Research Article

www.ijrap.net

(ISSN Online:2229–3566, ISSN Print:2277–4343)

A PROSPECTIVE, SINGLE-ARM CLINICAL EVALUATION OF PRINKWELLNESS VAGINAL SUPPOSITORIES IN THE MANAGEMENT OF PRIMARY DYSMENORRHEA

K. Hemalatha [1], Nagarjuna Mummidi [2]*, Srivatsa GS [3], Rajasekhar G [4]

[1] Principal Investigator, Udhbhava Hospital, Ittamadu, Banashankari, 3rd Stage, Bengaluru, Karnataka, India

[2] Co-Founder, Prinkwellness (Hyd Hemp India Private Limited), Hyderabad, Telangana, India

[3] Managing Director, Samahitha Research Solutions, Bengaluru, Karnataka, India

[4] Co-Founder, Prinkwellness (Hyd Hemp India Private Limited), Hyderabad, Telangana, India

Received on: 20/12/25 Accepted on: 28/1/26

***Corresponding author**

E-mail: nagarjuna2425@gmail.com

DOI: 10.7897/2277-4343.17112

ABSTRACT

Background: Primary dysmenorrhea is a common gynaecological condition associated with recurrent menstrual pain and reduced quality of life. Limitations of long-term systemic therapies have encouraged exploration of localized treatment options. Objective: To evaluate the safety and efficacy of Prinkwellness vaginal suppositories in the management of primary dysmenorrhea. Materials and Methods: This prospective, single-arm, open-label clinical study was conducted at a single center. A total of 100 women aged 18–50 years with primary dysmenorrhea were enrolled, and 90 participants completed the study. Prinkwellness vaginal suppositories were administered over two consecutive menstrual cycles at doses of 100 mg in the first cycle and 120 mg in the second cycle. Pain intensity was assessed using the Visual Analogue Scale (VAS) at Baseline (Day 0), Day 30, and Day 60. Health-related quality of life was evaluated using the Short Form-36 (SF-36) questionnaire at Day 30 and Day 60. Safety was assessed through monitoring of adverse events and treatment tolerability. Results: Mean VAS pain scores decreased significantly from 8.02 ± 1.35 at Baseline to 1.68 ± 0.89 at Day 60 ($p < 0.0001$). Improvements were observed across multiple SF-36 domains. No serious adverse events were reported. Conclusion: Prinkwellness vaginal suppositories were associated with significant reduction in menstrual pain and improvement in quality of life, with a favourable safety and tolerability profile.

Keywords: Primary dysmenorrhea, Menstrual cramps, Vaginal suppositories, Visual Analogue Scale, Quality of life, SF-36.

INTRODUCTION

Primary dysmenorrhea is a common gynaecological condition characterized by recurrent, cramp-like pain during menstruation in the absence of identifiable pelvic pathology.[1] It typically begins within 6–12 months of menarche, coinciding with the establishment of ovulatory cycles, and is most prevalent among adolescents and young women.[2] Clinically, primary dysmenorrhea presents with lower abdominal pain that may radiate to the back and thighs and is frequently accompanied by systemic symptoms such as nausea, vomiting, diarrhoea, headache, fatigue, and dizziness.[3] These symptoms can range from mild discomfort to severe pain requiring medical intervention.

Globally, dysmenorrhea affects a substantial proportion of menstruating women, with prevalence estimates ranging from 50% to 90% depending on age group, diagnostic criteria, and population studied.[4,5] Epidemiological data indicate that primary dysmenorrhea accounts for the majority of dysmenorrhea cases, particularly in adolescents and young adults.[4] Despite its high prevalence, dysmenorrhea remains under-recognized and undertreated, often due to sociocultural normalization of menstrual pain and limited healthcare-seeking behavior.[6] The condition is a leading cause of school and work absenteeism and is associated with reduced academic performance, decreased productivity, and impaired psychosocial well-being.[7]

The underlying pathophysiology of primary dysmenorrhea is closely linked to excessive synthesis and release of uterine prostaglandins, particularly prostaglandin F2α and prostaglandin E2, during the late luteal and menstrual phases of the cycle.[8] Elevated prostaglandin levels result in increased uterine contractility, heightened basal tone, reduced uterine blood flow, and localized ischemia, which collectively contribute to pain generation.[9] Additional mediators, including leukotrienes, vasopressin, and inflammatory cytokines, may further amplify nociceptive signaling and exacerbate uterine hyperactivity.[8,9]

Current management of primary dysmenorrhea primarily focuses on symptomatic relief. Non-steroidal anti-inflammatory drugs (NSAIDs) are considered first-line therapy due to their inhibition of cyclooxygenase enzymes and subsequent reduction in prostaglandin synthesis.[1,2] Hormonal therapies, including combined oral contraceptives and progestin-only regimens, are commonly used in women who do not respond adequately to NSAIDs or who desire contraception.[2] Although these treatments are effective for many patients, approximately 20–25% of women report inadequate pain relief or intolerance.[10] Additionally, NSAIDs may cause gastrointestinal disturbances, renal effects, and cardiovascular risks with prolonged use, while hormonal therapies may be associated with nausea, weight changes, mood disturbances, and contraindications in certain populations.[11] These limitations highlight the need for alternative or adjunctive therapeutic approaches that are safe, effective, and acceptable for long-term or repeated use.

Local drug delivery via the vaginal route offers a promising alternative for gynaecological conditions, including dysmenorrhea. Vaginal administration allows for targeted drug

absorption in the cervico-uterine region, bypasses first-pass hepatic metabolism, and may reduce systemic adverse effects compared with oral formulations.[12] Vaginal drug delivery systems have been explored for both local and systemic therapeutic purposes due to their favorable pharmacokinetic and tolerability profiles.[13] In the context of menstrual pain, localized therapy may provide direct relief by acting on uterine and pelvic tissues while minimizing systemic exposure.

Prinkwellness vaginal suppositories have been developed as a non-oral, localized intervention intended to provide symptomatic relief from menstrual cramps. The formulation is designed for vaginal administration, allowing gradual release and absorption of active constituents at body temperature. By offering a localized approach, such suppositories may address unmet needs among women seeking non-systemic or non-hormonal options for managing dysmenorrhea.

Given the high prevalence of primary dysmenorrhea, its significant impact on quality of life, and the limitations associated with existing systemic therapies, there is a clear clinical rationale for evaluating localized treatment options. Therefore, the present prospective, single-arm clinical study was undertaken to assess the safety, tolerability, and efficacy of Prinkwellness vaginal suppositories in women with primary dysmenorrhea, using validated pain and quality-of-life assessment tools.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, single-arm, open-label, single-centre clinical study conducted to evaluate the safety and efficacy of Prinkwellness vaginal suppositories in women with primary dysmenorrhea. The study was exploratory in nature and designed to assess changes in menstrual pain intensity and quality of life over two consecutive menstrual cycles.

