# INPLASY PROTOCOL

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**Conflicts of interest:**
**None declared.**

# Comparative Effectiveness of Different Exercises for Reducing Pain Intensity in Primary Dysmenorrhea: A Network Meta-Analysis of Randomized Controlled Trials

Tsai, IC[1]; Chang, KV[2].

**Review question / Objective:** **To evaluate the effectiveness of different exercise interventions in reducing pain associated with primary dysmenorrhea in women.**
**Condition being studied:** **The network meta-analysis adopted the PICO framework (population, intervention, comparison, outcome) with the following specifications: (1) P: female human participants with primary dysmenorrhea; (2) I: exercise interventions; (3) C: control group without intervention or with alternative exercise interventions; and (4) O: alterations in pain intensity. The diagnosis of primary dysmenorrhea can be made using the definition recommended by the American College of Obstetricians and Gynecologists.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 March 2023 and was last updated on 15 March 2023 (registration number INPLASY202330050).

## INTRODUCTION

**Review question / Objective:** **To evaluate the effectiveness of different exercise interventions in reducing pain associated with primary dysmenorrhea in women.**

**Rationale:** **Numerous studies have investigated the effectiveness of exercise as a means of managing primary dysmenorrhea. However, the existing literature is characterized by a lack of consensus regarding the optimal exercise type. Different types of intervention such as relaxation exercise (including progressive muscle relaxation and self-administered massage), strength training, aerobic activity, yoga, mixed exercises, and Kegel maneuver have been studied. The aim of this network meta-analysis is to rank the**

mean differences in pain intensity reduction and the differences in dropout risk associated with different exercise interventions in primary dysmenorrhea patients. This information will provide more specific recommendations for individuals who are considering exercise as a means of pain management.

**Condition being studied:** The network meta-analysis adopted the PICO framework (population, intervention, comparison, outcome) with the following specifications: (1) P: female human participants with primary dysmenorrhea; (2) I: exercise interventions; (3) C: control group without intervention or with alternative exercise interventions; and (4) O: alterations in pain intensity. The diagnosis of primary dysmenorrhea can be made using the definition recommended by the American College of Obstetricians and Gynecologists.

## METHODS

**Search strategy:** Two authors (I.-C.T. and K.-V.C.) conducted independent electronic searches in the PubMed, Cochrane Reviews, Cochrane CENTRAL, Web of Science, and ClinicalTrials.gov databases using the following keywords: ('primary dysmenorrhea' OR 'dysmenorrhea' OR 'menstrual cramps' OR 'painful periods') AND ('exercise' OR 'yoga' OR 'aerobic' OR 'training' OR 'sports' OR 'physical activity' OR 'workout' OR 'fitness' OR 'training') AND ('randomized' OR 'randomised' OR 'random'). The search strategy covered the period from the earliest record in each database to the database search date, which was February 25, 2022.

**Participant or population:** Female human participants with primarydysmenorrhea.

**Intervention:** Exercise interventions

**Comparator:** Control group without intervention or with alternative exercise interventions.

**Study designs to be included:** Randomized controlled trials.

**Eligibility criteria:** The study employed the following inclusion criteria: (1) randomized controlled trials that recruited female human participants with primary dysmenorrhea, (2) randomized controlled trials that investigated the quantitative assessment of pain intensity pre- and post-exercise, (3) control group that received either no intervention, regular care or another exercise, and (4) trials that had available data on pain intensity assessment or evaluation of changes in pain intensity pre- and post-intervention at either 4 weeks or 8 weeks.

**Information sources:** PubMed, Cochrane Reviews, Cochrane CENTRAL, Web of Science, and ClinicalTrials.gov .

**Main outcome(s):** The primary outcomes evaluated in this study were changes in pain intensity measured by VAS following exercise intervention or no intervention. Data from both 4-week and 8-week evaluations were included in the analysis.

**Additional outcome(s):** The secondary outcome measure was the 8-week risk difference of dropout.

**Data management:** Two independent authors (Tsai IC and Chang KV) extracted data from the evaluated studies, including demographic data, study design, details of the implemented exercise protocol, and the primary and secondary outcome values. In situations where data were unavailable within the published articles, we contacted the corresponding authors to obtain the original data.

**Quality assessment / Risk of bias analysis:** To assess the methodological rigor of the studies included in our analysis, we employed the Cochrane risk of bias tool for randomized trials (version 2, RoB 2, London, UK). This tool comprises six core elements for evaluating the quality of a study, which include the randomization process, intervention adherence, missing outcome data, outcome measurement, selective reporting, and the overall risk of bias.

**Strategy of data synthesis:** Due to the inclusion of multiple types of exercises and the evaluation of differences between them, we employed a random-effects model for this network meta-analysis. The analysis was conducted using MetaInsight (version 4.0.2, Complex Reviews Support Unit, National Institute for Health Research, United Kingdom) with frequentist framework. MetaInsight is a web-based service for network meta-analysis. MetaInsight's statistical core is based on R software and utilizes the netmeta package for frequentist statistical calculations. The user-friendly web interface is created using R-shiny to facilitate broader usage.

**Subgroup analysis:** For exercise selection, we categorized typical exercise types, including relaxation exercises, strength training, aerobic activity, yoga, and Kegel maneuvers. Exercises that combined two or more of these categories were classified as mixed exercises.

**Sensitivity analysis:** When transforming the baseline and post-intervention pain intensity measurements into mean and standard deviation of changes, it is necessary to assume a pre-post correlation coefficient. In this study, we adopted a coefficient of 0.8. To examine whether the chosen coefficient would impact the study results, we performed a sensitivity analysis by running the effect sizes of the VAS value changes with a coefficient of 0.5. We then checked for the effects, direction, statistical significance, and ranking of the results.

**Language restriction:** No language limit.

**Country(ies) involved:** Taiwan.

**Keywords:** primary dysmenorrhea, exercise interventions, menstrual pain, network meta-analysis relaxation exercise.

**Dissemination plans:** Publication.

**Contributions of each author:**
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