

# Osteopathic uterus manipulation and cranial stimulation influence on anterior uterocervical angle in primary dysmenorrhea: A randomized controlled trial protocol

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## Abstract

**Background and purpose:** Prevalence rate of primary dysmenorrhea exceeds 90 per cent and is common cause of absenteeism among teenagers and young females. The aim of this study is to assess biological and psychological effects of Osteopathic uterus manipulation and cranial stimulation in primary dysmenorrhea cases.

**Methods:** Single blinded two group pre-test post-test randomized controlled trial will be conducted on 46 females between the age group of 18-35 years. Participants will be randomly divided into interventional group A and control group B. Group A will receive osteopathic uterus manipulation and cranial stimulation along with conventional physiotherapy while group B will be on conventional physiotherapy alone. One week of treatment will start 2 days before previous periodic date and will continue for 4 consecutive menstrual cycles. International physical activity questionnaire will assess physical activity of each participant. Pre and post diagnostic ultrasonography will calculate any change in the longitudinal axis and vertical axis of the uterine cervix and measure anterior uterocervical angle. Pain, anxiety and depression levels will be measured by Visual Analogue Scale and Depression, Anxiety and Stress Scale-21 items respectively.

**Discussion:** The study assesses the role of Osteopathic Uterus Manipulation and Cranial Stimulation in management of primary dysmenorrhea patients.

**Keywords:** Pain, Physical activity, Quality of Life, Ultrasonography, Women Health.

## INTRODUCTION

Primary Dysmenorrhea is one of the common gynaecological problems, primarily affecting teenagers and youthful females.<sup>1</sup> There is the relationship of the feminine cycle with stomach torment, squeezing, lumbago, and action impediments.<sup>2</sup> Also there is growing evidence of psychological aetiology in the females

suffering from dysmenorrhea who tend to have greater negative attitudes towards this illness.<sup>3,4</sup> Mental health issues revolve around are high emotional disturbance, anxiety, and somatic complaints.<sup>5</sup> The studies predicted that the narrow anterior uterocervical angle (UCA) is associated with primary dysmenorrhea and pain severity. Narrower UCA certainly increases the

resistance from the uterine cavity. Hence it is important to measure the uterocervical angle as it is directly linked to the severity of the primary dysmenorrhea.<sup>6</sup>

The Manipulation of soft tissues helps in improving mechanical, circulatory, and neurological responses. It benefits the venous and lymphatic circulation and decongests the body. It also plays a vital role in the lessening of hyper-tonicity and spasms. Previous studies have shown that a three-cycle course of five osteopathic treatments could help women in dealing with primary dysmenorrhea.<sup>7</sup> Cranial electrotherapy stimulation (CES) is a non-invasive electrotherapy treatment that has been shown to decrease anxiety, depression, and insomnia significantly. CES decreases the delta activity which helps in the reduction of fatigue and increases alpha activity. This further induces relaxation and decrease the beta activity which consequently reduces the negative thought process.<sup>8</sup> Deep breathing exercises reduce the intensity of pain, increases oxygenation of the blood, and also increases pulmonary ventilation.<sup>9</sup> Music therapies are effective in treating various disorders of depression, anxiety and mood swings. Listening to classical music

results in the alleviation of PMS symptoms.<sup>10</sup> The strong musculature of the core is designed to handle the normal forces as well as when the body is under the stress of the menstrual cycle. The aim of this study is to assess the changes in anterior uterocervical angle and cervical length and to find out the effect of non-invasive management on pain, anxiety and depression levels of primary dysmenorrhea patients.

### **Material and Methods:**

Trial Registration:

Ethical approval has been taken from the Institutional Ethics Committee of X University. This study is registered at Clinical Trials Registry-India. (CTRI/2021/03/031838) on 04/03/2021 and Universal Trial Number is U1111-1265-3764. Trial will be conducted in the Outpatient Department of X Institute.

Study design:

The study is single-centre, single-blind two-group pre-test post-test study design. Fig. 1 demonstrates an overview of protocol.

