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## TECHNICAL NOTE

# Yoga for Health Care in Korea: A Protocol for Systematic Review of Clinical Trials



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#### **KEYWORDS**

clinical trials; evidence-based approach; meridian; systematic review; yoga

#### **Abstract**

This systematic review aims to evaluate the therapeutic effects of yoga therapy using an evidence-based approach and investigates the relationship between yoga and the meridian energies based on all available clinical studies in Korea.

Sixteen electronic databases will be searched from the inception of the study until January 2016. All clinical evidences that evaluate any type of yoga and any type of control in individuals with any type of condition will be eligible. The methodological quality will be assessed using the Cochrane risk of bias tool for randomized clinical trials and the Newcastle—Ottawa scale for nonrandomized studies. Two authors will independently assess each study for eligibility and the risk of bias, and then they will extract the data. With its extensive, unbiased search of the Korean literature from various databases without any language restrictions, this systematic review will be useful for both practitioners in the field of yoga research as well as for patients.

#### 1. Introduction

Yoga is defined as "a part of Ayurvedic medicine that can consist of one or more of the following: specific physical postures, breathing exercises, mindfulness meditation, spirit for health and lifestyle modifications" [1] and it is

related to acupuncture meridian treatments in the complementary and alternative medicine (CAM) field [2]. According to a large survey conducted in the USA, approximately 31 million adults worldwide are estimated to have practiced yoga in their lifetime, with almost half using yoga to promote wellness or immune function,

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prevent health problems, or manage a specific health condition [3].

Yoga has been practiced by healthy and ill individuals around the world as a treatment option for a long time. Currently, yoga is also widely used to improve health and to cure diseases. The reasons for this prevalent use are multidimensional because yoga is considered as an effective way to promote health, strengthen wellbeing, and prevent diseases. In addition, the regular practice of yoga establishes suppleness and muscular strength, provides pain control, and increases longevity [4].

Many clinical studies on yoga have shown that it is beneficial for reducing certain symptoms in a number of conditions, which include asthma, eating disorders, schizophrenia, multiple sclerosis, anxiety, and depression. Research also reports that yoga is successful in generating the relaxation response and in maintaining health and well-being in healthy participants [5,6]. In Korea, yoga is popular and is regarded as a form of mind—body medicine; it is often considered part of CAM and it is actively researched and plays an important role in the healthcare system [7–9].

Specifically, yoga, as an aspect of CAM blends ancient and modern techniques that improve and balance the body's meridian pathways, releasing blocked energy and adjusting the individual's health condition with his/her life. In addition, yoga poses assist with the 14 acupuncture meridians by maintaining the health and functioning of the associated organs [10]. The ancient texts state that yoga medicine is a form of energy medicine. Energy medicine is largely identified with acupuncture and related treatments of acupuncture meridians in CAM, all of which are of concern with balancing the flow of *qi* in the meridians [11].

Many systematic reviews have been published to evaluate the therapeutic effects of yoga therapy using an evidence-based approach. We identified 323 systematic reviews of yoga research that were indexed in PubMed from the inception of this study until January 2016. Because many Korean studies are not included in English-based core medical databases, and many Korean clinical trials on yoga have only been reported in Korean journals, it is difficult to include Korean trials in a systematic review. Searching trials in Korean databases is very challenging, because these databases do not support English-language searches and there is no unified database. A comprehensive search of yoga articles for a competent systematic review is very important to avoid the risk of language bias. Therefore, it is necessary to more comprehensively summarize the evidence base of clinical trials in Korean literature to inform future systematic approaches to the study of yoga. This summary could be valuable in providing yoga research data that are not accessible by non-Korean researchers. In addition, the effects of any treatment or intervention may vary depending on the individual's race or nationality. Therefore, although other systematic reviews of yoga research exist, a domestic review is necessary for the application and expansion of yoga research.

For these reasons, this review aims to systematically evaluate all available clinical evidence of yoga therapy using an evidence-based approach and then to investigate the relationship between yoga and acupuncture meridian energies based on all available clinical studies in Korea.

#### 2. Materials and methods

The protocol of this systematic review has been registered on PROSPERO 2013 (registration number: CRD42013004941) [12]. This systematic review protocol was conducted and reported using the Preferred Reporting Items for Systematic Reviews and Meta-analyses statement guidelines [13]. We will adhere to the guidance provided in the Cochrane Handbook for Systematic Reviews of Interventions [14].

