DOI: 10.7860/JCDR/2025/81095.21998

Research Protocol

Ayurveda Section

Effect of the *Havishya* Diet (*Rajaswala Paricharya*) versus Routine Care in Managing Menstrual Disorders: A Randomised Controlled Trial Protocol

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ABSTRACT

Introduction: In India, over 50% of females under the age of 30 years experience symptoms such as lower abdominal pain, lower backache, changes in bowel function, difficulty concentrating and reduced physical and mental efficiency during their menstrual cycles. There is a pressing need for strategies that facilitate trouble-free menstruation, thereby enhancing the productivity of students and working women.

Need of the study: Although menstrual disorders are not life-threatening, they significantly affect Quality of Life (QOL). Therefore, it is crucial to develop a dietary management strategy that is safe, simple to follow and effective in addressing menstrual disorders. Such an approach could provide valuable options for women seeking natural, non pharmaceutical treatments.

Aim: To evaluate the efficacy of the *Havishya* diet (rice porridge) compared with routine lifestyle practices in managing menstrual disorders.

Materials and Methods: This open-label, single-centre, parallel, randomised controlled trial will be conducted at Central Ayurveda Research Institute (CARI), Punjabi Bagh, New Delhi, India, over three consecutive menstrual cycles (three months) from December 2024 to November 2025. A total of 136 participants will be enrolled, accounting for a 10% dropout rate, with 68 participants in each group. The trial group will follow the *Rajaswala Paricharya* diet, consuming 200–250 grams of rice porridge daily, divided into two meals according to appetite. The control group will maintain a routine lifestyle without adopting the *Havishya* diet for the same duration. Participants will be assessed using the Visual Analogue Scale (VAS) for lower abdominal pain, the Patient Health Questionnaire-9 (PHQ-9) for psychological stress and the Bristol Stool Scale (BSS) for Gastrointestinal (GI) movements on the fifth day of their menstrual cycle prior to the intervention. Changes in these measures will be evaluated on the fifth day of the menstrual cycle following the intervention across the three cycles. The first cycle will serve as the baseline assessment, followed by evaluations during the subsequent cycles. Statistical analysis will be performed using paired t-tests and Chi-square tests, with statistical significance set at $p \leq 0.05$.

Keywords: Bristol stool scale, Lower abdominal pain, Patient health questionnaire-9, Psychological stress, Visual analogue scale

INTRODUCTION

Menstrual disorders encompass a range of physical and psychological changes that occur before and during menstruation. Most women experience some level of pain during their menstrual cycle, along with other symptoms such as diarrhoea, vomiting, dizziness, difficulty concentrating, headaches and nausea [1]. Physiological symptoms of menstrual disorders can include bloating, swollen or tender breasts, changes in appetite, hard stools and fatigue. Psychological symptoms may involve sleep disturbances (either excessive or insufficient sleep), food cravings, mood swings, tension or anxiety, irritability or hostile behaviour, difficulties with concentration or memory and feelings of sadness or depression [2]. The intensity of these symptoms can range from moderate to severe. Common medical treatments for menstrual disorders include Non Steroidal Anti-Inflammatory Drugs (NSAIDs) as prostaglandin inhibitors, oral contraceptives that inhibit ovulation, hormonal therapies, vitamin supplements, dietary modifications and regular exercise. Exercise is particularly beneficial as it releases endorphins, which are natural chemicals that help relieve pain [3–5].

In Ayurveda, "Shuddh Aartava," or pure menstruation, is a key concept. It is considered one of the four essential factors for successful conception. A menstrual cycle free from discomfort indicates optimal reproductive health. Menstruation without any disorders is regarded as a sign of a well-balanced physiological state conducive to a healthy reproductive system [6].

The Ayurvedic classics emphasise the importance of a specific lifestyle and dietary regimen (referred to as *Rajaswalacharya*) to be followed during menstruation. *Acharya Sushrut* specifically recommended a diet of *Havishya* (rice porridge) for the first three days of menstruation [5].

The present study aims to evaluate and compare the efficacy of the *Rajaswala Paricharya* diet, specifically *Havishya* (rice porridge), against routine care in the management of menstrual disorders.