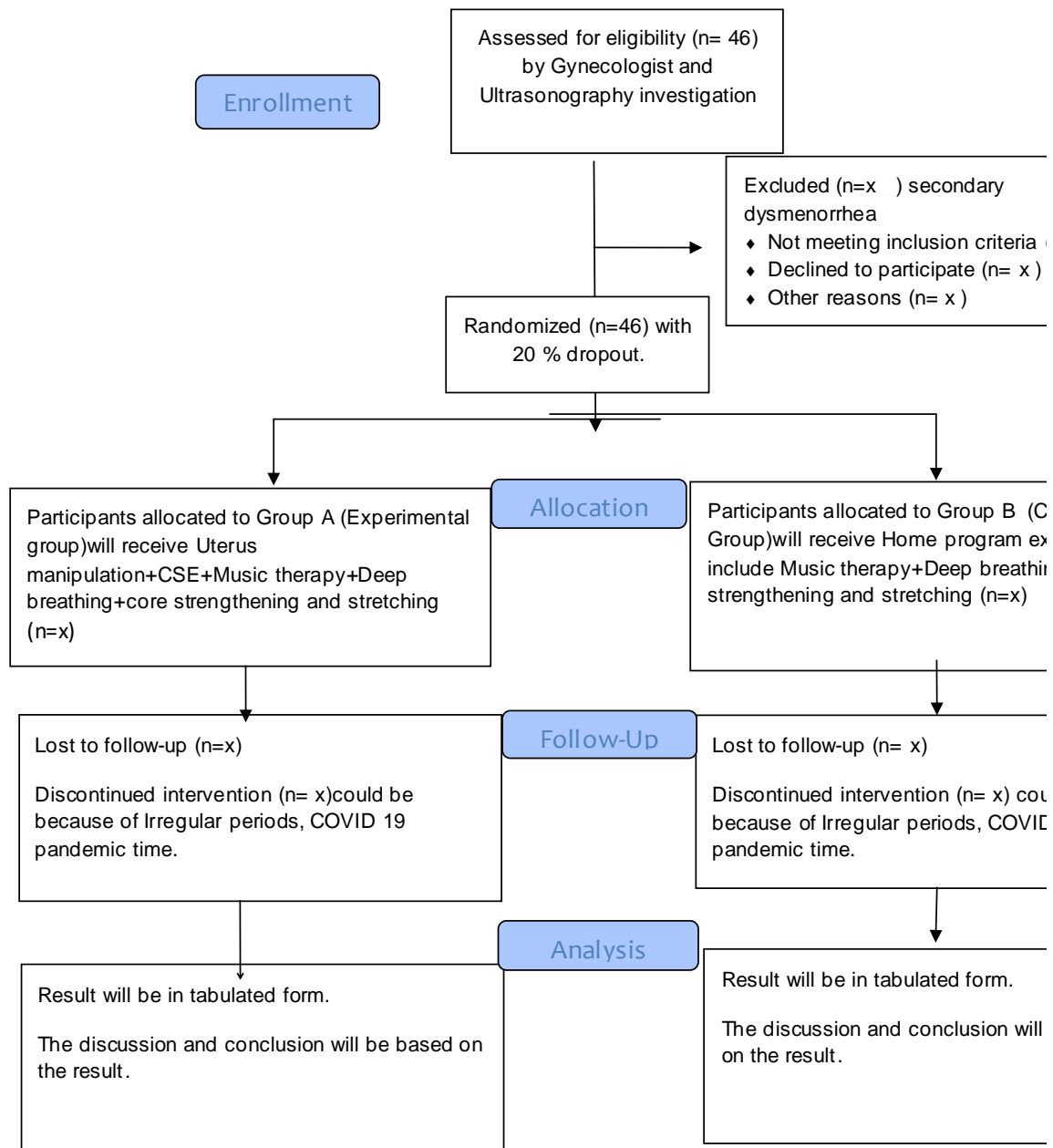


Fig. 1: Flow chart of study protocol

**Sample size Calculations:**

The sample size was calculated using G\* Power 3.1.9.4 statistical software. The calculated effect size is 1.0, the significance level set is 0.05 and power set is 95% confident interval. At 20% drop out rate consideration, 23 samples in each group were calculated making the total sample size equal to 46. 11

**Participants Recruitment:**

Forty Sixty primary dysmenorrhea diagnosed patients between age group of 18 to 35 years will be recruited in the study according to the selection criteria. Patients will be referred from Maharishi Markandeshwar Institute of Medical Sciences and Research, Gynaecology and Radiology outpatient department. Demographic data such as the name, age, gender, occupation, address of each patient will be documented in a pre-designed Performa for the eligible patients. Information about the participants, inclusion & exclusion criteria are given in Table 1. Written consent form from the voluntary participation will be taken. Every participant will be assured that there will be no harm, the information obtained from them will be used for research purpose and their privacy will be maintained.

