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A STANDARDIZED GINGER EXTRACT IMPROVES SEXUAL FUNCTION AND SEXUAL QUALITY OF LIFE IN WOMEN WITH PRIMARY DYSMENORRHEA: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL

Prashanth Kumar Babu[1], Pushank Nagar[2], Abhimanyu Prashar*[3], Himanshu Trikambhai Makwana[4], Rakesh Kumar Yadav[5], Sachin Shrivastav[6], Jayant Deshpande[7], Mohammed Shuaib Khan[8], Nehru Sai Suresh Chalichem[9]

[1]Department and institute: Ennature Biopharma, Unit of India Glycols Limited, Dehradun, Uttarakhand India Email address: Prashanth.K.Babu@indiaglycols.com
[2]Department and institute: Ennature Biopharma, Unit of India Glycols Limited, Dehradun, Uttarakhand India Email address: pushank.nagar@indiaglycols.com
[3]Department and institute: Ennature Biopharma, Unit of India Glycols Limited, Dehradun, Uttarakhand India Email address: abhimanyu.prashar@indiaglycols.com
[4]Department and institute: Ennature Biopharma, Unit of India Glycols Limited, Dehradun, Uttarakhand India Email address: Himanshu.T.Makwana@indiaglycols.com
[5]Department and institute: Ennature Biopharma, Unit of India Glycols Limited, Dehradun, Uttarakhand India Email address: Rakesh.K.Yadav@indiaglycols.com
[6]Department and institute: Ennature Biopharma, Unit of India Glycols Limited, Dehradun, Uttarakhand India Email address: Sachin.Shrivastav@indiaglycols.com
[7]Department and institute: Edison Life Sciences LLC, Email address: nijay_deshpande@yahoo.com
[8]Department and institute: R&D, Ennature Biopharma, Unit of India Glycols Limited, Dehradun, Uttarakhand India Email address: Shuaib.Khan@indiaglycols.com
[9]Department and institute: R&D, Ennature Biopharma, Unit of India Glycols Limited, Dehradun, Uttarakhand India Email address: Nehru.S.Suresh@indiaglycols.com
***Corresponding Author**: Abhimanyu Prashar**

ABSTRACT

Background: Primary dysmenorrhea adversely affects sexual function and quality of life, yet these outcomes are rarely evaluated in clinical trials. Ginger (*Zingiber officinale*) possesses anti-inflammatory and analgesic properties, but its effects on sexual health in women with dysmenorrhea remain unexplored.

Methods: In this randomized, double-blind, placebo-controlled, multi-center trial, 96 women with primary dysmenorrhea received either standardized Ginger extract (100 mg twice daily, n=49) or placebo (n=47) for 90 days. Sexual function was assessed using the Female Sexual Function Index (FSFI), and sexual quality of life was evaluated using the Sexual Quality of Life-Female (SQoL-F) questionnaire. Assessments were conducted across three post-dosing menstrual cycles (C1, C2, C3).

Results: At C3, the ginger group showed significant improvement in FSFI total score (16.1% increase; 26.50±1.55 to 30.76±2.07; $p<0.0001$), moving participants from near-threshold sexual dysfunction (cutoff 26.55) to normal sexual function. Significant improvements were observed across all FSFI domains: desire (25.8%), arousal (16.1%), lubrication (43.4%), orgasm (10.5%), satisfaction (4.2%), and pain (5.1% above baseline). SQoL-F total score increased by 28.3% (72.77±2.45 to 93.39±5.50; $p<0.0001$), with improvements across psychosexual feelings (36.7%), relationship satisfaction (7.5%), self-worth (24.3%), and sexual repression (57.7%). In contrast, the placebo group showed significant deterioration in all domains ($p<0.0001$). The intervention was well tolerated with no adverse effects on estradiol levels or vaginal microbiome.

Conclusion: Standardized Ginger extract produces clinically meaningful improvements in sexual function and sexual quality of life in women with primary dysmenorrhea, representing a safe, non-hormonal therapeutic option.

KEYWORDS: Primary dysmenorrhea; Ginger extract; sexual function; Female Sexual Function Index; sexual quality of life; menstrual pain

INTRODUCTION

Primary dysmenorrhea is one of the most common gynecological conditions affecting women of reproductive age, characterized by recurrent, cramping lower abdominal pain occurring in the absence of identifiable pelvic pathology, often accompanied by systemic symptoms such as nausea, fatigue, and mood disturbances [1,2]. The worldwide prevalence is high, affecting approximately 73% of menstruating women, with the highest rates reported in Central America (89.6%) and Oceania (75.8%) [3]. The pathophysiology is primarily driven by increased uterine prostaglandin F2α (PGF2α) synthesis, leading to heightened contractility, ischemia, and pain [4]. Conventional management includes nonsteroidal anti-inflammatory drugs (NSAIDs) and hormonal contraceptives; however, NSAIDs carry gastrointestinal, renal, and cardiovascular risks, and up to 20% of patients

are NSAID-resistant, while hormonal options are contraindicated or undesirable for many due to side effects and personal preferences [1, 5, 6].