Study Setting

The study was conducted at Udhbhava Hospital, Ittamadu, Banashankari 3rd Stage, Bengaluru, Karnataka, India. The site functioned as the sole investigative centre for participant recruitment, treatment administration, and follow-up assessments. Pranav Diabetes Center was not involved in participant recruitment, clinical procedures, data collection, analysis, or study conduct; its role was limited solely to providing independent ethical review and approval. A No Objection Certificate from Pranav Diabetes Center has been obtained to confirm absence of any conflict of interest.

Ethical Approval and Regulatory Compliance

Ethical clearance for the study was obtained from the Pranav Diabetes Center Ethics Committee prior to initiation of any study-related procedures.
Name of Ethics Committee: Pranav Diabetes Center Ethics Committee
Ethics Committee Approval: Obtained prior to study initiation
Type: Institutional Ethics Committee

Although the study was conducted at Udhbhava Hospital, ethical approval was obtained from the Pranav Diabetes Center Ethics Committee because the study site did not have a formally constituted and registered Institutional Ethics Committee at the time of study initiation. The approving Ethics Committee is an accredited and competent body authorized to review and approve clinical research protocols and provide ethical oversight for the conduct of the study at the specified site.

The Ethics Committee reviewed the complete study Protocol, Informed Consent Form, and all relevant study documents and approved the conduct of the study at Udhbhava Hospital. Written informed consent was obtained from all participants prior to enrollment.

The study was conducted in accordance with the Declaration of Helsinki (2013)[14] and adhered to ICH-GCP (E6 R2) guidelines.[15] Participant confidentiality and safety were maintained throughout the study duration.

Study Population

Women aged **18 to 50 years** with a documented history of primary dysmenorrhea were screened for eligibility. Primary dysmenorrhea was defined as recurrent menstrual pain occurring in the absence of identifiable pelvic pathology, based on clinical history and investigator assessment.[1]

Eligibility Criteria

Inclusion Criteria

- Females aged 18–50 years
- History of menstrual cramping pain for at least 6 months, lasting a minimum of 2 days per menstrual cycle
- Baseline VAS pain score ≥5
- Regular menstrual cycles
- Willingness to comply with study procedures and provide written informed consent

Exclusion Criteria

- Evidence of secondary dysmenorrhea (e.g., endometriosis, uterine fibroids, pelvic inflammatory disease)
- Use of intra-uterine contraceptive devices
- Pregnancy or lactation
- Presence of systemic illness or significant gynecological pathology
- Known hypersensitivity to vaginal dosage forms or study product components

Intervention and Dosage

Participants received Prinkwellness vaginal suppositories, to be administered intravaginally during two consecutive menstrual cycles:
Cycle 1: 100 mg suppository, once during menstruation
Cycle 2: 120 mg suppository, once during menstruation

Participants were instructed on proper vaginal administration techniques and advised not to use any other medications for menstrual pain relief during the study period.

Intervention Product Composition and Quality Control

The investigational product evaluated in this study, Prinkwellness vaginal suppositories, is a non-oral intravaginal formulation developed for the symptomatic management of primary dysmenorrhea. The formulation comprises natural ingredients selected for their physicochemical suitability for vaginal administration, including *Theobroma cacao* (Cocoa Butter), *Cera alba* (White Beeswax), *Cannabis sativa* extract (Hemp extract), and *Mentha piperita* (Peppermint essential oil).

All raw materials used in the preparation of the investigational product were procured from certified suppliers and were accompanied by valid Certificates of Analysis (COAs). Quality parameters verified through COAs included identity, purity, and relevant physicochemical characteristics. Cocoa Butter was assessed for melting point, acid value, peroxide value, iodine value, saponification value, and refractive index. White Beeswax

was evaluated for melting range, ester value, acid value, saponification value, and absence of adulterants. Peppermint essential oil met quality specifications for refractive index, specific gravity, optical rotation, and purity. Hemp extract was subjected to laboratory testing to confirm its identity and controlled constituent profile.

The formulation process was designed to ensure batch-to-batch consistency and suitability for intravaginal use. The suppositories were formulated to melt at body temperature, allowing localized delivery of the formulation while maintaining safety and tolerability. Copies of the Certificates of Analysis for all raw materials were maintained as part of quality documentation and were available for verification.

Study Procedures and Visit Schedule

Baseline Visit (Day 0): Informed consent, demographic data collection, medical and menstrual history, physical examination, vital signs, VAS assessment and investigational product dispensation.

Follow-up Visit (Day 30): Physical examination, vital signs, VAS assessment, SF-36 QOL questionnaire assessment, assessment of investigational product tolerability, adverse event monitoring and investigational product dispensation.

End-of-Study Visit (Day 60): Final physical examination, vital signs, VAS assessment, SF-36 QOL questionnaire assessment, documentation of symptom relief, tolerability, and adverse events.

Outcome Measures

Primary Outcome

Change in menstrual pain intensity from Baseline to Day 60, assessed using the Visual Analogue Scale (VAS), a validated 10-cm scale ranging from 0 (no pain) to 10 (worst imaginable pain).[16]

Secondary Outcome

Change in health-related quality of life was assessed using the Short Form-36 (SF-36) questionnaire, a widely used and validated generic health survey instrument comprising 36 items across eight health domains. The SF-36 questionnaire was obtained from the RAND Corporation and was used in accordance with permitted guidelines for non-commercial academic research, with appropriate attribution.[17]

Safety Assessment

Safety was evaluated throughout the study through monitoring of:

- Adverse events
- Physical examination findings
- Vital signs
- Overall tolerability of the vaginal suppository

All adverse events were recorded and assessed for severity and possible relationship to the study product.

Statistical Analysis

Continuous variables were summarized as mean ± standard deviation (SD). Changes from baseline in VAS and SF-36 scores were analyzed using paired t-tests. A p-value of <0.05 was considered statistically significant. Statistical analyses were performed using standard statistical methods.[18]

Table 1: Baseline demographic and clinical characteristics of study participants

Parameters	Mean	SD	Median	Min	Max	Count
Age	28.44	5.5	29	18	39	90
BMI	22.40	1.08	22.2	20	26.2	90
Respiratory Rate (bpm)	15.38	1.07	15	13	19	90
Pulse Rate (bpm)	72.13	3.06	72	65	80	90
Body Temperature	36.65	0.16	36.6	36.4	37.1	90
Systolic	116.88	4.53	116	108	130	90
Diastolic	74.98	3.25	74	68	85	90

Table 2: Participant disposition and study completion status

Category	Number of Participants (n)	Percentage (%)
Screened	100	100
Enrolled	100	100
Completed	90	90
Withdrawn	10	10
Reason for Withdrawal	Lost to follow up	NA
Adverse events	NA	NA

Table 3: Mean Visual Analogue Scale (VAS) pain scores at Baseline, Day 30, and Day 60

Study Visit	Time Point	Mean VAS Score ± SD
Visit 1	Baseline (Day 0)	**8.02 ± 1.35**
Visit 2	Day 30	**5.08 ± 0.81**
Visit 3	Day 60	**1.68 ± 0.89**

