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Research Protocol

Ayurveda Section

Evaluation of the Efficacy of *Yavanna* (*Rajaswala Paricharya* diet) versus Routine Care in the Management of *Kashtartava* (Primary Dysmenorrhoea): A Randomised Controlled Trial Protocol

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ABSTRACT

Introduction: Menstrual pain is a common problem among women of reproductive age, negatively affecting their daily activities and quality of life. In Ayurveda, a classic diet and lifestyle regimen is recommended during menstruation, known as *Rajaswala Paricharya*. Adhering to this diet during menstruation in otherwise healthy women is thought to produce shuddhaartava (i.e., a painless, healthy menstrual cycle).

Aim: To assess the efficacy of the *Rajaswala Paricharya* diet (*Yavanna* – barley porridge diet) compared to routine care (Mefenamic acid) in cases of primary dysmenorrhoea.

Need of the study: Modern medical treatments for dysmenorrhoea (primary dysmenorrhoea) include Non Steroidal Anti-Inflammatory Drugs (NSAIDs) and oral contraceptives, which may produce certain side-effects such as gastrointestinal disturbances, stomach ulcers, and allergic reactions. Therefore, the present study aims to develop a treatment that is simple to administer, highly effective in alleviating the condition and has minimal or no side-effects, ensuring patient acceptance.

Materials and Methods: A single-centre, randomised, single-blinded, parallel-group controlled trial will be conducted at MGACH, Wardha, Maharashtra, India, over three consecutive cycles (a three-month period) from July 2024 to March 2025. The subjects will be divided into two groups: the control group and the experimental group. The experimental group will follow the *Rajaswala Paricharya* diet (*Yavanna*) by consuming 100-250 grams of barley per day in two divided meals, according to appetite, as the intervention. The control group will take a tablet of mefenamic acid at 250 mg twice daily during menstruation for three consecutive cycles. Patients will be assessed for pain using changes in the Working ability, Location, Intensity, Days of pain, Dysmenorrhea (WaLIDD) score and the Visual Analog Scale (VAS) score on the first three days of the menstrual cycle over four consecutive cycles (the first cycle after registration for baseline assessment followed by three consecutive cycles for after-treatment assessment). Statistical analysis will be conducted using a paired t-test and Chi-square test, with statistical significance set at p-value ≤0.05.

Keywords: Days of pain, Inflammation, Intensity, Location, Menstruation, Visual analogue scale, Working ability

INTRODUCTION

"Cramping pain that occurs just before or during menstruation in the lower abdomen, radiating to the lower back and thighs, which is not associated with any other pelvic pathology, is known as primary dysmenorrhoea" [1]. The prevalence of menstrual pain is high among women of reproductive age [2]. Dysmenorrhoea in adolescent women severely affects their daily activities and quality of life [3]. The menstrual cycle in females has been termed *Rituchakra* in Ayurveda. This physiological process of menstruation (*Rituchakra*) can be assessed clinically by the symptoms of ovulation (*ritumati lakshan*) and the characteristics of menstrual blood (*shuddha artava lakshan*). According to Ayurveda, normal menstruation bleeding (*Shuddha artava*) is defined as occurring once a month without pain and burning, with the excreted menstrual blood being thin and watery (i.e., without clots), moderate in amount (neither scanty nor excessive) and resembling the colour of a red lotus flower, red lac, or rabbit's blood [4]. Deviations from *shuddha artava lakshan*, particularly in terms of pain, are seen as a condition known as primary dysmenorrhoea, where there is no known pathology. In Ayurveda, dysmenorrhoea is not classified as a separate disease entity. The term *Krichartava* is used for dysmenorrhoea and is described as a symptom of various other gynaecological pathologies (*yoni roga*) [5]. In the classics, it is mentioned that one should observe a specific diet and lifestyle regimen (*Rajaswala paricharya*) during menstruation, which will result in *shuddha artava lakshan* (i.e., menstrual blood signs and symptoms indicative of good reproductive health in women). The diet prescribed during menstruation as *Rajaswala paricharya* is *yava* (Hordeum vulgare or barley) processed with cow's milk as porridge, which should be consumed in moderation (not to the point of full satiety) according to appetite. Observing this diet during menstruation in otherwise healthy women is believed to produce *shuddha artava* (i.e., a painless, healthy menstrual cycle) [6-8].

Several theories exist regarding the pathophysiology of primary dysmenorrhoea; however, one of the most convincing is the increased synthesis of prostaglandins (types E2 and F2α) {Cyclooxygenase (COX) metabolite of arachidonic acid} [9]. Elevated levels of prostaglandins lead to vasoconstriction and ischaemia, resulting in dysrhythmic uterine contractions and pain. The modern medical treatment for dysmenorrhoea (primary dysmenorrhoea) includes NSAIDs and Oral Contraceptive Pills (OCPs). These medications may produce certain side-effects, such as gastrointestinal disturbances, stomach ulcers, allergic reactions, etc. [10]. Research has been conducted to identify effective pharmacological treatments for dysmenorrhoea [11,12]; however, no studies have focused on exploring dietary solutions for this condition.