Beyond physical discomfort, primary dysmenorrhea imposes a substantial and often underrecognized burden on sexual health and intimate relationships. Research shows that dysmenorrhea negatively affects emotional well-being, interpersonal functioning, and sexual health [7]. Women with severe spasmodic dysmenorrhea report lower coital frequency, reduced orgasmic attainment, diminished orgasmic satisfaction, and greater sexual frustration compared with those with milder forms [8]. The psychogenic burden independent of physiological uterine contractions appears to impair orgasmic capacity and overall sexual satisfaction, suggesting that effective pain management might translate into meaningful improvements in sexual function and quality of life [8]. Despite this, sexual health outcomes are rarely included in clinical trials for dysmenorrhea, representing a critical gap in comprehensive patient-centered care.

Given the limitations of conventional therapies, there is growing interest in plant-based interventions, which are often perceived as safer and may offer multi-targeted anti-inflammatory and analgesic effects [9, 10]. Ginger (*Zingiber officinale*) is a widely used medicinal plant with a long history of use for pain and gastrointestinal disorders [11]. Its bioactive gingerols and shogaols inhibit cyclooxygenase and lipoxygenase pathways, reducing prostaglandin synthesis [12]. Several systematic reviews and meta-analyses confirm that ginger significantly reduces menstrual pain, with efficacy comparable to NSAIDs in some studies [11,13]. However, most existing trials are short-term, focus solely on pain intensity, and lack evaluation of broader outcomes such as sexual function or quality of life.

Notably, no previous clinical study has directly examined the effects of ginger on sexual function and sexual quality of life in women with primary dysmenorrhea. Nevertheless, indirect evidence from healthy populations suggests plausible benefits: a placebo-controlled trial found that oral ginger improved sexual function and sexual quality of life in women [14], and a large cross-sectional study reported positive associations between habitual ginger consumption and sexual desire and arousal [15]. These findings, combined with the well-documented pain-relieving effects of ginger, provide a strong rationale for investigating whether ginger supplementation can also alleviate the sexual health impairments associated with dysmenorrhea.

Therefore, the present randomized, double-blind, placebo-controlled trial was designed to comprehensively evaluate the efficacy and safety of a standardized Ginger extract in women with primary dysmenorrhea, with a specific focus on sexual function (assessed by the Female Sexual Function Index, FSFI) and sexual quality of life (assessed by the Sexual Quality of Life-Female questionnaire, SQoL-F), alongside pain, symptom burden, general wellness, menstrual fluid flow, and mechanistic biomarkers including PGF2α and estradiol levels, as well as vaginal microbiome stability.

METHODOLOGY

Study Design and Setting

This study was a randomized, double-blind, placebo-controlled, multi-center clinical trial conducted to evaluate the efficacy and safety of a standardized ginger extract in otherwise healthy women with primary dysmenorrhea. The study spanned five menstrual cycles, including two pre-dosing cycles (C-1 and C-2) for baseline assessment and three post-dosing cycles (C1, C2, and C3) following randomization and treatment initiation. A total of 11 study visits were conducted, including two visits per menstrual cycle (on Day 1 and Day 3) and one visit for enrollment/randomization (Day 5 of the C-2 cycle). Participants were randomized in a 1:1 ratio to receive either the test product or matching placebo, administered orally twice daily for 90 days. The study protocol, informed consent form, and all associated documents were approved by the respective Independent Ethics Committees prior to study initiation. The trial was registered with the Clinical Trials Registry - India (CTRI/2025/05/086338) and conducted in accordance with ICH GCP E6 (R3), applicable regulatory guidelines, and the 2024 revision of the Declaration of Helsinki. A detailed description of the complete methodology, including participant flow, randomization procedures, and all outcome assessments, has been published elsewhere [16]. The present manuscript focuses specifically on the sexual function and sexual quality of life outcomes, which represent a subset of the secondary endpoints from the main study.

Participants

Eligible participants were healthy, educated, married women aged 20–30 years, with a regular sexual life, no history of childbirth or abortion, and residing in metropolitan areas. Subjects were required to have a history of primary dysmenorrhea for at least two consecutive menstrual cycles prior to screening, with moderate pain intensity (Visual Analog Scale score ≥4 to ≤6) during at least four of the previous six cycles. Participants were required to be non-allergic to the investigational product, willing to use menstrual cups throughout the study, willing to provide informed consent, and agree to use condoms as the sole contraceptive method. Exclusion criteria included secondary dysmenorrhea, fertility-related disorders, a history of severe gastrointestinal conditions, urinary tract infection, positive pregnancy test or breastfeeding, history of abortion, hypoactive sexual desire disorder, lack of a sexual partner, or a spouse residing in a different location. Written informed consent was obtained from all participants prior to the initiation of any study-related procedures.

Interventions

The investigational product and matching placebo capsules were manufactured by Ennature Biopharma, a division of India Glycols, Dehradun, India. Each test capsule contained 100 mg of a formulated ginger extract (Gingeren™)

with food-grade excipients, standardized to ≥20%. Participants received the assigned intervention orally twice daily after food for 90 days. Compliance was assessed through returned capsule counts at each visit. The placebo group received microcrystalline cellulose capsules matched to the investigational product in size, shape, and color.