Table 4: SF-36 General Health

General Health-SF 36							
		1. In general, would you say your health	2.Compared to one year ago, how would you rate your health in general now	3.I seem to get sick a little easier than other people	4.I am as healthy as anybody I know	5.I expect my health to get worse	6 My health is excellent
		1 Poor 2 Fair 3 Good 4 Very Good 5 Excellent	1 Much worse than one year ago 2 Somewhat worse now than one year ago 3 About the same 4 Somewhat better now than one year ago 5 Much better now than one year ago	1 Definitely true 2Mostly true 3Don't know 4Mostly false 5 Definitely false	1 Definitely false 2 Mostly false 3 Don't know 4 Mostly true 5 Definitely true	1 Definitely true 2 Mostly true 3 Don't know 4 Mostly false 5 Definitely false	1 Definitely false 2 Mostly false 3 Don't know 4 Mostly true 5 Definitely true
Visit 1	Mean	2.13	2.11	1.35	1.71	3.71	1.75
	SD	0.62	0.62	0.48	0.544	0.45	0.48
Visit 2	Mean	3.21	3.72	2.33	3.78	3.79	3.7
	SD	0.41	0.45	0.47	0.41	0.74	0.46
Visit 3	Mean	3.8	4.19	4.2	4.19	4.3	4.26
	SD	0.647	0.40	0.402	0.39	0.47	0.46

Table 5: Limitations of Activities – SF-36

Limitations Of Activities										
	7. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	8. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	9. Lifting or carrying groceries	10. Climbing several flights of stairs	11. Climbing one flight of stairs	12. Bending, kneeling, or stooping	13. Walkin g more than a mile	14. Walkin g severe blocks	15. Walking one block	16. Bathing or dressing yourself
	1 Yes, Limited a lot 2 Yes, Limited a Little 3 No, Not Limited at all	1 Yes, Limited a lot 2 Yes, Limited a Little 3 No, Not Limited at all	1 Yes, Limited a lot 2 Yes, Limited a Little 3 No, Not Limited at all	1 Yes, Limited a lot 2 Yes, Limited a Little 3 No, Not Limited at all	1 Yes, Limited a lot 2 Yes, Limite d a Little 3 No, Not Limited at all	1 Yes, Limited a lot 2 Yes, Limited a Little 3 No, Not Limited at all	1 Yes, Limited a lot 2 Yes, Limited a Little 3 No, Not Limited at all	1 Yes, Limited a lot 2 Yes, Limited a Little 3 No, Not Limited at all	1 Yes, Limit ed a lot 2 Yes, Limit ed a Little 3 No, Not Limit ed at all	1 Yes, Limit ed a lot 2 Yes, Limit ed a Little 3 No, Not Limited at all
Visit 1	1.22	1.8	1.7	1.2	1.2	1.21	1.18	1.2	1.71	1.71
	0.41	0.39	0.42	0.4	0.43	0.39	0.42	0.45	0.45	0.45
Visit 2	1.86	2.03	1.85	1.95	1.95	1.94	1.86	2.05	1.97	1.91
	0.42	0.64	0.43	0.51	0.42	0.65	0.47	0.54	0.42	0.69
Visit 3	2.7	2.73	2.84	2.76	2.85	2.8	2.81	2.75	2.86	2.82
	0.4	0.44	0.36	0.42	0.35	0.35	0.39	0.43	0.34	0.38

Table 6: Physical Health Problems

Physical Health Problems					
		17. Cut down the amount of time you spent on work or other activities	18. Accomplished less than you would like	19. Were limited in the kind of work or other activities	20. Had difficulty performing the work or other activities
		1 Yes 2 No	1 Yes 2 No	1 Yes 2 No	1 Yes 2 No
Visit 1	Yes	69	72	70	73
	No	21	18	20	17
Visit 2	Yes	62	56	61	53
	No	28	34	29	37
Visit 3	Yes	16	16	21	21
	No	74	74	69	69

Table 7: Emotional Health Problems

Emotional Health Problems				
		21. Cut down the amount of time you spent on work or other activities	22.Accomplished less than you would like	23. Didn't do work or other activities as carefully as usual
		1 Yes 2 No	1 Yes 2 No	1 Yes 2 No
Visit 1	Mean	1.16	1.12	1.13
	SD	0.37	0.39	0.34
Visit 2	Mean	1.28	1.35	1.25
	SD	0.45	0.48	0.43
Visit 3	Mean	1.83	1.81	1.81
	SD	0.37	0.39	0.39

Emotional Health Problems				
		24.Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	25. How much bodily pain have you had during the past 4 weeks?	26. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
		1 Not at all 2 Slightly 3 Moderately 4 Severe 5 Very Severe	1 None 2 Very Mild 3 Mild 4 Moderate 5 Severe 6 Very Severe	1 Not at all 2 A little bit 3 Moderately 4 Quite a bit 5 Extremely
Visit 1	Mean	4.28	4.83	4.32
	SD	0.65	0.63	0.76
Visit 2	Mean	2.8	2.97	2.84
	SD	0.62	0.74	0.51
Visit 3	Mean	1.15	1.24	1.25
	SD	0.36	0.43	0.43

Table 8: Energy and Emotion

Energy and Emotion					
		28. Have you been a very nervous person?	29. Have you felt so down in the dumps that nothing could cheer you up?	32. Have you felt downhearted and blue?	33. Did you feel worn out?
		1 All of the time 2 Most of the time 3 A good Bit of the Time 4 Some of the time 5 A little bit of the time 6 None of the Time	1 All of the time 2 Most of the time 3 A good Bit of the Time 4 Some of the time 5 A little bit of the time 6 None of the Time	1 All of the time 2 Most of the time 3 A good Bit of the Time 4 Some of the time 5 A little bit of the time 6 None of the Time	1 All of the time 2 Most of the time 3 A good Bit of the Time 4 Some of the time 5 A little bit of the time 6 None of the Time
Visit 1	Mean	1.9	1.92	1.88	1.66
	SD	0.68	0.70	0.69	0.76
Visit 2	Mean	3.12	3.16	3.22	3.24
	SD	0.68	0.70	0.46	0.43
Visit 3	Mean	5.37	5.24	5.56	5.64
	SD	0.47	0.47	0.5	0.5

Energy and Emotion						
		27. Did you feel full of pep?	30. Have you felt calm and peaceful?	31. Did you have a lot of energy?	34. Have you been a happy person?	35. Did you feel tired?
		1 All of the time 2 Most of the time 3 A good Bit of the Time 4 Some of the time 5 A little bit of the time 6 None of the time	1 All of the time 2 Most of the time 3 A good Bit of the Time 4 Some of the time 5 A little bit of the time 6 None of the Time	1 All of the time 2 Most of the time 3 A good Bit of the Time 4 Some of the time 5 A little bit of the time 6 None of the Time	1 All of the time 2 Most of the time 3 A good Bit of the Time 4 Some of the time 5 A little bit of the time 6 None of the Time	1 All of the time 2 Most of the time 3 A good Bit of the Time 4 Some of the time 5 A little bit of the time 6 None of the Time
Visit 1	Mean	5.1	5.1	4.9	4.8	5.03
	SD	0.65	0.6	0.61	0.65	0.70
Visit 2	Mean	2.91	3.32	3.18	3.16	4.5
	SD	0.43	0.46	0.39	0.37	1.07
Visit 3	Mean	1.47	1.6	1.7	1.8	5.36
	SD	0.65	0.76	0.66	0.72	0.77