Table no 1: *Inclusion & Exclusion criteria*

<b><u>Inclusion Criteria(Premenstrual symptoms)</u></b>	<b><u>Exclusion Criteria</u></b>
➤ Medical, Physiotherapy and Nursing female students of regional medical university.	➤ Hypertension
➤ Age group 18-35 years	➤ Diabetes
➤ Willing Participants	➤ any other chronic disease
➤ Participants were diagnosed with primary dysmenorrhea according to	➤ Secondary dysmenorrhea.
	➤ Neurological disorder
	➤ Cardio logical disorder
	➤ Tumour
	➤ Abdominal surgery(appendectomy, cholecystectomy,anore

pathos-physiology of dysmenorrhea.	of ctala surgery,bowel,resections,hernia surgery)
➤ Low back pain	➤ Irregular periods
➤ Thigh pain	
➤ Tiredness	
➤ Headache	
➤ Abdominal pain	
➤ Anxiety	

**Randomization:**

Block randomization will be used to randomly assign the patients into two groups using block of 6x6 matrix using SNOSE method (randomization sequence, the use of sequentially numbered, opaque sealed envelopes) with 23 patients in each group. Patients diagnosed with primary dysmenorrhea induced by periodic pain along with symptoms of anxiety and/or depression, with compromised quality of life will be assigned to both the group randomly. 12

**Intervention:**

Group A will receive osteopathic uterus manipulation and cranial nerve stimulation along with conventional physiotherapy. Group B will perform conventional physiotherapy including deep breathing exercise, core strengthening, active static stretching exercises and music therapy as a home exercise programme. The treatment time will be of 1 hour duration daily for one week during each menstrual cycle starting 2 days before previous periodic date and will continue for 4 consecutive menstrual cycles.

Cranial electric stimulation: Patient position: Supine lying, Therapist position: Stands at the foot end of the couch, Treatment time 30 min. The current is applied by easy-to-use clip electrodes that will be attached on the ear lobes, occipital area, mastoid processes, or temples with Mode:2, Current Density =1 mA, Current density =5µA\cm<sup>2</sup>, Pulse duration= Auto adjustable (1-5ms)8

### Uterus manipulation:

The principles of testing and treatment in visceral osteopathy according to Barral were followed. The patient will be lying down in supine position with her legs bent. Therapist places one hand just above the symphysis, on the side opposite to the rectus abdominis attachment point and applies gentle pressure posteriorly to the area lateral to the uterus fundus for testing. Both hand are positioned on sides of the uterus and then translate the organ. Ovaries and Broad Ligament of the Uterus: The patient will be lying down in supine position with her legs stretched out. The therapist place one hand on a line ASIS-symphysis, somewhat medial to the edge of the psoas and visualizes the projection of the ovary. Slowly slide hand backwards into the depth to cause this ligament to relay. Tubo-Ovarian Motility is tested posterior-superiorly during expiration phase and anterior- inferiorly during inspiration. Treatment is performed by following unimpaird movement at end point for few cycles and then following impaired movement to the new end point. 13

### Conventional Physiotherapy

Self Static stretching: 1 set of 3 repetitions of hamstring muscle, quadratus lumborum and quadriceps muscle with 45 seconds hold.4

Core strengthening: 1 set of 10 repetitions of cat and camel exercise and plank exercise with 30 seconds hold.4

### Deep breathing exercise:

Patient is in sitting position. Inhale slowly and deeply through nose for 5 seconds with shoulders relaxed. Hold breath for 4 seconds and exhale passively. 9

### Music therapy:

Patient is in supine lying. Listen to the classical relaxing music Yaman Raag early evening with headphones in peaceful environment for 20 minutes. 10

### Outcome measures:

Primary and secondary outcome measures summary is given in Table 2.