Outcome Measures

Primary Endpoints: The primary endpoints were the reduction in dysmenorrhea pain assessed using the Visual Analog Scale (VAS), a validated 10-cm horizontal line anchored by "no pain" (score 0) and "worst imaginable pain" (score 10), and the Working Ability, which has already been published [16].

Secondary Endpoints: Sexual function was assessed using the Female Sexual Function Index (FSFI), a validated 19-item, multidimensional, self-administered questionnaire evaluating six domains: sexual desire, arousal, lubrication, orgasm, satisfaction, and pain [17]. Domain scores are multiplied by predefined factors and summed to generate a total score ranging from 2 to 36, with higher scores indicating better sexual function. Based on published validation studies, an FSFI total score of 26.55 was used as the reference cutoff for distinguishing women with and without sexual dysfunction; scores ≤26.55 were considered indicative of sexual dysfunction [18]. Sexual quality of life was assessed using the Sexual Quality of Life-Female (SQoL-F) questionnaire, a validated 18-item instrument evaluating emotional well-being, sexual self-esteem, relationship satisfaction, and psychological impact related to sexual life [19]. Responses are summed and transformed to yield a total score ranging from 0 to 100, with higher scores indicating better sexual quality of life.

Other secondary endpoints included menstrual symptom burden assessed by the Menstrual Distress Questionnaire (MEDI-Q) [20, 21], general wellness assessed by the General Wellness Questionnaire (GWQ) [22], menstrual fluid flow measurement using calibrated menstrual cups, and global assessments including Subject's Global Assessment of Symptoms, Physician's Global Assessment of Response to Supplementation, and Physician's Global Impression of Change.

Randomization and Blinding

Each subject was assigned a unique identification number. Randomization was performed using a web-based tool (GraphPad Prism version 10.6.1) with sealed, subject-specific envelopes containing randomization codes. Subjects were randomized in a 1:1 ratio to the test or placebo group. The investigational product and placebo were identical in appearance to ensure blinding. Both investigators and participants were blinded to treatment allocation.

Sample Size

The sample size was calculated based on a previously published study in subjects with primary dysmenorrhea[13], which reported mean (SD) pain scores of 5.12 (2.69) for ginger and 6.58 (2.02) for placebo. A total sample size of 100 subjects (50 per group) was planned to achieve 90% power at a two-sided alpha level of 0.05, assuming a 20% dropout rate. The study methodology has been given in Figure *1*.

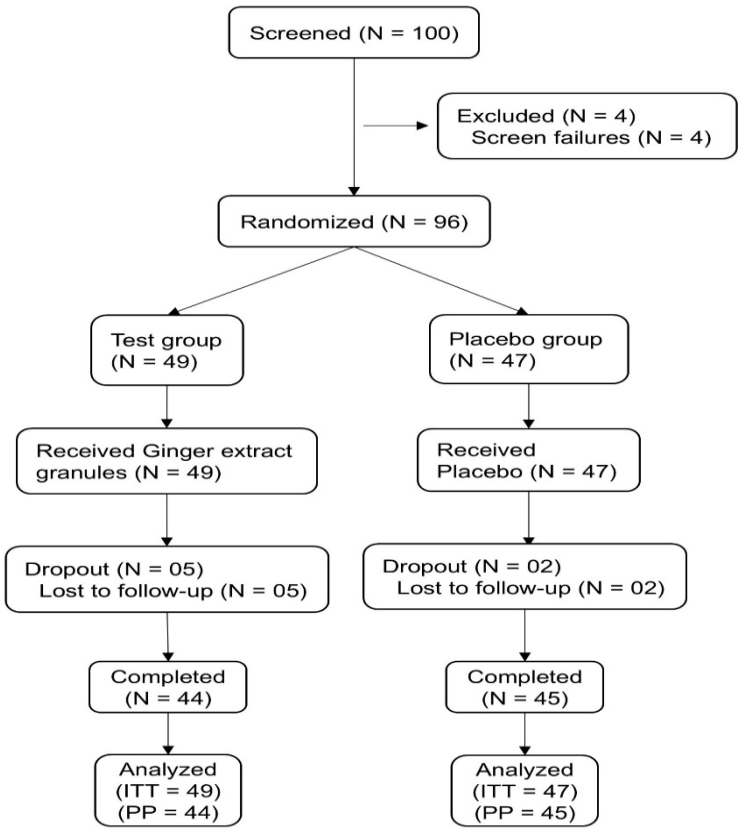

Fig. 1 Flow of Participants in the Study and Allocation of Intervention

ITT = Intent-to-treat; PP = Per protocol

Statistical Analysis

Descriptive and inferential statistics were applied to all continuous and ordinal variables. Between-group comparisons were performed using independent t-tests or Mann-Whitney U tests, depending on data distribution. Within-group comparisons were conducted using paired t-tests or Wilcoxon signed-rank tests. Statistical significance was set at a two-sided alpha level of 0.05. Missing data were handled using Last Observation Carried Forward (LOCF). Subjects were categorized into intention-to-treat (ITT), per-protocol (PP), and safety populations. The ITT population included all randomized subjects who received at least one dose and had at least one post-baseline assessment, the PP population included subjects who completed the study as per protocol, and the safety population included all subjects who received at least one dose of the study product. PP and ITT populations were used for efficacy analyses, while the safety population was used for safety assessments. For the sexual function and sexual quality of life outcomes reported in this manuscript, both ITT and PP analyses were performed, with ITT results presented as primary.