Table 9: Social Activities

Social Activities		
		36. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?
		1.All of the time 2.Most of the time 3.A good Bit of the Time 4.Some of the time 5.A little bit of the time 6.None of the Time
Visit 1	Mean	1.96
	SD	0.72
Visit 2	Mean	3.35
	SD	0.48
Visit 3	Mean	5.3
	SD	0.55

Table 10: Frequency of Menstrual Cramps

Frequency of Menstrual cramps			
	Visit 1	Visit 2	Visit 3
Yes	90	48	20
No	0	42	70

Table 11: Feedback about Prinkwellness Vaginal Suppositories

		Ease of Use: How easy was the product to use?	Onset Time	Duration of relief	Comparison to other products
		1.Very easy 2.Easy 3.Neutral 4.Difficult 5.Very difficult	1.Within 5 minutes 2.10-20 minutes 3.30+ minutes	1.Up to 1 hour 2.3 hours 3.6 hours 4.8+ hours	1.More effective 2.As effective 3.Less effective
Visit 2	Mean	3.13	2.93	1.15	2.21
	SD	0.34	0.25	0.36	0.41
Visit 3	Mean	2.72	1.66	2.15	1.54
	SD	0.45	0.47	0.61	0.5

Table 12: Symptom Relief and Experience After Using Prinkwellness Vaginal Suppositories

Symptom Relief and Experience				
		Pain: Did the product help alleviate your menstrual pain?	Nausea: Did the product reduce nausea symptoms?	Bloating: Did you notice any improvement in bloating?
		1.Yes 2.No	1.Yes 2.No 3.Not Applicable	1.Yes 2.No 3.Not Applicable
Visit 2	Mean	1.16	1.13	1.13
	SD	0.37	0.34	0.34
Visit 3	Mean	1	1	1.15
	SD	0	0	0.36

Table 13: Overall Feedback at the End of the Study

	Satisfaction	Which Dosage has worked the best for you (1 or 2)	Would you consider using this product regularly?	Would you recommend this product to others experiencing menstrual cramps?	Do you have any suggestions to improve the product?
	1 2 3 4 5 6 7 8 9 10	1.100 mg 2. 120 mg	1.Yes 2.No 3.Maybe	1.Yes 2.No	1.Yes 2.No
Visit 3	7.8	2	1.46	1	2