REVIEW OF LITERATURE

While global health initiatives often prioritise adolescent reproductive health and sanitation, they frequently neglect the traditional practices

endorsed by Ayurveda. Ayurvedic practitioners play a vital role in promoting *Rajaswala paricharya* as a means to enhance female reproductive health. This approach is designed to prevent *Dosha* imbalances, mitigate the formation of *Ama* and strengthen *Agni*. Adherence to these guidelines may enable women to experience a reduction in menstrual symptoms and better manage the physiological and psychological changes associated with menstruation.

A systematic review conducted by Proctor ML and Murphy PA, which included seven Randomised Controlled Trials (RCTs), concluded that magnesium, vitamin B6 and vitamin B1 are effective in relieving menstrual pain while also taking adverse effects into account [12]. Furthermore, Pattanittum P et al., conducted a systematic review encompassing 27 RCTs and found that herbal interventions, such as fennel, fenugreek, cinnamon, damask rose, guava and rhubarb, demonstrate efficacy comparable to that of NSAIDs in the treatment of menstrual pain [11].

An in-vitro experimental study by Zdun´czyk Z et al., revealed that barley, husked oat, naked oat and buckwheat waste possess antioxidant properties. A diet enriched with barley was shown to enhance the activity of Glutathione Peroxidase (GPx) while reducing the levels of thiobarbituric acid reactive substances [13]. Kulkarni DV et al., indicated in their review article that barley exhibits antioxidant, anticholesterol and oestrogenic activities, as well as inducing apoptosis due to the presence of phenolic acids, flavonoids, lignans, tocopherols, phytosterols and folate [14]. In a similar vein, Xu Y et al., demonstrated in their meta-analysis that whole grains have an inverse association with inflammatory markers, including C-reactive protein, IL-6 and TNF [15].

Moreover, Lee YS et al., reported in an in-vitro study that LOMEN P0, a mixed extract of *Hordeum vulgare* (barley) and *Chrysanthemum zawadskii*, inhibited prolactin secretion in hyperprolactinaemic mice, normalised hormonal imbalances and significantly diminished inflammatory marker expression in uterine tissue [16].

The present study aims to evaluate and compare the efficacy of the *Rajaswala paricharya* diet-specifically, a barley porridge diet-against routine care involving mefenamic acid in the management of primary dysmenorrhoea.

Primary objective:

- To evaluate the efficacy of the *Rajaswala paricharya* diet (*Yavanna*- barley porridge diet) in primary dysmenorrhoea.
- To evaluate the efficacy of routine care (Mefenamic Acid) in primary dysmenorrhoea.

Secondary Objective: To compare the efficacy of the *Rajaswala paricharya diet* (*Yavanna*- barley porridge diet) and routine care (Mefenamic Acid) in primary dysmenorrhoea.

Null hypothesis: The *Rajaswala paricharya diet* (*Yavanna*-barley porridge diet) will not be as efficacious as mefenamic acid in primary dysmenorrhoea.

Alternate hypothesis: The *Rajaswala paricharya diet* (*yavanna*-barley porridge diet) will be equally or more efficacious than mefenamic acid in in primary dysmenorrhoea.

MATERIALS AND METHODS

A single-centred, randomised, single-blinded, parallel-group controlled trial will be conducted at MGACH in Wardha, Maharashtra, India. Participants will be allocated to either the intervention or control group in a 1:1 ratio. This study design adheres to the Standard Procedure Items Recommendations for Interventional Trials (SPIRIT) guidelines. This study has been approved by the Institutional Ethics Committee of MGACH in Wardha, Maharashtra, India, under the approval number MGACHRC/IEC/Sep2023/776. It has also been registered with the Clinical Trial Registry of India as CTRI/2024/05/067559. The study will be conducted over three consecutive menstrual cycles for each patient from July 2024 to March 2025.

Female patients experiencing pain during menstruation, who attend the Outpatient Department (OPD) or screening camps at MGACHRC in Sawangi, Wardha, will be screened for eligibility. Only those who provide prior written consent will be enrolled in the study. The investigator (researcher) will remain blinded to the treatment assignments of the participants.

Following a baseline assessment by the investigator, each patient will be assigned to a pharmacist, who will implement the intervention and control treatments according to a randomised table. The pharmacist will explain to the patients how to prepare and take the intervention diet, including the timing and method of consumption. The pharmacist will receive training from the investigating researcher regarding these responsibilities. Blinding will only be revealed in cases of adverse events or emergencies.