Ethical Considerations

The study protocol, informed consent form, and all associated documents were approved by the Pranav Diabetes Centre Ethics Committee(CTSRS/ 2501-01/17 Apr 25) prior to study initiation. Adverse events were monitored throughout the study and recorded in the Case Report Form from informed consent until study completion. AEs were coded using MedDRA and categorized per CTCAE version 5.0. Serious adverse events, discontinuations, and clinically significant laboratory abnormalities were documented and reported as per regulatory and ethics requirements. Vital signs, including body temperature, blood pressure, pulse rate, and respiratory rate, were assessed at all study visits. Safety laboratory evaluations, including hematology, lipid profile, thyroid profile, liver function tests, renal function tests, electrolytes, and urinalysis, were conducted during the pre-dosing period (C-2) and at the end of the study (C3).

RESULTS:

The baseline demographic characteristics of the study participants were comparable between the test and placebo groups (Table 1). The mean age of subjects was 25.08 ± 2.62 years in the test group and 25.00 ± 2.34 years in the placebo group. Body weight was similar between groups, with mean values of 60.12 ± 3.25 kg in the test group and 61.12 ± 4.00 kg in the placebo group. The mean height was 157.47 ± 4.95 cm and 157.49 ± 6.35 cm in the test and placebo groups, respectively. The mean body mass index (BMI) was 24.31 ± 1.92 kg/m^2 in the test group and 24.72 ± 2.22 kg/m^2 in the placebo group. Overall, no clinically meaningful differences were observed between the two groups for any of the baseline demographic parameters, indicating that the groups were well-balanced prior to intervention. None of the subjects reported any medical history or prior and concomitant medication usage.

Table 1 Baseline Demographic Characteristics

Characteristics	Test (n = 49)	Placebo (n = 47)
Age (years)	25.08 ± 2.62	25.00 ± 2.34
Body weight (kg)	60.12 ± 3.25	61.12 ± 4.00
Height (cm)	157.47 ± 4.95	157.49 ± 6.35
BMI (kg/m^2)	24.31 ± 1.92	24.72 ± 2.22

Each value represents Mean ± SD. No statistically significant differences were found between the groups in any of the parameters.

Sexual Function Assessed by the Female Sexual Function Index (FSFI)

FSFI - Total Score

In the ITT population, baseline FSFI total scores were comparable between the test (26.50 ± 1.55) and placebo (26.20 ± 1.37) groups (Table 3). At Cycle 1, both groups showed modest reductions (test: 4.0% decrease; placebo: 6.8% decrease; both $p < 0.01$), with no significant between-group difference. At Cycle 2, the test group maintained scores near baseline (26.60 ± 1.22; not significant), while the placebo group remained reduced (4.9% decrease; $p < 0.01$), with a significant between-group difference ($p < 0.0001$). At Cycle 3, the test group demonstrated a substantial improvement, corresponding to a 16.1% increase from baseline ($p < 0.0001$), reaching a mean score of 30.76 ± 2.07. Considering the established FSFI cutoff for female sexual dysfunction of 26.55 [34], participants in the test group improved from a baseline value near this threshold to a level well within the range indicative of normal sexual function. In contrast, the placebo group showed a marked decline (43.2% decrease; $p < 0.0001$), with the mean score decreasing to 14.89 ± 5.80. Between-group comparison at Cycle 3 confirmed a highly significant difference ($p < 0.0001$). The PP findings were consistent with the ITT analysis.

FSFI Domain Scores

Desire Domain: The test group showed consistent improvements, with increases of 9.6% at C1 ($p < 0.01$), 12.4% at C2 ($p < 0.0001$), and 25.8% at C3 ($p < 0.0001$) from baseline. The placebo group demonstrated minimal change at C1 and C2, followed by a substantial decline at C3 (36.1% decrease; $p < 0.0001$). Between-group differences were significant at all time points ($p < 0.05$ to $p < 0.0001$) (Table 3).