Korean trials listed in Korean databases and journals and published in Korean or any other languages will be eligible. No language restrictions will be imposed. The Korean trials indexed in English-based databases will also be considered. One author (JC) will conduct searches in 16 electronic databases, which includes 11 Korean databases, and the review will be performed from the respective inceptions of the databases to the present, without any language restrictions: MEDLINE, CINAHL, EMBASE, AMED, Cochrane CENTRAL, the Korean Studies Information Service System, DBPIA, Korea Institute of Science and Technology Information, Research Information Service System, Korea Med, Korean Medical Database, Oriental Medicine Advanced Searching Integrated System, National Digital Library, Korean Traditional Knowledge Portal, Research Information Center for Health, and the National Assembly Library (Table 1). The search strategy will be based on two concepts: the first will include all terms for yoga and the second will include clinical trials. The two concepts will be combined using the Boolean operators AND or OR. Our search strategy will include the main keywords "yoga" and "trials" and "Korea" (Table 2).

We will also manually search our departmental files and six complementary and alternative Korean medical journals related to yoga therapy (Journal of Korean Medicine, Korean Journal of Oriental Physiology and Pathology, Journal of Korean Oriental Internal Medicine, Journal of Korean Academy of Nursing, Korean Academic Society of Rehabilitation Nursing, and Journal of Sport and Leisure Studies). Additionally, the reference lists of all identified articles will be further searched to identify potentially relevant papers. Hard copies of all articles will be obtained and the full text will be read.

All types of clinical studies including randomized controlled trials, clinical controlled trials, case series, and case reports, which identify the therapeutic effects of yoga compared with no treatment, placebo, or conventional medication, will be included.

All types of participants, even healthy individuals, will be included because our research aim is to present all of the features of yoga research in Korean literature. The review will include all trials of any duration that investigated the effects of any type of yoga, regardless of style or training regimen, with language restrictions. We will compare the placebo or lack of treatment with yoga therapies used alone or in combination with other conventional treatments.

We will evaluate all clinical trials of yoga as a treatment for any condition or symptom. Hence, the posttreatment differences between the intervention and

| Database title   | Publisher   | Website   |
|--|---|---|
| National Assembly Library Research Information Sharing Service (RISS) Korean Studies Information Service System (KISS) DBPIA | National Assembly Library of the Republic of Korea<br>Korea Education & Research Information Service<br>Korean studies information<br>Kyobo Book Center & Nurimedia (Korea) | www.nanet.go.kr<br>www.riss4u.net<br>kiss.kstudy.com<br>www.dbpia.co.kr |
| Korean Medical Database(KM base)<br>KoreaMed   | Medical Research Information Center<br>Korean Association of Medical Journal Edition  | kmbase.medric.or.kr<br>www.koreamed.org                                 |
| Korea Institute of Science and<br>Technology Information (KISTI)   | Korea Institute of Science and<br>Technology Information  | www.kisti.re.kr   |
| Oriental Medicine Advanced<br>Searching Integrated System (OASIS)  | Korea Institute of Oriental Medicine  | oasis.kiom.re.kr  |
| National Digital Library Korean Traditional Knowledge Portal Research Information Center for Health                          | The National Library of Korea<br>Korea Institute of Oriental Medicine<br>Research Information Center for Health   | www.dlibrary.go.kr<br>www.koreantk.com<br>www.richis.org                |

control groups will be assessed descriptively according to the various conditions. The adverse effects that are likely to be related to the treatment will also be evaluated. Additionally, we will investigate the efficacy of yoga by testing the associations between yoga and acupuncture/meridian. Moreover, we will compare the discrepancies or consistencies for each condition in the included studies with the conclusions of previous systematic reviews (Table 3).

#### 3. Procedure

The data screening and selection process will be performed independently by two authors (JC and JAL) and will be

verified by the third author (JHJ). When disagreements on the selection are not resolved through discussions, the arbiter (MSL) will decide (Fig. 1).