Primary objective:

- To evaluate the effect of the *Rajaswala Paricharya* diet (*Havishya*—rice porridge) in menstrual disorders.
- To evaluate the efficacy of routine care management in menstrual disorders.

Secondary objective: To compare the efficacy of the *Rajaswala Paricharya* diet (*Havishya*—rice porridge) and routine care management in menstrual disorders.

Hypothesis

Null hypothesis: There is no significant difference in efficacy between the *Havishya* (rice porridge) *Rajaswala Paricharya* diet and routine care without *Havishya* (rice porridge) in menstrual disorders.

Alternate hypothesis: The *Havishya* (rice porridge) *Rajaswala Paricharya* diet will be more efficacious than routine care without *Havishya* (rice porridge) in menstrual disorders.

REVIEW OF LITERATURE

The prevalence of dysmenorrhoea, a common menstrual disorder, is reported to be around 80% among adolescents and ranges from 16-91% in individuals of reproductive age, with severe pain experienced by 2-29% of this population. Additionally, menstrual disorders can account for up to 12% of monthly absences from work or school. The prevalence of Premenstrual Syndrome (PMS) has been reported to range between 20% and 32% in premenopausal women and 30% to 40% in the reproductive female population. In India, the estimated prevalence of menstrual disorders is approximately 43%, with most studies focusing on adolescent and college-aged females [4].

A study conducted on the impact of menstruation on the daily routines of students at a medical college in Delhi, India [7], aimed to explore the prevalence of menstrual disorders among unmarried undergraduate medical students and their treatment-seeking behaviours. All participants completed a pretested, semistructured questionnaire. Data analysis revealed that PMS (67%) and dysmenorrhoea (33%) were perceived by the participants as the most distressing menstrual challenges. The most common effects on daily routines included prolonged resting hours (54%) and inability to study (50%) [7]. More than half of the participants (52%) discussed their concerns with their mothers and 60% opted for allopathic treatment for their menstrual issues [7]. These observations highlight the need for careful evaluation of unaddressed menstrual problems, as they can adversely affect daily routines and QoL.

A clinical study by Pai P et al., examined the impact of *Rajaswala Paricharya* on menstrual cycles and associated symptoms, reporting a significant increase in compliance and indicating benefits of the intervention. This research suggests that *Rajaswala Paricharya* helps women cope with the significant physical and psychological changes during their menstrual cycle, effectively reducing many associated symptoms [8]. These findings emphasise the importance of addressing untreated menstrual problems due to their potential impact on daily routines and QoL.

In recognition of the need for effective alternatives, other health systems such as Ayurveda offer promising approaches. A holistic perspective, grounded in the principles of *doshas, dhatus* and *malas*, is central to Ayurvedic medicine. Ayurvedic literature indicates that menstruation-related symptoms often arise from nonadherence to '*Rajaswala Charya*,' a guiding code for this period. Following *Rajaswala Paricharya* can empower women to manage the physical and mental stress associated with menstruation, ultimately alleviating symptoms and fostering resilience [9-11].

The present study aims to evaluate and compare the efficacy of the *Rajaswala Paricharya* diet, specifically *Havishya* (rice porridge), against routine care in the management of menstrual disorders.

MATERIALS AND METHODS

A single-centre, randomised, parallel-group controlled trial will be conducted at the Central Ayurveda Research Institute (CARI), Punjabi Bagh (West), New Delhi, India, with participants allocated to either the intervention or control group in a 1:1 ratio. This study design adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines. The study has been approved by the Institutional Ethics Committee of MGACH, Wardha, Maharashtra, India (Approval No.: MGACHRC/IEC/March 2023/700) and the Institutional Ethics Committee of CARI, Punjabi Bagh (West), New Delhi, India (Approval No.: F.No.-1-12/2020-CARICD/Tech/IEC/Dec 2024/605). It is also registered with the Clinical Trial Registry of India (CTRI/2024/05/068187).

The study will be conducted over three consecutive menstrual cycles for each participant, from December 2024 to November 2025. Female patients experiencing pain and stress during menstruation, who attend the Outpatient Department (OPD) or screening camps at CARI, will be screened for eligibility. Only those providing prior written consent will be enrolled.