Arousal Domain: The test group showed progressive improvement, with a 16.1% increase at C3 ($p < 0.0001$), while the placebo group showed a marked decline (46.3% decrease; $p < 0.001$). Between-group differences were significant at all time points ($p < 0.0001$) (Table 3).
Lubrication Domain: The test group demonstrated consistent improvements (7.3% at C1, $p < 0.01$; 23.6% at C2, $p < 0.0001$; 43.4% at C3, $p < 0.0001$), while the placebo group showed significant decline at C3 (33.1% decrease; $p < 0.001$). Between-group differences were significant throughout ($p < 0.0001$) (Table 3).
Orgasm Domain: Both groups showed initial reductions at C1. At C3, the test group demonstrated marked improvement (10.5% increase; $p < 0.0001$), whereas the placebo group showed substantial decline (38.2% decrease; $p < 0.0001$). Between-group difference was highly significant at C3 ($p < 0.0001$) (Table 3).
Satisfaction Domain: The test group showed recovery and improvement above baseline at C3 (4.2% increase; $p < 0.01$), while the placebo group showed substantial decline (48.0% decrease; $p < 0.0001$). Between-group difference at C3 was highly significant ($p < 0.0001$) (Table 3).
Pain Domain: At C3, the test group demonstrated improvement above baseline (5.1% increase; $p < 0.01$), indicating reduced pain during sexual activity, while the placebo group showed marked decline (53.4% decrease; $p < 0.0001$). Between-group difference at C3 was highly significant ($p < 0.0001$) (Table 2).

Table 2: Sexual Function in the ITT Population

Cycles	Test group (n = 49)	Placebo group (n = 47)	Statistics	
			Within-group *p*-value (Test / Placebo)†	Between-group *p*-value‡
Female Sexual Function Index: Total Score				
Baseline	26.50 ± 1.55	26.20 ± 1.37	NA	NS
C1	25.44 ± 1.63	24.41 ± 3.46	$p < 0.01$ / $p < 0.01$	NS
C2	26.60 ± 1.22	24.92 ± 2.24	NS / $p < 0.01$	$p < 0.0001$
C3	30.76 ± 2.07	14.89 ± 5.80	$p < 0.0001$ / $p < 0.0001$	$p < 0.0001$
Female Sexual Function Index: Desire				
Baseline	3.96 ± 0.50	3.96 ± 0.50	NA	NS
C1	4.34 ± 0.63	4.02 ± 0.67	$p < 0.01$ / NS	$p < 0.05$
C2	4.45 ± 0.55	4.03 ± 0.62	$p < 0.0001$ / NS	$p < 0.001$
C3	4.98 ± 0.68	2.53 ± 1.12	$p < 0.0001$ / $p < 0.0001$	$p < 0.0001$
Female Sexual Function Index: Arousal				
Baseline	4.22 ± 0.33	4.17 ± 0.39	NA	NS
C1	4.26 ± 0.44	3.63 ± 0.84	NS / $p < 0.01$	$p < 0.0001$
C2	4.38 ± 0.32	3.79 ± 0.60	$p < 0.05$ / $p < 0.01$	$p < 0.0001$
C3	4.90 ± 0.41	2.24 ± 1.15	$p < 0.0001$ / $p < 0.001$	$p < 0.0001$
Female Sexual Function Index: Lubrication				
Baseline	3.69 ± 0.51	3.53 ± 0.40	NA	NS
C1	3.96 ± 0.34	3.43 ± 0.72	$p < 0.01$ / NS	$p < 0.0001$
C2	4.56 ± 0.42	3.64 ± 0.59	$p < 0.0001$ / NS	$p < 0.0001$
C3	5.29 ± 0.55	2.36 ± 1.17	$p < 0.0001$ / $p < 0.001$	$p < 0.0001$
Female Sexual Function Index: Orgasm				
Baseline	4.67 ± 0.46	4.71 ± 0.40	NA	NS
C1	3.94 ± 0.42	4.20 ± 0.83	$p < 0.0001$ / $p < 0.001$	NS
C2	4.07 ± 0.35	4.41 ± 0.49	$p < 0.0001$ / $p < 0.01$	$p < 0.001$
C3	5.16 ± 0.64	2.91 ± 0.95	$p < 0.0001$ / $p < 0.0001$	$p < 0.0001$
Female Sexual Function Index: Satisfaction				
Baseline	5.22 ± 0.32	5.13 ± 0.39	NA	NS
C1	4.63 ± 0.52	4.77 ± 0.87	$p < 0.0001$ / $p < 0.05$	NS
C2	4.56 ± 0.40	4.81 ± 0.84	$p < 0.0001$ / $p < 0.05$	NS
C3	5.44 ± 0.48	2.67 ± 0.98	$p < 0.01$ / $p < 0.0001$	$p < 0.0001$

Female Sexual Function Index: Pain				
Baseline	4.74 ± 0.36	4.70 ± 0.37	NA	NS
C1	4.33 ± 0.56	4.35 ± 0.69	$p < 0.0001$ / $p < 0.01$	NS
C2	4.58 ± 0.56	4.24 ± 0.68	NS / $p < 0.001$	$p < 0.01$
C3	4.98 ± 0.43	2.19 ± 1.23	$p < 0.01$ / $p < 0.0001$	$p < 0.0001$

Values represent mean ± SD; baseline is average of 2 pre-dosing cycles (C-1 and C-2); C1, C2, and C3 represents post-baseline cycles 1, 2, and 3 respectively; significance was assessed at a two-sided alpha of 0.05; NA - Not applicable; NS - Non-significant.
†Within-group changes from the baseline were evaluated using paired t-tests or Wilcoxon signed-rank test.
‡Between-group comparisons were performed using two-sample t-tests or the Mann-Whitney U test.