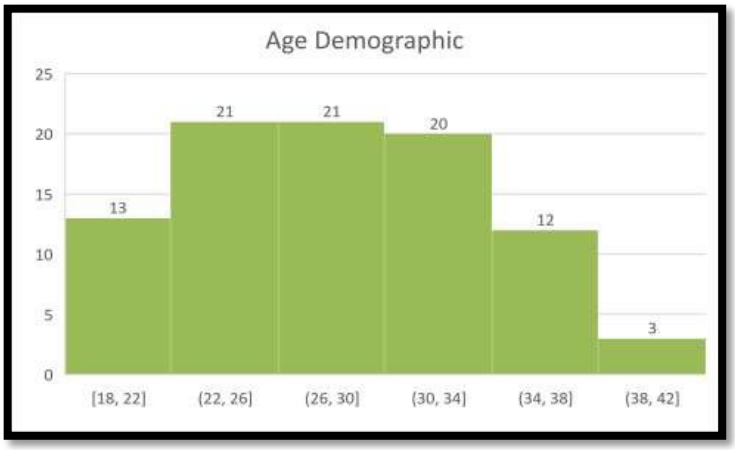


Figure 1: Age Demographic

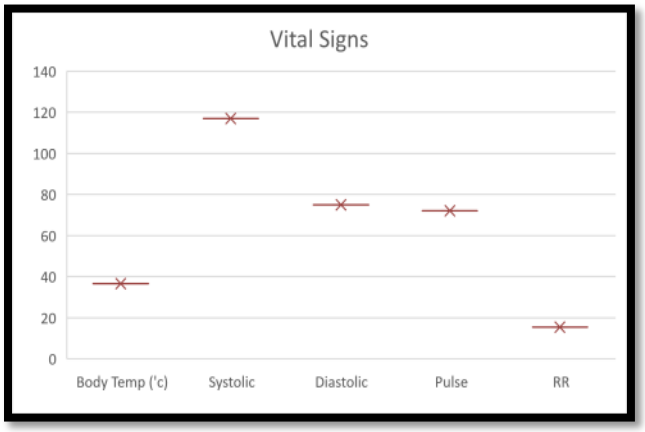


Figure 2: Vital Signs Interpretation of Baseline Characteristics

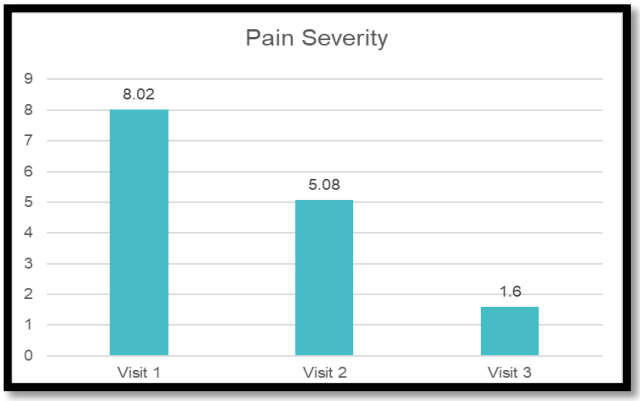


Figure 3: Pain Severity – VAS Scores

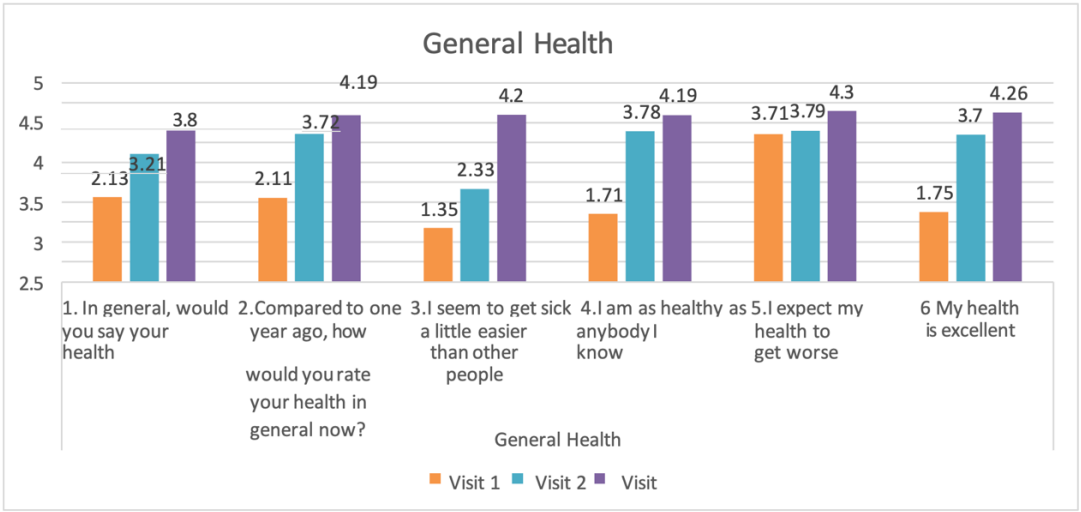


Figure 4: General Health Scale

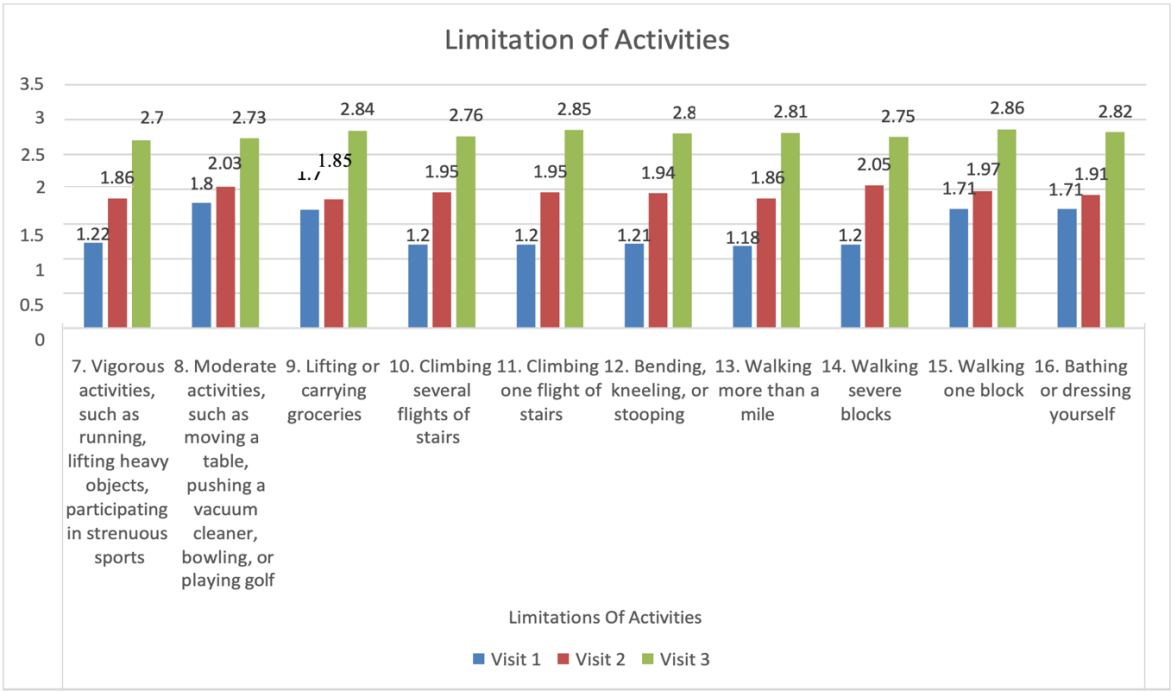


Figure 5: Limitations of Activities

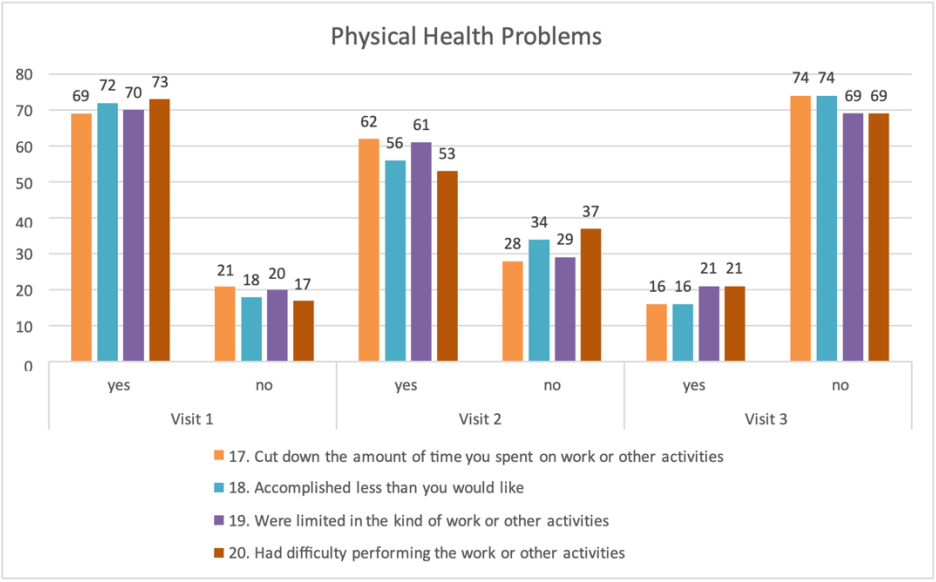
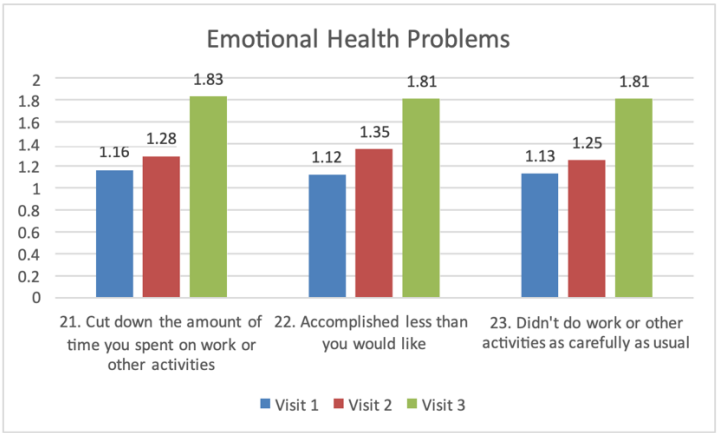


