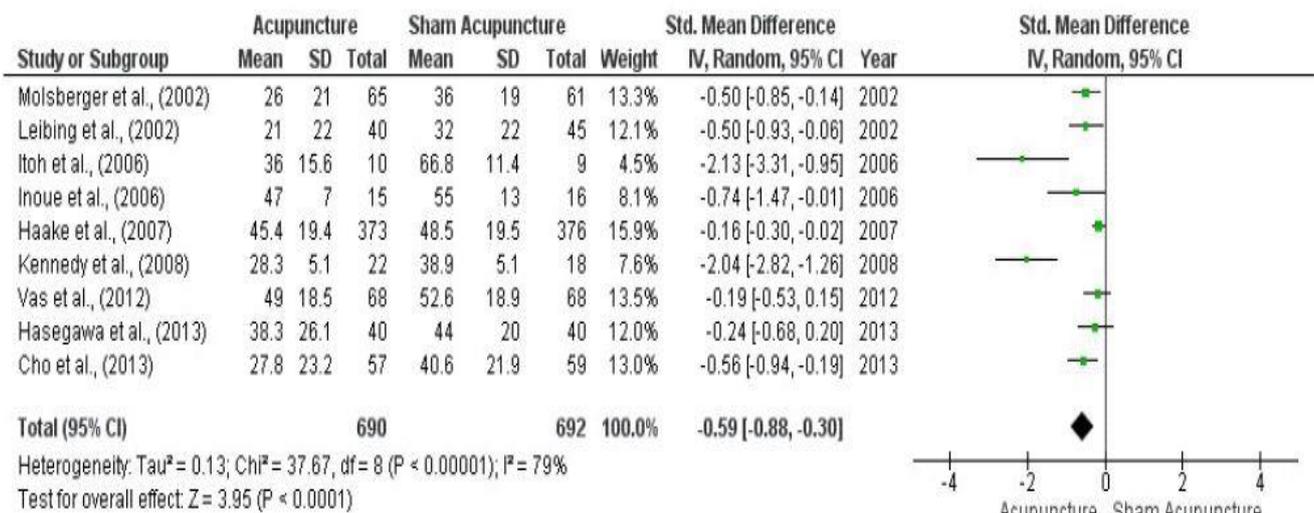


Figure 2 Forest Plot

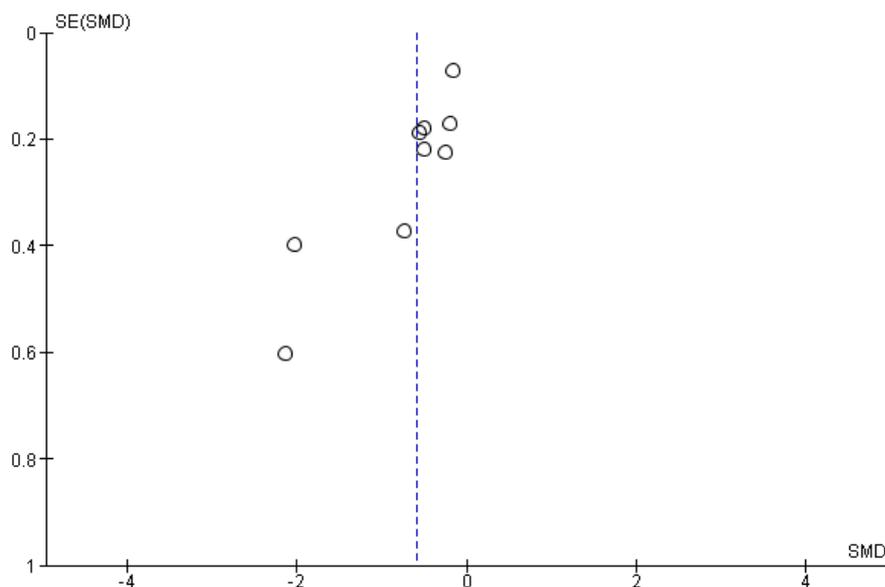


Figure 3 Funnel Plot

A funnel plot is a plot that depicts the size of the effect of each study on the estimate of its accuracy, usually the standard error. The interpretation of the funnel plot results shows that there is no publication bias as indicated by: 1. The plot is symmetrical on the right and left sides, 2. Unbalanced distances between plots indicate an overestimate, 3. SE value < 0.5.

## DISCUSSION

Acupuncture is a therapeutic method by stabbing at points on the body's surface to treat diseases and other health conditions. Acupuncture is the stimulation of certain points on the body with various techniques using hands or electrical stimulation (Wijaya, 2013).

There are more than 361 acupuncture points that have entered the international nomenclature, these 361 points are divided into 14 meridians (acupuncture channels) (Godson and Wardle, 2019). Acupuncture points are electrically active cells that have low electrical resistance and high conductivity, so acupuncture points easily conduct electricity than other cells. The mechanism of action of acupuncture consists of 4 ways, namely through (Saputra and Sudirman, 2009)

Low back pain is a condition with discomfort or acute pain in the fifth and sacral (L5-S1) lumbar segments. This pain can be local pain, radicular pain, or both. This pain is felt between the corners of the lower ribs to the lower buttocks, namely in the lumbar or lumbo-sacral area, originating from muscles, bone nerves, joints or other structures from the spinal area (Andini, 2015).