Sexual Quality of Life Assessed by Sexual Quality of Life-Female (SQoL-F)

SQoL-F - Total Score

Baseline SQoL-F scores were comparable between the test (72.77 ± 2.45) and placebo (72.89 ± 3.11) groups (Table 4). The test group showed consistent improvements, with increases of 10.9% at C1, 14.8% at C2, and 28.3% at C3 from baseline ($p < 0.0001$ for all). The placebo group demonstrated an initial decline at C1 (5.3% decrease; $p < 0.0001$), followed by minimal recovery at C2, and a marked decline at C3 (31.8% decrease; $p < 0.0001$). Between-group differences were significant at all time points ($p < 0.0001$). The PP findings were consistent with the ITT analysis.

SQoL-F Factor Scores

Factor 1 (Psychosexual Feelings): The test group showed consistent improvements (14.4% at C1, 17.6% at C2, 36.7% at C3; $p < 0.0001$), while the placebo group showed marked decline at C3 (28.6% decrease; $p < 0.0001$). Between-group differences were significant throughout ($p < 0.0001$).

Factor 2 (Sexual and Relationship Satisfaction): The test group demonstrated sustained improvements (3.6% at C1, $p < 0.01$; 6.9% at C2, $p < 0.0001$; 7.5% at C3, $p < 0.001$), while the placebo group showed progressive decline (35.6% decrease at C3; $p < 0.0001$). Between-group differences were significant throughout ($p < 0.0001$).

Factor 3 (Self-Worthlessness): The test group showed progressive improvement (24.3% increase at C3; $p < 0.0001$), while the placebo group showed substantial decline (33.1% decrease; $p < 0.0001$). Between-group differences were significant at all time points ($p < 0.0001$).

Factor 4 (Sexual Repression): The test group demonstrated marked improvement (28.5% at C1, 35.5% at C2, 57.7% at C3; $p < 0.0001$ for all), indicating reduced sexual repression. The placebo group showed no meaningful change at C1 and C2, followed by marked decline at C3 (28.4% decrease; $p < 0.0001$). Between-group differences were significant throughout ($p < 0.0001$) (Table 3).

Table 3: **Sexual Quality of Life in the ITT Population**

Cycles	Test group (n = 49)	Placebo group (n = 47)	Statistics	
			Within-group *p*-value (Test / Placebo)†	Between-group *p*-value‡
Sexual Quality of Life-Female: Total Score				
Baseline	72.77 ± 2.45	72.89 ± 3.11	NA	NS
C1	80.73 ± 3.25	69.06 ± 3.77	$p < 0.0001$ / $p < 0.0001$	$p < 0.0001$
C2	83.53 ± 3.49	71.47 ± 4.52	$p < 0.0001$ / NS	$p < 0.0001$
C3	93.39 ± 5.50	49.70 ± 9.57	$p < 0.0001$ / $p < 0.0001$	$p < 0.0001$
Sexual Quality of Life-Female: Factor 1 (Psychosexual Feelings)				
Baseline	27.38 ± 1.63	26.94 ± 2.12		NS
C1	31.33 ± 1.78	26.38 ± 1.66	$p < 0.0001$ / NS	$p < 0.0001$
C2	32.20 ± 1.97	27.15 ± 2.33	$p < 0.0001$ / NS	$p < 0.0001$
C3	37.43 ± 2.35	19.23 ± 3.79	$p < 0.0001$ / $p < 0.0001$	$p < 0.0001$
Sexual Quality of Life-Female: Factor 2 (Sexual and Relationship Satisfaction)				
Baseline	22.16 ± 1.45	22.37 ± 1.79	NA	NS
C1	22.96 ± 1.51	20.38 ± 2.12	$p < 0.01$ / $p < 0.0001$	$p < 0.0001$
C2	23.69 ± 1.65	20.64 ± 2.19	$p < 0.0001$ / $p < 0.0001$	$p < 0.0001$
C3	23.82 ± 2.50	14.40 ± 2.80	$p < 0.001$ / $p < 0.0001$	$p < 0.0001$

Sexual Quality of Life-Female: Self-Worthlessness				
Baseline	12.90 ± 0.85	12.95 ± 0.95	NA	NS
C1	13.18 ± 1.05	11.91 ± 1.12	NS / $p < 0.0001$	$p < 0.0001$
C2	13.71 ± 0.91	12.68 ± 0.89	$p < 0.0001$ / NS	$p < 0.0001$
C3	16.04 ± 1.34	8.66 ± 2.60	$p < 0.0001$ / $p < 0.0001$	$p < 0.0001$
Sexual Quality of Life-Female: Sexual Repression				
Baseline	10.33 ± 1.10	10.64 ± 1.09	NA	NS
C1	13.27 ± 0.95	10.38 ± 1.05	$p < 0.0001$ / NS	$p < 0.0001$
C2	14.00 ± 1.04	11.00 ± 1.18	$p < 0.0001$ / NS	$p < 0.0001$
C3	16.29 ± 1.02	7.62 ± 1.42	$p < 0.0001$ / $p < 0.0001$	$p < 0.0001$

Values represent mean ± SD; baseline is average of 2 pre-dosing cycles (C-1 and C-2); C1, C2, and C3 represents post-baseline cycles 1, 2, and 3 respectively; significance was assessed at a two-sided alpha of 0.05; NA - Not applicable; NS - Non-significant.
†Within-group changes from the baseline were evaluated using paired t-tests or Wilcoxon signed-rank test.
‡Between-group comparisons were performed using two-sample t-tests or the Mann-Whitney U test.