Figure 6. Physical Health Problems



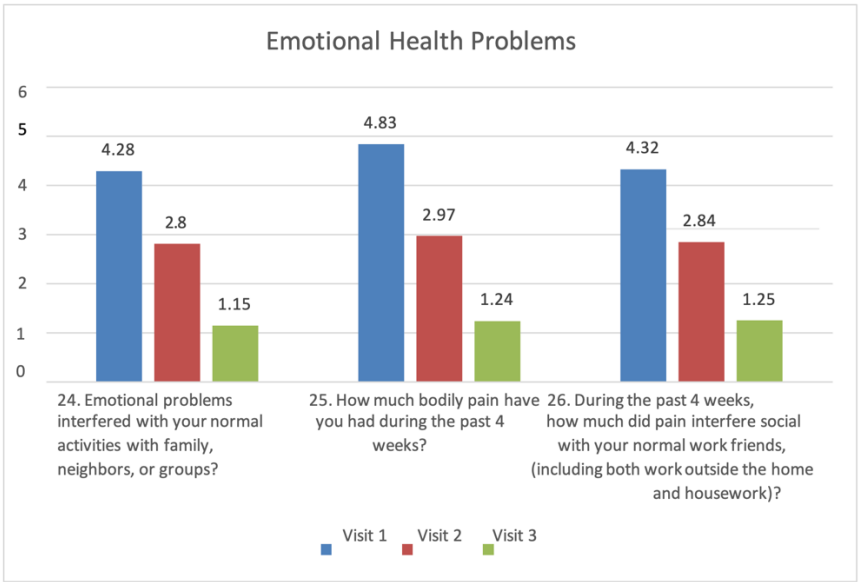
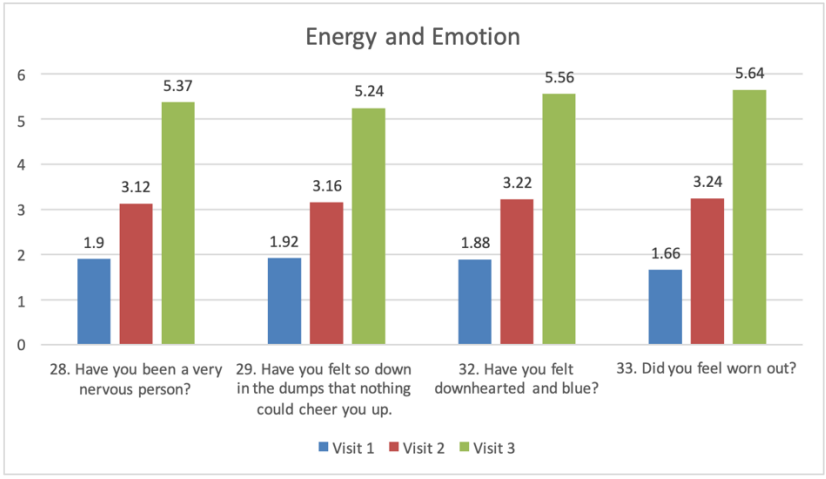


Figure 7: Emotional Health Problems



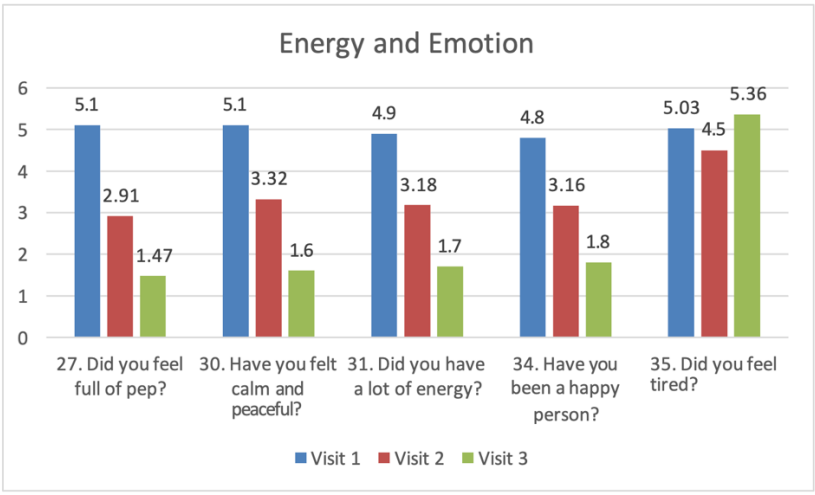


Figure 8: Energy and Emotion

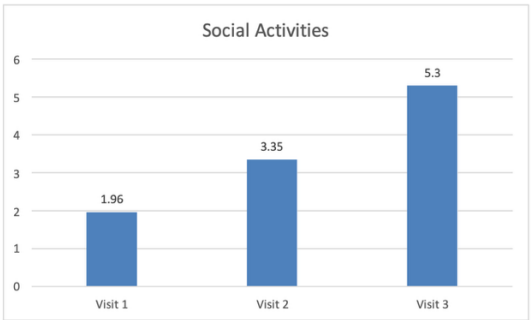


Figure 9: Social Activities

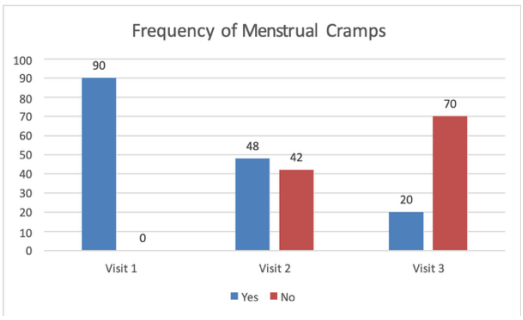


Figure 10: Frequency of Menstrual Cramps

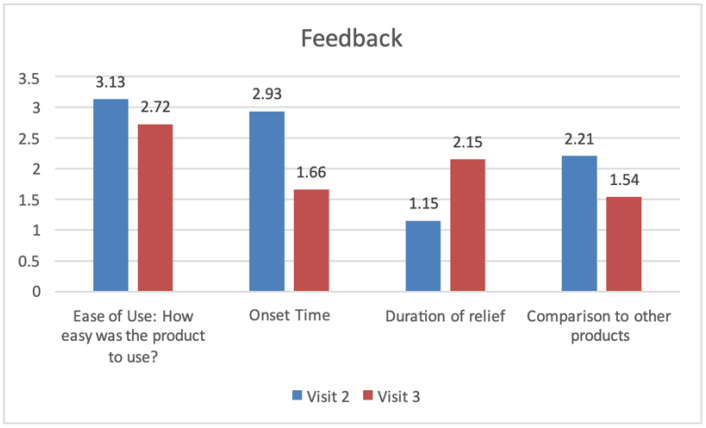


Figure 11: Feedback About Prinkwellness Vaginal Suppositories

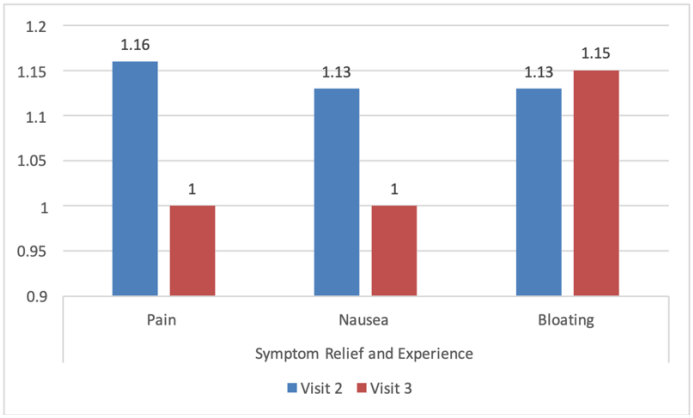


Figure 12: Symptom Relief and Experience After Using Prinkwellness Vaginal Suppositories