Acupuncture is a non-pharmacological therapy that can reduce the degree of low back pain. Acupuncture is widely used in many countries on the Asian continent and

over time it is increasingly being used in Western countries (Shergis et al., 2016). Acupuncture is a medical therapy by inserting a special needle (filiform needle) at acupuncture points that have been mapped on the human body. Needle insertion at acupuncture points has a local effect through the axon (nerve fiber), releasing neuropeptides and increasing blood flow at the puncture site (White, 2017).

Acupuncture can be used for therapy for low back pain, besides the use of acupuncture is quite safe if done by professionally trained people because of few side effects and can help reduce pain (Carolyn, 2014). Acupuncture has been widely used as a method for treating low back pain. According to the literature, it is concluded that acupuncture has an effect on reducing pain and improving functional in low back pain (Shin et al., 2011). Fuentes et al. (2020) confirmed the effectiveness of acupuncture on low back pain. Acupuncture is an effective treatment for low back pain, even when compared to other interventions (sham acupuncture, usual care, or no treatment) (Fuentes et al., 2020)

This study took the topic of the effectiveness of acupuncture in patients with low back pain, where the independent variable in this study was acupuncture and the dependent variable in this study was low back pain. Confounding factors are things that cannot be avoided in a study, but can be controlled. Confounding factors affect the relationship or effect of exposure to disease events estimated (estimated) by studies that are not the same as the relationship or effect that actually occurs in the target population, aka the study results are invalid (incorrect) (Murti, 2018).

This study uses research that controls confounding factors, this can be seen from the inclusion and exclusion conditions

required in this study, so that they can control confounding factors that can make the research invalid. There are 9 articles that have passed the inclusion and exclusion requirements of a number of primary studies that were included in this systematic review and meta-analysis. Then the number of respondents, the mean and standard deviation (SD) values were combined and processed using the RevMan 5.3 application. The mean and standard deviation (SD) values were obtained from the low back pain measurement scale, namely the Visual Analogue Scale

According to the literature that has been found, there are several ways to help determine the impact of pain using a unidimensional (single) or multidimensional pain assessment scale. The Visual Analogue Scale is a unidimensional assessment scale (Mardana, 2017). Official structured pain assessment tools can facilitate pain assessment. The Visual Analogue Scale is a psychometric response scale used to measure subjective characteristics or attitudes and has been used in the past for many cases, as well as in research and social science investigations. The Visual Analogue Scale was first described in 1921 and is known as the "graphical rating method". The word "visual" in terms of visual analogue scales emphasizes the concrete nature of this type of scale (a straight line), in contrast to evaluation scales which are abstract and cannot represent what is perceived. The word "analog" emphasizes on infinitely variable variables, which are constantly changing formats (Klimek, 2017). One of the main benefits of Visual Analogue Scale is that it is very easy and simple to use. However, for the post-operative period, the Visual Analogue Scale is of little use because the Visual Analogue Scale requires visual and motor coordination and concentration skills (Klimek, 2017).

The results of data processing using the RevMan 5.3 application on 9 articles from Brazil, Japan, South Korea, Germany, Northern Ireland, and Spain showed that giving acupuncture therapy was able to reduce the degree of low back pain with Standardized Mean Difference (SMD) by 0.59 compared to acupuncture. sham (sham/ placebo acupuncture), and this was stated to be statistically significant with a significance value (SMD -0.59; 95% CI = -0.88 to -0.30;  $p < 0.001$ ).

The results of the interpretation of the Funnel Plot figure indicate that there is publication bias. This is indicated by the asymmetry of the right and left sides of the plot. On the right side there are 5 circles and on the left side there are 3 circles. The left side of the funnel plot in this study has a Standard Error ( $SE > 2$ ) and the right side of the funnel plot in this study has a Standard Error ( $SE < 0.5$ ). On the left side there is a large distance from the other plots, this indicates an overestimate where the data obtained is more in favor of the acupuncture group. This shows that acupuncture is not as significant as the interpretation of the Forest Plot.

This study is in line with a previous systematic review by Lee., et al (2013) which stated that acupuncture was more effective for pain relief than sham acupuncture (2 studies; mean difference, 9.38; 95% confidence interval: 17.00, 1.76).

This study strengthens the previous systematic review by Xu., et al (2013), where in previous studies acupuncture proved to be more effective than other treatments (SMD, -0.26; 95% CI, -0.56 to 0.05) while acupuncture was compared with sham acupuncture was not observed.

#### **AUTHORS CONTRIBUTION**

Nurtama Aditya Nugraha as the main researcher is the executor of the research,

collecting research data, formulating research articles, and processing data. Bhisma Murti plays a role in formulating the framework of thinking and analyzing research data. Hanung Prasetya plays a role in the background and discussion of the research.

### FUNDING

This study is self-funded.

### CONFLICT OF INTEREST

There is no conflict of interest in this study.

### ACKNOWLEDGMENT

The researchers would like to thank the Ministry of Health of the Republic of Indonesia, the Health Polytechnic of the Ministry of Health of Surakarta, the Sebelas Maret University Library. Electronic databases: Clinical Key, Google Scholar, MEDLINE/PubMed, Science Direct, Scopus.

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