General Wellness by General Wellness Questionnaire (GWQ)
GWQ - Gastric Discomfort
Baseline scores were comparable between the test (2.62 ± 0.89) and placebo (2.91 ± 1.01) groups (Table 4). The test group showed consistent reductions across cycles (37.0% at C1, 39.3% at C2, and 50.0% at C3; $p < 0.0001$ throughout). The placebo group demonstrated a modest reduction at C1 (19.6%; $p < 0.05$), followed by minimal change at C2 and no meaningful improvement at C3 (1.7% reduction; not significant). Between-group differences were significant at all time points ($p \leq 0.001$). The PP findings were consistent with the ITT analysis.

Table 4: General wellness in the ITT population

Cycles	**Test group (n = 49)**	**Placebo group (n = 47)**	**Statistics**	
			Within-group *p*-value (Test / Placebo)†	**Between-group *p*-value‡**
General Wellness Questionnaire: Gastric Discomfort				
Baseline	2.62 ± 0.89	2.91 ± 1.01	NA	NS
C1	1.65 ± 0.69	2.34 ± 1.13	$p < 0.0001$ / $p < 0.05$	$p < 0.001$
C2	1.59 ± 0.54	2.62 ± 0.97	$p < 0.0001$ / NS	$p < 0.0001$
C3	1.31 ± 0.47	2.96 ± 1.04	$p < 0.0001$ / NS	$p < 0.0001$
General Wellness Questionnaire: Cold Symptoms				
Baseline	1.83 ± 0.70	1.95 ± 1.87	NA	NS
C1	1.14 ± 0.35	1.38 ± 0.64	$p < 0.0001$ / $p < 0.001$	$p < 0.05$
C2	1.02 ± 0.14	1.02 ± 0.15	$p < 0.0001$ / $p < 0.0001$	NS
C3	1.14 ± 0.35	1.83 ± 0.60	$p < 0.0001$ / NS	$p < 0.0001$
General Wellness Questionnaire: Digestive Health				
Baseline	3.68 ± 0.49	3.81 ± 0.55	NA	NS
C1	4.04 ± 0.79	3.38 ± 0.95	$p < 0.01$ / $p < 0.05$	$p < 0.001$
C2	4.35 ± 0.52	3.38 ± 0.49	$p < 0.0001$ / $p < 0.001$	$p < 0.0001$
C3	4.63 ± 0.49	2.83 ± 0.52	$p < 0.0001$ / $p < 0.0001$	$p < 0.0001$

Values represent mean ± SD; baseline is average of 2 pre-dosing cycles (C-1 and C-2); C1, C2, and C3 represents post-baseline cycles 1, 2, and 3 respectively; significance was assessed at a two-sided alpha of 0.05; NA - Not applicable; NS - Non-significant.
† Within-group changes from the baseline were evaluated using paired t-tests or Wilcoxon signed-rank test.
‡ Between-group comparisons were performed using two-sample t-tests or the Mann-Whitney U test.
Vaginal Microbiome
Vaginal microbiome analysis across all study visits (Cycles C-1, C-2, C1, C2, and C3) demonstrated a stable and healthy microbial profile in all participants. At all time points, vaginal swab evaluations showed predominance of normal vaginal flora with consistent presence of *Lactobacilli*, indicating maintenance of physiological eubiosis.

No evidence of gonococcal or chlamydial infection was detected at any visit. Additionally, there were no cases of bacterial vaginosis, candidiasis, trichomoniasis, or loss of *Lactobacillus* predominance observed either during the pre-dosing or post-dosing periods. Overall, the vaginal microbiome remained stable throughout the study, with no intervention-related dysbiosis or adverse microbiological changes identified.

DISCUSSION

Primary dysmenorrhea extends beyond monthly pelvic pain, exerting a substantial and often underrecognized burden on sexual health and intimate relationships. Women with severe spasmodic dysmenorrhea report lower coital frequency, reduced orgasm incidence, and diminished orgasmic satisfaction compared with those experiencing milder symptoms. The severe-pain group also exhibits greater sexual frustration, irritability, and incomplete progression through the sexual response cycle. Cross-sectional evidence indicates that dysmenorrhea impacts multiple dimensions of quality of life, with notable effects on sexual function and decreased social activities. Women with moderate-to-severe dysmenorrhea have been observed to meet the threshold for sexual dysfunction as measured by the total FSFI score. These findings underscore that primary dysmenorrhea, beyond its physiological mechanisms of uterine contractility, imposes a substantial psychogenic burden that adversely affects orgasmic capacity and overall sexual well-being [8]. Accordingly, the inclusion of sexual health outcomes in the clinical evaluation of dysmenorrhea is important, as increasing pain severity appears to contribute to difficulties in achieving orgasm and sustaining positive sexual experiences [8].