The data extraction will be carried out by two independent reviewers (JC and JHJ) using a predefined form and subsequently validated by the third reviewer (JAL) and the fourth (MSL). Hence, the extracted data will include specific details depending on the study design. The extracted data will be tabulated for further analysis (Tables 4—6). We will independently assess the bias in the included studies using the criteria from the Cochrane Handbook version 5.1.0 [15]. Each domain is scored as: High risk of bias (ROB; —), Low ROB (+), or Unclear ROB (?). Quality assessments will be carried out by two reviewers (JC and JHJ) independent of each other. Any

|                         | Search term  |                  |
|-------------------------|--|------------------|
|                         | English-based DB   | Korean DB        |
| #1 Yoga related         | Yoga [MeSH] OR Yoga* OR Yogic OR Pranayam* OR meditation or pranayama or asana*              | 요가 OR 경락         |
| #2 Design related<br>#3 | Clinical trial [publication type] OR Trial OR random* OR clinic*<br>Korea [AD] or Korea [PL] | 임상 OR 대조군 OR 무작위 |
| #4                      | #1 AND #2 AND #3   | #1 AND #2        |

| First<br>author (y) | Condition   | Type of<br>database                 | No. of primary<br>studies<br>(Korean) | Author's<br>conclusion (quote)    | SR results<br>(+/-) | Newly eligib<br>RCTs compa<br>previou | red with      |
|---------------------|-------------|-------------------------------------|---------------------------------------|-----------------------------------|---------------------|---------------------------------------|---------------|
|                     |             |                                     |                                       |                                   |                     | No. of RCTs (ref)                     | Results (+/-) |
| Study 1             | Condition 1 | English/Korean/<br>Chinese/Japanese | 7 (4)                                 | Provide<br>suggestive<br>evidence | + or –              | [1]                                   | +/-           |

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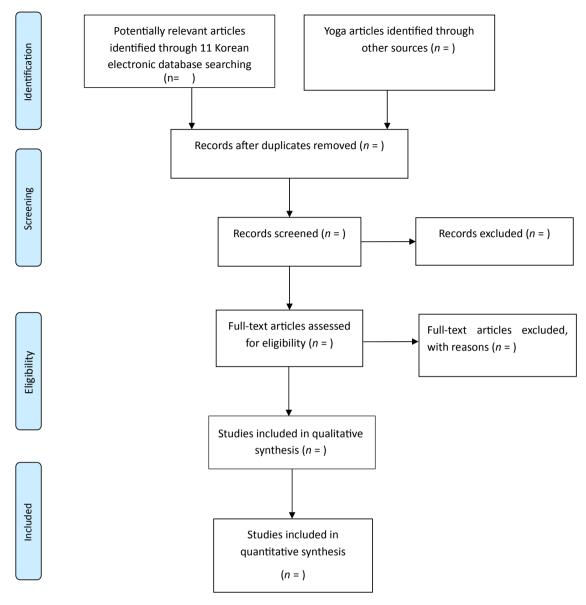


Figure 1 Identification and screening of articles.

disagreements will be resolved through discussions. We will use the Newcastle—Ottawa scale for nonrandomized studies [16].

The differences between the intervention and control groups will be assessed. For the continuous data, we will use the mean difference and 95% confidence intervals (CIs) to measure the treatment effect. In the case of outcome variables with different scales, we will use the standard mean difference and 95% CIs.

The data will be pooled in a formal meta-analysis, if statistical, clinical, and methodological homogeneity allow. The generic inverse variance method for dichotomous outcomes will be used to provide an overall estimate of effect. Standard errors of the mean and log odd ratios will be derived from individual studies. For studies with sufficient data for

statistical pooling, odd ratios and 95% CIs were computed using Cochrane Collaboration software (RevMan 5.0 for Windows; The Nordic Cochrane Center, Copenhagen). For homogeneous datasets, summary estimates of the treatment effect will be calculated using the fixed effects model. We will regard substantial heterogeneity when the Cochrane's Q test result will be determined with p < 0.10, and  $I^2$  above 50%. Unless excessive statistical heterogeneity is present, we will then pool the data across studies for a meta-analysis using a random-effects model, and we will use the fixed effect model as a sensitivity analysis.