Participants will be randomised using a computer-generated simple randomisation method for treatment assignment. Following a baseline assessment, the investigator will implement the intervention and control treatments according to the randomised allocation table. The investigator will provide detailed instructions on preparing and consuming the intervention diet, including timing and method of consumption.

Inclusion criteria: Female participants willing to provide written informed consent, patients diagnosed with menstrual disorders, age between 18 and 25 years, patients experiencing menstrual disorders for at least the past two consecutive cycles will be included in the study.

Exclusion criteria: Participants age below 18 or above 25 years, patients with hormonal abnormalities receiving hormonal therapy, patients with detectable organic pelvic pathology, patients with major systemic diseases will be excluded from the study.

Sample size calculation: The formula used for sample size calculation is as follows:

$n=\{2 * (Z(1-\alpha/2)+Z(1-\beta))^2 * \sigma^2\}/d^2$

Where:

- n=required sample size per group
- $Z(1-\alpha/2)$=Z-score for significance level (1.96 for α=0.05, two-sided)
- $Z(1-\beta)$=Z-score for desired power (0.84 for 80% power)
- σ=standard deviation (assumed to be 1.0 based on prior data) [8]

$n=\{2 * (1.96+0.84)^2 * (1.0)^2\}/(0.48)^2$

$n=\{2 * (2.8)^2 * 1\}/0.2304$

$n=\{2 * 7.84\}/0.2304$

$n=15.68/0.2304\approx68$

n=68 participants per group

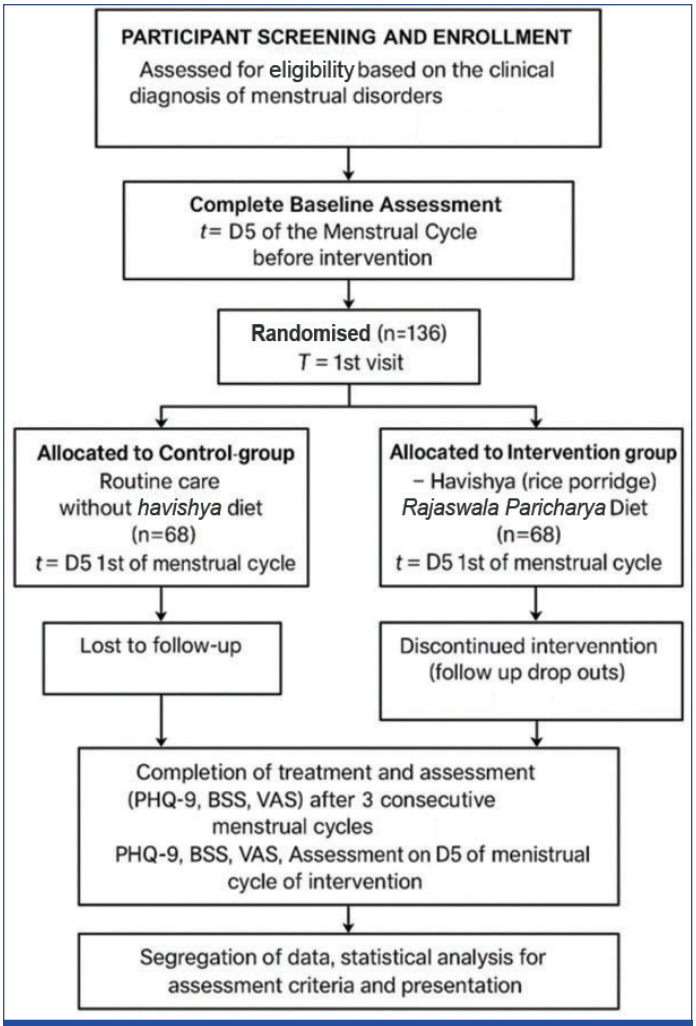
To compare two independent means, standard formula was used, assuming a significance level of 5% (two-sided), a power of 80%, a standard deviation of 1.0 and a minimum clinically important difference of 0.48 points on the VAS. The required sample size was calculated to be 68 participants per group. This estimation is consistent with findings from previous studies [8] and includes a 10% adjustment for expected dropouts, resulting in a total required sample size of 136 participants [Table/Fig-1].