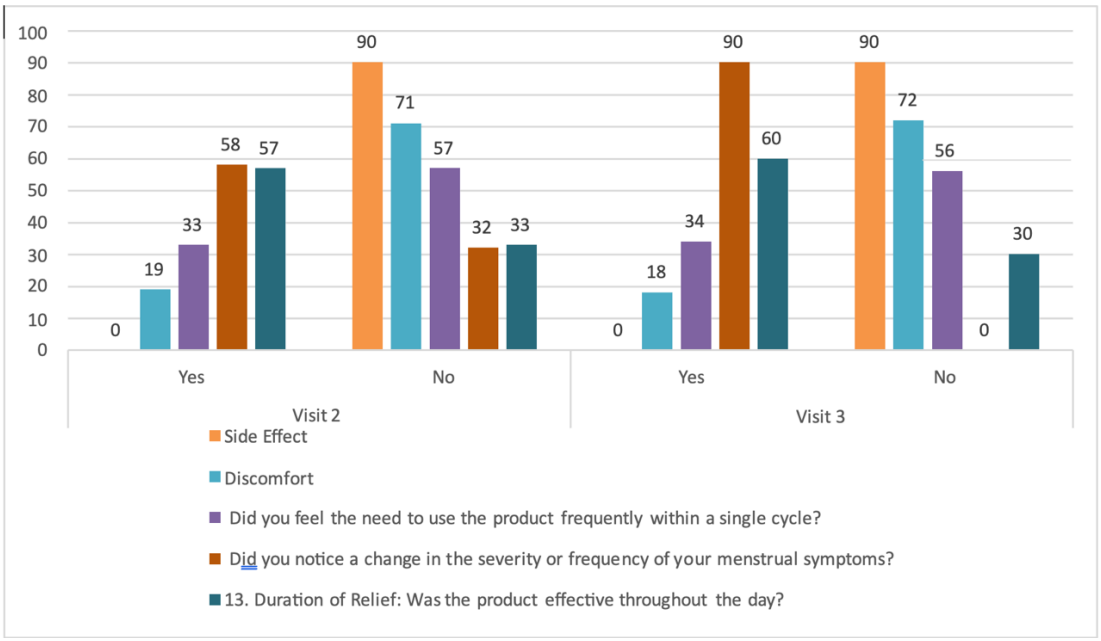


Figure 13: Overall Feedback at the End of the Study

RESULTS

Study Population and Participant Disposition

A total of 100 women were screened and enrolled in the study. Of these, 90 participants completed the study, while 10 participants were lost to follow-up. All enrolled participants who received at least one dose of the investigational product and had post-baseline assessments were included in the efficacy and safety analyses.

The study population consisted of women aged 18–50 years with a documented history of primary dysmenorrhea. Baseline demographic and clinical characteristics were comparable across the study cohort and were considered representative of women experiencing moderate to severe menstrual pain.

Primary Efficacy Outcome: Pain Intensity (VAS)

Menstrual pain intensity was assessed using the Visual Analogue Scale (VAS) at Baseline (Day 0), Day 30, and Day 60.

At Baseline, the mean VAS pain score was 8.02 ± 1.35, indicating severe menstrual pain. A progressive and statistically significant reduction in pain intensity was observed over the study duration. Mean VAS scores decreased to 5.08 ± 0.81 at Day 30 and further reduced to 1.68 ± 1.34 at Day 60.

The reduction in VAS score from Baseline to Day 60 was statistically significant ($p < 0.0001$), corresponding to an approximate 79% reduction in pain intensity. This improvement indicates a clinically meaningful reduction in menstrual pain following use of Prinkwellness vaginal suppositories over two consecutive menstrual cycles.

Secondary Outcome: Quality of Life (SF-36)

Health-related quality of life was assessed using the Short Form-36 (SF-36) questionnaire at Day 30 and Day 60. Improvements were observed across multiple SF-36 domains, including physical functioning, bodily pain, vitality, and general health perception.

Participants demonstrated progressive enhancement in both physical and mental component scores over the study period. The observed improvements suggest a positive impact of pain reduction on overall daily functioning and well-being. The changes from baseline were statistically significant for the majority of evaluated SF-36 domains.

Safety and Tolerability

Safety evaluation was performed throughout the study duration. No serious adverse events were reported during the study. The investigational product was well tolerated, with no participant discontinuations attributable to adverse events.

Reported adverse events, if any, were mild in nature and resolved without the need for medical intervention. No clinically significant abnormalities were observed in vital signs or physical examination findings during follow-up visits.

Overall, the safety findings indicate that Prinkwellness vaginal suppositories were well tolerated when administered intravaginally during menstruation over two consecutive cycles.

Summary of Key Findings

- Statistically significant reduction in menstrual pain as measured by VAS
- Clinically meaningful improvement observed by Day 30, with further improvement by Day 60
- Improvement in quality-of-life parameters assessed using SF-36
- Favorable safety and tolerability profile with no serious adverse events.

DISCUSSION

This present prospective, single-arm clinical study evaluated the safety and efficacy of Prinkwellness vaginal suppositories in women with primary dysmenorrhea. The findings demonstrate a statistically significant and clinically meaningful reduction in menstrual pain severity, accompanied by improvements in health-related quality of life over two consecutive menstrual cycles. Importantly, the intervention was well tolerated, with no serious adverse events reported, supporting its potential role as a localized, non-oral therapeutic option for menstrual pain management.

Interpretation of Primary Outcome
Menstrual pain intensity, assessed using the Visual Analogue Scale (VAS), showed a progressive reduction from Baseline to Day 60, with an approximate 79% decrease in mean pain scores. This magnitude of pain reduction is clinically relevant and aligns with thresholds commonly considered meaningful in dysmenorrhea research.[16] The improvement observed by Day 30 and its further reduction by Day 60 suggest a sustained therapeutic effect across consecutive cycles rather than transient symptom relief.

The pathophysiology of primary dysmenorrhea is closely associated with excessive uterine prostaglandin production, leading to uterine hypercontractility, ischemia, and pain.[8,9] Conventional NSAID therapy targets this mechanism by inhibiting prostaglandin synthesis; however, not all women achieve adequate pain control or tolerate systemic treatment.[10,11] The substantial reduction in pain observed in this study supports the potential of localized vaginal therapy as an alternative approach for symptom relief in women who prefer to avoid systemic medications.

Quality-of-Life Outcomes
In addition to pain reduction, participants demonstrated improvements across multiple domains of the SF-36 questionnaire, reflecting enhancement in both physical and mental well-being. Dysmenorrhea has been shown to adversely affect daily functioning, emotional health, and productivity, often extending beyond the days of active pain.[6,7] The observed quality-of-life improvements in this study suggest that effective pain control may translate into broader functional benefits, reinforcing the clinical relevance of the findings beyond numerical pain score reductions.

Previous studies have highlighted the substantial productivity loss and psychosocial burden associated with menstruation-related symptoms.[7] Effective and acceptable interventions that reduce pain may therefore have downstream benefits on academic performance, work attendance, and overall well-being.