Eligibility criteria:

Inclusion criteria:

- Females willing to provide written informed consent.
- Patients diagnosed with primary dysmenorrhoea.
- Age group 18-25 years.
- Females suffering from painful menstruation with at least three consecutive regular menstrual cycles (21-35 days) with normal bleeding.
- Patients with moderate dysmenorrhoea (as per WaLIDD score) [17].

Exclusion criteria:

- Subjects aged below 18 or above 25 years.
- Patients undergoing any hormonal therapy.
- Subjects with hormonal abnormalities such as hypothyroidism, hyperthyroidism, or polycystic ovarian disease.
- Subjects with pathological conditions such as fibroid uterus, endometriosis, adenomyosis, etc.
- Subjects with painful menstruation due to any other gynaecological pathology (secondary dysmenorrhoea).
- Subjects taking any contraceptives or IUCDs.

Sample size calculation: Based on the evaluation of a previous study [18], the baseline mean VAS score is found to be 5.29 and the post-treatment score (after mefenamic acid) at 12 weeks is found to be 2.82. The difference in VAS scores pre- and post-treatment is considered the main effect. Taking 12.3% as the equivalence margin, with α=5% and β=10%, the sample size is calculated to be 70 per group, considering a 1:1 allocation ratio. Considering a 10% dropout rate, the adjusted sample size is calculated as 77 per group. The formula used for sample size calculation is as follows:

$$n=\frac{(Z\alpha+Z\beta)^2 \{P_1 (1-P_1) + (P_2 (1-P_2)\}}{(\delta)^2}$$

$N=(1.64+1.28)^2\times(0.529)\ (1-0.529)+0.282\ (1-0.282)/(0.123)^2$

Sample size (N)=70 per group.

Drop out 10%=7

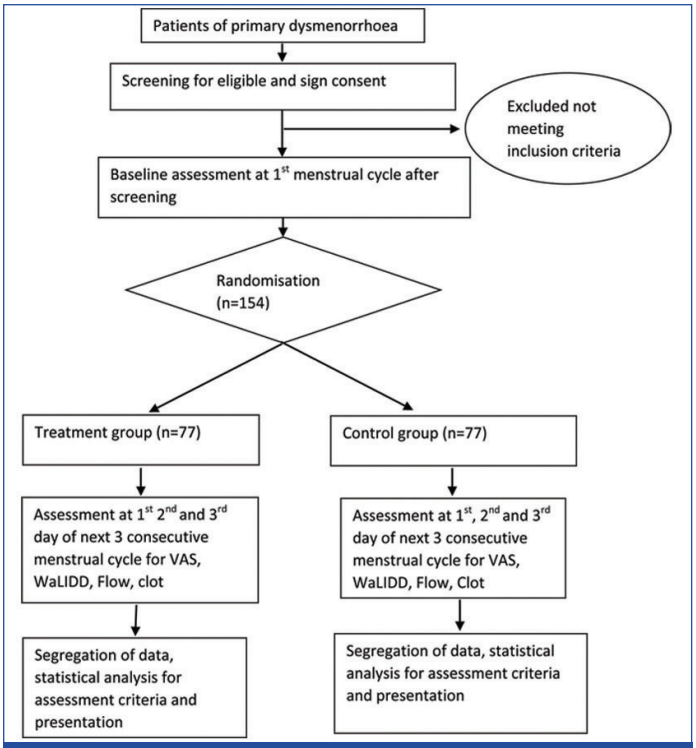
Total sample size=77.

The adjusted sample size is therefore 154, i.e., 77 participants per group, with an allocation ratio of 1:1 [Table/Fig-1].

Intervention

The experimental group will follow a dietary intervention involving hulled barley porridge prepared with cow's milk. Patients will receive hulled barley and will prepare the porridge independently, adhering to the following instructions provided by the pharmacist:

Soak approximately 50-75 grams of hulled barley (*Yava*) for a duration of three to four hours. The quantity may be adjusted based on individual appetite; however, the porridge should constitute the primary component of the diet. Upon completion of soaking, drain



[Table/Fig-1]: Consort flow diagram.

and rinse the barley. Then add a volume of water equal to four times the amount of soaked barley. Combine the barley with cow's milk and cook in a covered pan over low heat until the barley is sufficiently softened. The grains should be tender enough to be easily mashed with fingers, which typically requires about 40 minutes. Sweeten with sugar according to individual taste preferences.

Patients are instructed to adhere to this dietary regimen from the first day of menstrual bleeding through to the last day, consuming two portions daily with a total intake of 100 to 250 grams, divided into two meals based on appetite.