Intervention

The experimental group will participate in a dietary intervention involving the preparation of rice porridge using cow's milk. Participants will receive rice and will prepare the porridge independently by following instructions provided by the researcher.

Preparation method:

1. Clean approximately 50 grams of rice with water and set it aside for two to three minutes. The amount of rice can be adjusted according to individual appetite, but it should remain the primary component of the diet.
2. Boil 500 mL of water and mix it with 250 mL of cow's milk.
3. Add the cleaned rice to the mixture in a pan and cook over low heat until the grains are sufficiently softened. The rice should be tender enough to be easily mashed with fingers, typically taking about 30–40 minutes.



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

4. At the end of cooking, add 20 mL of cow ghee and sweeten the porridge with sugar according to individual taste preferences.

Participants are instructed to follow this dietary regimen for the first three days of their menstrual cycle over three consecutive cycles, consuming two portions daily. The total intake should range between 350 and 400 grams, divided into two meals, depending on individual appetite.

The control group will continue their routine care without following the *Rajaswala Paricharya* diet during the first three days of their menstrual cycle for three consecutive cycles.

Strategies to Improve Adherence to the Study Protocol

Dietary adherence will be assessed at each follow-up visit (on the fifth day of each menstrual cycle) by evaluating the approximate quantity consumed. Participants will also receive repeated phone reminders regarding the prescribed diet and its timing.

Outcome Measures

Primary Outcome Measures:

1. **Psychological Stress- PHQ-9 [12]:** Psychological stress will be evaluated using the PHQ-9, a validated tool for assessing the severity of depressive symptoms. This questionnaire consists of nine items rated on a 4-point Likert scale:

   Not at all (0)

   Several days (1)

   More than half the days (2)

   Nearly every day (3)

   The total score ranges from 0 to 27 and is interpreted as follows:

   0-4: Minimal or no depression

   5-9: Mild depression

   10-14: Moderate depression

   15-19: Moderately severe depression

   20-27: Severe depression

   The PHQ-9 will be assessed at baseline and on the fifth day of menstruation following the intervention for three consecutive cycles. A reduction in the PHQ-9 score will indicate improvement in psychological wellbeing.

2. **Lower Abdominal Pain -VAS [13]:** The severity of pain will be measured using VAS, a reliable tool for evaluating subjective pain levels. The scale consists of a 10 cm horizontal line with endpoints labelled as:

   0 cm: No pain

   10 cm: Worst imaginable pain

   Participants will mark their pain level on the line at baseline and on the fifth day of menstruation following the dietary intervention for three consecutive cycles. The distance from the "no pain" end to the mark provides the pain score. A lower postintervention score indicates reduced pain intensity.

Secondary Outcome Measure

Gastrointestinal (GI) Movement - Bristol Stool Scale (BSS) [14]: To assess changes in GI movements during menstruation, the BSS will serve as a secondary outcome measure. The BSS categorises stool into seven types, reflecting colonic transit time and bowel function:

1. Separate hard lumps, like nuts
2. Sausage-shaped but lumpy
3. Like a sausage but with cracks on the surface
4. Like a sausage or snake, smooth and soft (normal)
5. Soft blobs with clear-cut edges
6. Fluffy pieces with ragged edges, mushy
7. Watery, no solid pieces (diarrhoea)

Participants will self-report their stool type at baseline and on the fifth day of menstruation following the intervention for three consecutive cycles. Movement toward Types 3–4 will be considered normalisation of bowel function, while deviations toward Types 1–2 (constipation) or Types 6–7 (diarrhoea) indicate altered GI motility. This measure will help determine whether the rice porridge diet stabilises bowel habits during menstruation.

STATISTICAL ANALYSIS

Primary Outcome Analysis

1. Psychological Stress (PHQ-9)
2. Lower Abdominal Pain (VAS)

Within-group analysis:

- Repeated measures across the three cycles (baseline, cycle 1, cycle 2, cycle 3) will be analysed using:
  - Repeated Measures ANOVA (for normally distributed data), or
  - Friedman test (for non parametric data)
- Post-hoc pairwise comparisons (e.g., Bonferroni correction) will be used to assess changes over time within each group.