Rationale for Vaginal Route of Administration
The vaginal route of drug delivery offers several theoretical and practical advantages in the management of gynecological conditions. Vaginal administration allows for local absorption in the cervico-uterine region, bypasses first-pass hepatic metabolism, and may reduce gastrointestinal adverse effects commonly associated with oral NSAIDs.[12,13] This localized approach may be particularly relevant for women seeking non-oral, non-hormonal options for dysmenorrhea management.

The favorable tolerability observed in this study supports the acceptability of vaginal suppositories as a dosage form for menstrual pain management. No participants discontinued treatment due to discomfort or adverse effects, indicating good user acceptance under study conditions.

Safety Considerations
Safety findings from the study were reassuring, with no serious adverse events and no clinically significant abnormalities observed during follow-up. This is an important consideration, as long-term or repeated use of NSAIDs and hormonal therapies may be associated with gastrointestinal, renal, cardiovascular, or hormonal adverse effects.[11] The absence of significant safety concerns in this study supports the potential suitability of Prinkwellness vaginal suppositories for repeated cyclical use.

Study Strengths and Limitations
The strengths of this study include its prospective design, use of validated outcome measures (VAS and SF-36), and assessment over two consecutive menstrual cycles, allowing evaluation of consistency of response. The study also addresses a clinically relevant unmet need for localized, non-oral therapeutic options for dysmenorrhea.

However, several limitations should be acknowledged. The single-arm, open-label design limits causal inference and does not allow direct comparison with placebo or standard therapy. The absence of a control group raises the possibility of placebo effects or regression to the mean. Additionally, the study was conducted at a single center, which may limit generalizability. Future randomized, controlled, multicenter trials with larger sample sizes are warranted to confirm these findings and to compare the intervention directly with existing standard treatments.

Implications for Future Research
Further studies should explore the long-term safety and effectiveness of repeated cyclical use, evaluate comparative efficacy against NSAIDs or other non-pharmacological interventions, and assess patient preference and adherence in real-world settings. Incorporation of mechanistic endpoints related to prostaglandin activity or uterine contractility may also enhance understanding of the intervention's mode of action.

CONCLUSION

This prospective, single-arm clinical study demonstrated that Prinkwellness vaginal suppositories were associated with a statistically significant and clinically meaningful reduction in menstrual pain among women with primary dysmenorrhea. Participants showed a marked decrease in pain intensity over two consecutive menstrual cycles, along with improvements in health-related quality of life. The intervention was well tolerated, with no serious adverse events reported during the study period.

The findings suggest that localized vaginal therapy may offer a viable, non-oral alternative for the management of primary dysmenorrhea, particularly for women who experience inadequate relief, intolerance, or contraindications with conventional systemic treatments. While the results are encouraging, the absence of a control group and the single-center design warrant cautious interpretation.

Further randomized, controlled, multicenter studies with larger sample sizes are recommended to confirm these findings, compare efficacy with standard therapies, and evaluate long-term safety and patient acceptability. Nonetheless, this study contributes preliminary clinical evidence supporting the potential role of Prinkwellness vaginal suppositories as a safe and effective option in the symptomatic management of primary dysmenorrhea.

DECLARATIONS

Ethics Approval and Consent to Participate
The study Protocol, Informed Consent Form, and related documents were reviewed and approved by the Pranav Diabetes Center Ethics Committee prior to initiation of the study. Written informed consent was obtained from all participants before enrollment. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki (2013) and Good Clinical Practice guidelines.

ACKNOWLEDGEMENTS

The authors acknowledge the clinical staff and study participants for their cooperation and contribution to this study. The authors also thank the clinical research team for their support in study coordination and data management.

REFERENCES

1. American College of Obstetricians and Gynecologists. Dysmenorrhea and endometriosis in the adolescent. Obstet Gynecol. 2018;132(6):e249–e258.
2. French L. Dysmenorrhea. Am Fam Physician. 2005;71(2):285–291.
3. Harel Z. Dysmenorrhea in adolescents and young adults: etiology and management. J Pediatr Adolesc Gynecol. 2006;19(6):363–371.
4. Ju H, Jones M, Mishra G. The prevalence and risk factors of dysmenorrhea. Epidemiol Rev. 2014;36:104–113.
5. Armour M, Ferfolja T, Curry C, *et al.* The prevalence and academic impact of dysmenorrhea in adolescents. PLOS One. 2019;14(3):e0211184.
6. Wong CL, Ip WY, Lam LW. Self-care strategies among Chinese adolescent girls with dysmenorrhea. Pain Manag Nurs. 2016;17(4):262–271.
7. Schoep ME, Adang EMM, Maas JWM, *et al.* Productivity loss due to menstruation-related symptoms. BMJ Open. 2019;9:e026186.
8. Dawood MY. Primary dysmenorrhea: advances in pathogenesis and management. Obstet Gynecol. 2006;108(2):428–441.
9. Iacovides S, Avidon I, Baker FC. What we know about primary dysmenorrhea today. Hum Reprod Update. 2015;21(6):762–778.
10. Burnett M, Lemyre M. Primary dysmenorrhea consensus guideline. J Obstet Gynaecol Can. 2017;39(7):585–595.
11. Proctor M, Farquhar C. Diagnosis and management of dysmenorrhea. BMJ. 2006;332(7550):1134–1138.
12. Hussain A, Ahsan F. The vagina as a route for systemic drug delivery. J Control Release. 2005;103(2):301–313.
13. Das Neves J, Bahia MF. Gels as vaginal drug delivery systems. Int J Pharm. 2006;318(1–2):1–14.
14. World Medical Association. Declaration of Helsinki: Ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191–2194. Accessed on 10 January 2026.
15. International International Council for Harmonisation. ICH E6(R2): Good Clinical Practice Guideline. European Medicines Agency; 2016. Accessed on 10 January 2026.
16. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analog Scale for Pain. Arthritis Care Res. 2011;63(S11):S240–S252.
17. Ware JE, Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36): I. Conceptual framework and item selection. Med Care. 1992;30(6):473–483.
18. Altman DG. Practical Statistics for Medical Research. London: Chapman & Hall; 1991.
19. Dawood MY. Nonsteroidal anti-inflammatory drugs and changing attitudes toward dysmenorrhea. Am J Med. 1988;84(5A):23–29.
20. Latthe P, Mignini L, Gray R, Hills R, Khan K. Factors predisposing women to chronic pelvic pain: systematic review. BMJ. 2006;332(7544):749–755.
21. Proctor ML, Smith CA, Farquhar CM, Stones RW. Transcutaneous electrical nerve stimulation and acupuncture for primary dysmenorrhea. Cochrane Database Syst Rev. 2002;(1):CD002123

Cite this article as:

K. Hemalatha, Nagarjuna Mummidi, Srivatsa GS and Rajasekhar G. A prospective, single-arm clinical evaluation of prinkwellness vaginal suppositories in the management of primary dysmenorrhea. Int. J. Res. Ayurveda Pharm. 2026;17(1):50-62
DOI: http://dx.doi.org/10.7897/2277-4343.17112

Source of support: Prinkwellness (Hyd Hemp India Private Limited), Hyderabad, Telangana, India, Conflict of interest: None Declared