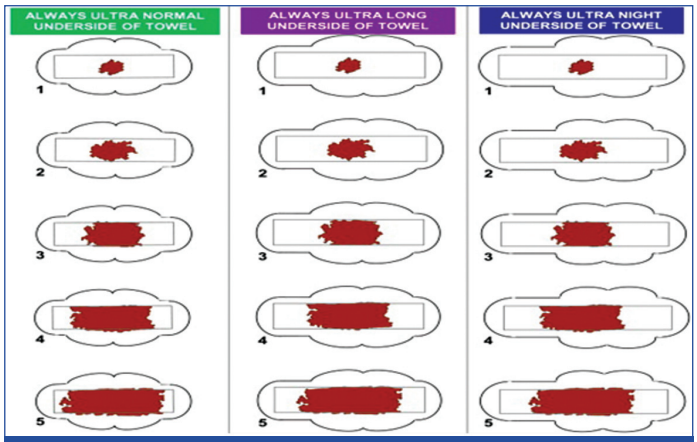
In contrast, the control group will receive mefenamic acid tablets at a dosage of 250 mg, to be taken twice daily from the first day of menstrual bleeding to the last day, for three consecutive menstrual cycles.

Primary outcome: The primary outcome of this study is pain. Pain will be assessed using two scales: first, the VAS and secondly, the WaLIDD score for dysmenorrhoea.

Visual Analogue Scale (VAS) [19]: This is a psychometric response scale consisting of a 10 cm long horizontal line with defining statements and scores. At the extreme left, at 0 cm, represents no pain (0 score), with increments at every 2 cm corresponding to mild, moderate, severe and very severe pain (scores 2, 4, 6 and 8, respectively). At the extreme right, at 10 cm, is the worst pain ever (score 10).

WaLIDD score: This is a validated tool for assessing pain in dysmenorrhoea. Scoring for each component of WaLIDD will be done and then, based on the total of the above components, a grading for dysmenorrhoea will be provided [17]. Pain assessment using both scales will be conducted on the first three days of the menstrual cycle for four consecutive menstrual cycles (the first cycle after registration will be assessed for baseline assessment and the next three consecutive cycles will be assessed after administering the intervention). The mean value will be considered for analysis.

Secondary outcome: Blood flow will be assessed using Pictorial Blood Loss Assessment Charts (PBAC) [20]. Patients will be instructed to use only whisper ultra-pads during menstruation. Scoring will be done by the patient according to the chart provided on the first day of menstruation, with the patient changing the pad every six hours and noting the score [Table/Fig-2]. The mean of the scores will be used for assessment.



[Table/Fig-2]: The prototype menstrual pictogram (SAP-c version) [20]. Image Courtesy:* [20].

Assessment for Clots in Menstrual Blood

The presence of a clot will be scored by the patient based on bleeding experienced on the 1st, 2nd and 3rd days. The maximum size of the clot observed during the first three days of bleeding will be recorded at the end of the 3rd day. The scoring criteria are as follows:

- No clots/ thin watery bleeding: 0
- Clots in the form of small fibrin threads: 1
- Thick clots of size 1 cm: 2
- Thick clots of size more than 1 cm: 3

STATISTICAL ANALYSIS

Statistical assessment: Statistical analysis will be performed using IBM Statistical Package for the Social Sciences (SPSS) software version 16.0. Variables will be presented as means along with their standard deviations. The analysis will involve the application of the paired t-test and the Mann-Whitney U test for continuous variables. Categorical variables will be evaluated using the Chi-square test. A confidence interval of 95% will be established and a p-value of ≤0.05 will be considered statistically significant.

Study timeline and assessment: VAS, WaLIDD, blood flow and clot size assessment charts will be provided to the patients. Patients will be reminded telephonically and encouraged to adhere to the intervention and to record their scores according to the provided charts on the first three days of the menstrual cycle. The study timeline is shown in [Table/Fig-3].

Timepoint	Enrolment/ screening	3rd day of menstrual cycle after enrolment	Postallocation 1st cycle			Postallocation 2nd cycle			Postallocation 3rd cycle		
Visit	0	1	1st day	2nd day	3rd day	1st day	2nd day	3rd day	1st day	2nd day	3rd day
Written consent	X										
Demographic information	X										
Physical examination	X										
Investigation	X										
Explain about assessment chart	X	X									

Allocation		X									
Baseline assessment		X									
Intervention			X	X	X	x	X	X	x	x	X
VAS		X	X	X	X	x	X	X	x	x	X
WaLIDD		X	X	X	X	x	X	X	x	x	X
Flow		X	X	X	X	x	X	X	x	x	X
Clot size		X			X			X			X
Intervention			X	X	X	x	X	X	x	x	X
Adverse event			X	X	X	x	X	X	x	x	X

[Table/Fig-3]: Timeline of the study.

Authors contribution: All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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