Between-group analysis:

- Mixed-design ANOVA (also known as split-plot ANOVA) will be used to assess the interaction between time (within-subject factor) and group (between-subject factor).
- If assumptions are violated, non parametric alternatives will be employed, such as the Mann-Whitney U test (for between-group comparisons at each time point) and Friedman + Wilcoxon tests (for within-group comparisons).

The primary analysis will focus on the difference in change over time in PHQ-9 and VAS scores between the intervention and control groups. Effect sizes (Cohen's d or partial eta squared) will be calculated.

Secondary Outcome Analysis:

3. Gastrointestinal (GI) Function (BSS)

Within-group analysis:

- Stool form will be assessed as ordinal data using the Friedman test within each group across baseline and the fifth day of each cycle.
- Pairwise comparisons using the Wilcoxon signed-rank test will be conducted if the Friedman test is significant.

Between-Group Analysis:

- At each cycle, BSS scores will be compared between groups using:
  - Mann-Whitney U test for ordinal data, or
  - Dichotomising stool types into "normal" (Type 3–4) vs. "abnormal" (Type 1–2 or 6–7) and using Chi-square or Fisher's exact test.

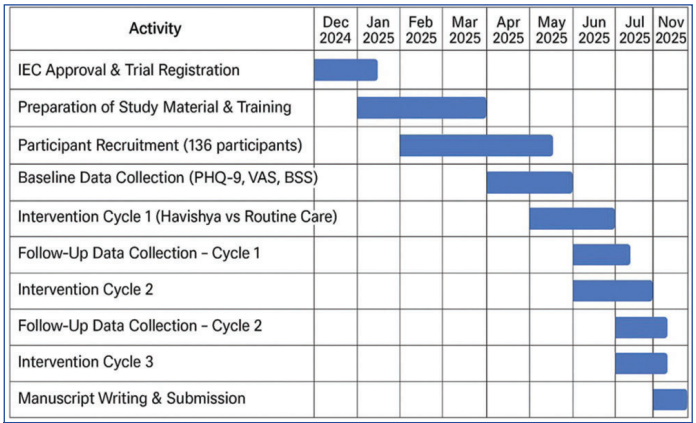
Trend analysis will be used to evaluate the direction and consistency of GI function changes both within and between groups.

Handling of missing data:

- Intention-to-Treat (ITT) analysis will be employed.
- Missing values will be handled using multiple imputation or Last Observation Carried Forward (LOCF) methods, as appropriate.

Statistical Software: All analyses will be conducted using Statistical Package for the Social Sciences (SPSS) (version 29.0) R (version 4.5.1), or Stata. A two-tailed p-value <0.05 will be considered statistically significant.

Study timeline and assessment: The study timeline is shown in the Gantt chart [Table/Fig-2]. Patients will be reminded via telephone and encouraged to adhere to the intervention. PHQ-9, VAS and BSS assessment scores will be recorded according to the timeline for the fifth day of the menstrual cycle for three consecutive cycles [Table/Fig-3].



[Table/Fig-2]: Gantt chart.

Cycle	Day	Trial /Control group	PHQ-9	VAS	BSS
Cycle 1	Day 1	□			
	Day 2	□			
	Day 3	□			
	Day 5		□	□	□
Cycle 2	Day 1	□			
	Day 2	□			
	Day 3	□			
	Day 5		□	□	□
Cycle 3	Day 1	□			
	Day 2	□			
	Day 3	□			
	Day 5		□	□	□

[Table/Fig-3]: Study timeline and assessment.

Authors contribution: All authors made significant contributions to the work reported, including conception, study design, execution, data acquisition, analysis and interpretation. All authors participated in drafting, revising, or critically reviewing the manuscript, provided final approval of the version to be published, agreed on the journal to which the article was submitted and accept accountability for all aspects of the work.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Aug 08, 2025
- Manual Googling: Aug 23, 2025
- iThenticate Software: Aug 25, 2025 (17%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval Obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Jun 03, 2025**
Date of Peer Review: **Jul 17, 2025**
Date of Acceptance: **Aug 27, 2025**
Date of Publishing: **Oct 01, 2025**