Table 2: Summary of Primary Outcome Measure Secondary Outcome Measure to be given to the patients.

Primary Outcome Measure	Secondary Outcome
Gynaecology	➤ Visual analogue scale
	➤ Dass <sup>21</sup> questionnaire
Ultrasonography	➤ International Physical activity questionnaire

### Primary outcome measure:

Gynaecological assessment: Initially history and examination will be taken by gynaecologist, patients with complaints of urinary and other infections, pelvic inflammatory disease, and any other types of abnormalities will be excluded from the study. Body Mass Index (BMI) according to WHO guidelines of each participant will be assessed. 14

Ultrasonography imaging: Ultrasonography is a diagnostic tool which helps in assessing primary dysmenorrhea. All measurements will be carried by Philips affinity 50 G machine with curvilinear probe (2-5 frequency). The longitudinal and transverse of uterine body and cervix is measured in mid sagittal plane. The UCA will be measured at internal cervical orifice, external cervical orifice, cervical canal, cervical or vaginal interface and uterine body. The UCA is an angle between line drawn from internal to external cervical Orifice and line drawn along the longitudinal axis of uterine body parallel to anterior wall of uterus passing through the internal cervical orifice. Cervical length is measured as distance between internal and external cervical orifice.6, 15

### Secondary Outcome measures:

Visual Analog scale (VAS): It will be used to assess pain of primary dysmenorrhea patients. The left end of the 10 cm horizontal line represents "no pain" while the right end denotes "severe pain". It is a reliable method where the patient will be asked to place a mark on the scale so that it can indicate severity of pain. 16

Depression, Anxiety and Stress Scale-21 items (DASS-21): The DASS-21, which served as the

gold standard tool, is a good way to screen for depressive disorders. It includes 21 items and each question has 0,1,2,3 points. The category labels: Normal, mild, moderate, severe, and extremely severe. Anxiety minimum score is 0 and 20+, depression minimum score is 0 and maximum 28+ and stress minimum score is 0 and maximum 34+.17

International Physical activity questionnaire: assesses the time spent on physical activity in the previous seven days. The physical activities lasting at least 10 minutes are considered.18

Data monitoring:

Both statistical analysis and databases will be performed by an independent researcher. Every group's therapy sessions will be monitored by a treating physiotherapist.

Statistical data analysis:

Statistical analyses will be performed using IBM® SPSS® statistics 21.0. Normal distribution of the data will be verified by Shapiro Wilk Level of significance or alpha level will be set at  $p$  value < 0.05 to be considered for statistically significant. Following normal distribution repeated measure ANOVA test and independent t-test will be used within the group and between the groups respectively. In case of non-normal distribution non-parametric will be used within the group i.e. Friedman test and Mann-Whitney U test between the group. Spearman rank correlation coefficient will be used to find out the association between UCA and VAS values.18

### Discussion:

Non-invasive treatment can improve the pelvic floor organ functioning by adjusting the proper blood flow, metabolism and promoting analgesic effect through endogenous mechanism. The UCA, between the cervical canal and the uterus frontal wall, is a newly investigated parameter by diagnostic ultrasonography. Recently, Dziadosz et al. reported that in the presence of a large UCA, uterine contents are directly and more easily displaced to the cervix. 14 Sahin et al. stated in their study that narrower UCA width leads to primary dysmenorrhea due to increase in resistance to ejections from uterine cavity during menstrual days.6 Israel RG et al expressed that

dysmenorrhea in high school girls who were involved in physical activities were less than non-exercise group. 19 A study by Morriss et al, found that CES has the potential to improve psychological illness such as anxiety, depression, stress, attitudes, belief, and thereby quality of life. 8, 20 Stress tends to enhance sympathetic activity and may increase menstrual pain by exacerbating uterine contraction. Studies indicate biological and psychological effectiveness of osteopathic manipulations in chronic pelvic pain cases. 7, 21 The present study is limited by the factor that it will be single centre study.

### Conclusion

This randomized controlled trial will verify the significance of osteopathic uterus manipulation and cranial Stimulation on cervical length and anterior uterocervical angle among primary dysmenorrhea patients and will provide clinical evidence of neurological and biomechanical factors of osteopathy manipulations in primary dysmenorrhea cases.

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