Study Protocol and Statistical Analysis Plan

Official Title: Combined Muscle Energy Technique and Myofascial Chain Stabilization Reduces Menstrual Pain and Improves Pelvic Alignment in Women With Primary Dysmenorrhea: A Prospective Study

NCT Number: [Pending]

Date: December 10, 2024

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1. Background and Rationale

Primary dysmenorrhea (PD), defined as menstrual pain without identifiable organic pathology, affects up to 90% of women of reproductive age. Conventional treatments, including NSAIDs and hormonal contraceptives, often offer only temporary relief. Emerging evidence indicates that pelvic girdle dysfunction and spino-pelvic misalignment are potential contributors to pain in PD. Abnormalities in pelvic tilt (PT), sacral slope (SS), and pelvic incidence (PI) may increase myofascial tension and impair neuromuscular coordination, thereby exacerbating menstrual discomfort. These musculoskeletal impairments may also contribute to altered uterine positioning and reduced pelvic circulation, mechanisms that have been linked to elevated prostaglandin activity and increased menstrual pain.

Muscle Energy Technique (MET) and myofascial chain-based pelvic stabilization training have been proposed as non-pharmacologic interventions targeting structural dysfunction and neuromotor control. This protocol outlines a prospective clinical trial comparing the efficacy of these techniques against conventional physiotherapy.

2. Objectives

Primary Objective:
To evaluate the effects of combined MET and myofascial chain stabilization training on pelvic alignment and menstrual pain in women with moderate-to-severe PD.

Secondary Objectives:
To assess changes in static balance (single-leg stance time, eyes closed) and pelvic symmetry (radiographic composite score) as functional correlates of biomechanical improvement.

3. Study Design

This study is a prospective, non-randomized controlled clinical trial conducted over four weeks of active intervention, with an additional 12-week follow-up via telephone. A 12-week post-intervention telephone follow-up will assess long-term effects. Participants

were assigned to either the Combined MET and MFC-Based Pelvic Stabilization group or the Conventional Physiotherapy group.

4. Participants

4.1 Inclusion Criteria

- Female, aged 18–45 years
- Regular menstrual cycles
- Clinical diagnosis of primary dysmenorrhea
- VAS score ≥ 4 during menstruation for at least six consecutive months
- Radiographic evidence of abnormal PT, SS, or pelvic asymmetry

4.2 Exclusion Criteria

- Secondary dysmenorrhea or gynecologic pathology
- Pregnancy or ongoing hormone therapy
- Congenital or structural musculoskeletal disorders
- Concurrent participation in other physiotherapy interventions

All participants provided written informed consent prior to enrollment.

5. Interventions

5.1 Combined MET and MFC-Based Pelvic Stabilization Group (n = 15)

Participants received:

- Muscle Energy Technique (MET) for iliac dysfunction and sacral torsion
- Pelvic stabilization training based on myofascial chain principles, including curl-ups, planks, and anti-rotation exercises
- Frequency: 3 sessions per week, 50 minutes per session, for 4 weeks

5.2 Conventional Physiotherapy Group (n = 15)

Participants received:

- Medium- and low-frequency electrotherapy
- Deep friction massage in the sacroiliac and iliac crest regions

- Frequency: 3 sessions per week, 50 minutes per session, for 4 weeks

All treatments were administered by licensed physical therapists.

6. Outcome Measures

6.1 Primary Outcome

- Change in average menstrual pain intensity measured by Visual Analog Scale (VAS, 0–10), from baseline to Week 4 and at 12-week follow-up.

6.2 Secondary Outcomes

1) Change in pelvic tilt (PT) measured by lateral radiograph (degrees)
2) Change in sacral slope (SS) measured by lateral radiograph (degrees)
3) Change in pelvic incidence (PI) measured by lateral radiograph (degrees)
4) Change in pelvic symmetry measured by X-ray composite score
5) Change in static balance measured by single-leg stance time (eyes closed, seconds)

7. Statistical Analysis Plan

All statistical analyses were conducted using SPSS version 27.0. The significance level was set at $p < 0.05$.

- Normality Testing: Shapiro–Wilk test
- Baseline Homogeneity: Independent sample t-tests for continuous variables
- Within-Group Comparisons: Paired sample t-tests for pre-post changes
- Between-Group Comparisons: ANCOVA with baseline scores as covariates
- Effect Sizes: Hedges' g for small-sample corrections

8. Ethics and Trial Registration

This study was approved by the Institutional Review Board of Shenzhen University General Hospital (Approval No.: 2025-Ethics-1-YLT). Written informed consent was obtained from all participants prior to enrollment. Clinical trial registration is in progress at ClinicalTrials.gov (NCT Number: [Pending]).

9. Appendices

Figure 1. Study design flowchart