Ethical approval is not required, given that this protocol is for a systematic review. The findings of this review will be widely disseminated through peer-reviewed publications and conference presentations.

| Table 4          | Table 4         Summary of randomized controlled trials of yoga for various conditions in Korean literature. | mized controlled | trials of yoga for | various cond | litions in Korean lite | erature.              |              |                       |                  |
|------------------|--|------------------|--------------------|--------------|------------------------|-----------------------|--------------|-----------------------|------------------|
| First            | Conditions/  | Experimental     | Control            | Primary      | Main result            | Follow-up(s)          | Adverse      | Association with      | Quality          |
| y (ref)          | size/age,  | (regime)         | (regime)           | measure      | differences)           |                       | 3            | meridian investigate? | 4334331114114    |
|                  | (mean or range)  |                  |                    |              |                        |                       |              |                       |                  |
| Study 1          | Condition  | Intervention     | Control            | Outcome      | Result select          | Period select Adverse | Adverse      | Yes/no                | Using Cochrane's |
|                  | type select  | type select      | select             | select       |                        |                       | event select |                       | risk of bias     |
| ref = reference. | erence.  |                  |                    |              |                        |                       |              |                       |                  |

| Table 5 Su               | ımmary of nonr      | Table 5         Summary of nonrandomized controlled trials of y                               | lled trials of y            | oga for various condi                                   | yoga for various conditions in Korean literature.  | ure.  |                      |                            |  |                       |
|--------------------------|---------------------|---|-----------------------------|---|--|---|----------------------|----------------------------|--|-----------------------|
| First author,<br>y (ref) | Study design        | First author, Study design Condition/total Data source<br>sample size/age,<br>(mean or range) |                             | Definition exposure/<br>methods used for<br>measurement | Definition exposure/ Definition outcome/ Main result Follow-up(s) Adverse Association Quality methods used for (between group events with acupuncture assessmer measurement differences) and meridian investigate? | Main result<br>(between group<br>differences) | Follow-up(s)         | Adverse<br>events          | Adverse Association Quality events with acupuncture assessment and meridian investigate? | Quality<br>assessment |
| Study 1                  | CCT or cohort       | CCT or cohort Condition<br>type select  | Intervention<br>type select | Outcome select  | Result select  | Period select Conclusion Adverse select event | Conclusion<br>select | Adverse<br>event<br>select | Yes/no   | Using<br>Ottawa       |
| CCT = contro             | lled clinical trial | CCT = controlled clinical trial; ref = reference.   |                             |   |  |   |                      |                            |  |                       |

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| Table 6 Su               | mmary o          | f case series and re  | eports of yoga              | Table 6 Summary of case series and reports of yoga for various conditions in Korean literature. | in Korean literature.  |   |                      |                         |  |
|--------------------------|------------------|---|-----------------------------|---|--|---|----------------------|-------------------------|--|
| First author,<br>y (ref) | Study<br>design  | Study Condition/total design sample size/age, (mean or range) | Data source                 | Definition exposure/<br>methods used for<br>measurement   | First author, Study Condition/total Data source Definition exposure/ Definition outcome/ Main result Follow-up(s) Adverse y (ref) design sample size/age, methods used for methods used for (between group events (mean or range) measurement measurement differences) | Main result<br>(between group<br>differences)       | Follow-up(s)         | Adverse<br>events       | Association with acupuncture and meridian investigate? |
| Study 1                  | CCT or<br>cohort | Condition<br>type<br>select                                   | Intervention<br>type select | Outcome select  | Result select  | Period select Conclusion Adverse<br>select event se | Conclusion<br>select | Adverse<br>event select | Yes/no   |
| CCT = control            | lled clinic      | CCT = controlled clinical trial; ref = reference.             | ence.                       |   |  |   |                      |                         |  |

#### 4. Anticipated results

Until now, no systematic reviews have examined the therapeutic effects of yoga on various conditions and its relationship with acupuncture and meridian energies in Korea. In particular, it is difficult to predict the effects of yoga in Korean literature on the basis of study findings. Therefore, it is important to identify the evidence that is currently available in Korea. This systematic review will provide a detailed summary of the current evidence related to the effectiveness of yoga in treating various conditions in the Korean research context. Additionally, we will investigate the relationship between acupuncture meridians and yoga. This review will be useful for both practitioners in the field of yoga research as well as for patients.

#### Disclosure statement

The author declares to have no conflicts of interest and no financial interests related to the material of this manuscript.

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The protocol was drafted by all authors. It was revised and the final version approved by all authors. The authors were supported by the Korea Institute of Oriental Medicine (K15080)

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