The present study provides compelling evidence that Standardized Ginger extract significantly improves sexual function and sexual quality of life in women with primary dysmenorrhea. In the test group, the mean FSFI total score increased from 26.50 ± 1.55 at baseline to 30.76 ± 2.07 at Cycle 3 (16.1% increase; $p < 0.0001$), while the placebo group showed a marked decline to 14.89 ± 5.80 (43.2% decrease; $p < 0.0001$). Considering that the established FSFI cutoff for female sexual dysfunction is approximately 26.55 [18], participants in the test group improved from a baseline value near this threshold to a level well within the range indicative of normal sexual function, representing a clinically meaningful enhancement. This improvement was observed across all FSFI domains, including desire (25.8% increase), arousal (16.1% increase), lubrication (43.4% increase), orgasm (10.5% increase), satisfaction (4.2% increase), and pain during sexual activity (5.1% improvement above baseline). The concurrent improvements in SQoL-F scores with a 28.3% increase in total score and marked improvements across psychosexual feelings (36.7%), sexual and relationship satisfaction (7.5%), self-worth (24.3%), and sexual repression (57.7%) indicate that the benefits of ginger extend beyond functional measures to encompass emotional well-being, self-confidence, and relationship satisfaction.

These findings are consistent with a prior randomized, double-blind, placebo-controlled trial by Afshar et al. [14], which demonstrated that oral ginger capsules significantly improved sexual function (FSFI: 27.93 ± 4.97 to 30.94 ± 3.43, $p < 0.001$) and sexual quality of life (SQoL-F: 93.74 ± 17.84 to 100.9 ± 11.14, $p < 0.001$) in reproductive-age women. However, that study was conducted in healthy women without dysmenorrhea, whereas the present study specifically addresses the sexually impairing effects of menstrual pain. Cross-sectional evidence from a large cohort of healthy individuals further supports these findings [20,21,23], demonstrating that habitual ginger consumption is positively associated with sexual desire, more frequent sexual behaviors, and feelings of sexual arousal during them. Experimental evidence indicates that ginger consumption counteracts the inhibiting effect of disgust on sexual arousal and increases sexual arousal toward erotic stimuli.

The mechanistic basis for these improvements is multifaceted. Ginger's bioactive constituents gingerols and shogaols inhibit cyclooxygenase and lipoxygenase pathways, reducing prostaglandin synthesis [12]. The reduction in PGF2α levels observed in the test group (11.6% decrease at Cycle 3) provides a plausible mechanism for the alleviation of dysmenorrhea-related pain, which in turn may reduce pain during sexual activity and enhance overall sexual comfort [24]. Additionally, 6-gingerol promotes cGMP production and increases nitric oxide generation. The nitric oxide-cyclic guanosine monophosphate (NO-cGMP) pathway plays a crucial role in female sexual activity by promoting vasodilation and increasing blood flow. This pathway appears to be an essential regulator of vaginal blood flow during sexual arousal and regulates the contractility of vaginal smooth muscle. Furthermore, Standardized Ginger extract have demonstrated androgenic activity, and evidence suggests that androgens play an important role in female sexual function.

The improvements observed in the FSFI Pain domain may be directly attributed to the reduction in PGF2α levels following supplementation. As PGF2α is a key mediator of uterine contractions and dysmenorrhea-related pain, its reduction likely contributes to decreased pelvic discomfort and improved comfort during sexual activity. Alleviation of menstrual pain may indirectly enhance other aspects of sexual function, including desire, arousal, and satisfaction, by reducing pain-related distress and improving overall well-being. The preservation of *Lactobacillus*-dominant vaginal flora and stable estradiol levels further support the reproductive safety profile of the intervention [25].

While the present study was specifically designed to evaluate the effects of the standardized ginger extract in women with primary dysmenorrhea, its findings may have broader implications for sexual health in general. It is scientifically plausible that the positive effects observed on sexual function and quality of life are not solely dependent on the alleviation of menstrual pain. The extract's direct modulation of the NO-cGMP pathway, its anti-inflammatory and analgesic properties, and its potential androgenic activity are biological mechanisms that could operate independently of dysmenorrhea status to enhance sexual response. This extrapolation is supported by

previous research in healthy women, where oral ginger was found to improve FSFI and SQoL-F scores [14], and by large cross-sectional studies associating habitual ginger consumption with increased sexual desire and arousal [15]. Therefore, while the present clinical trial does not directly establish efficacy in a healthy population, the convergent evidence from mechanistic studies and research in non-dysmenorrheic cohorts provides a strong and scientifically sound basis for hypothesizing that the extract may offer sexual health benefits beyond the context of menstrual pain. Nevertheless, any potential benefit in healthy women should be regarded as a biologically plausible and supportive extrapolation rather than a direct conclusion of the present study, and dedicated randomized controlled trials in women without dysmenorrhea are required to confirm its efficacy in that population.

LIMITATIONS

Several limitations warrant acknowledgment. First, although the FSFI and SQoL-F are validated instruments, they rely on self-reported outcomes, which may introduce reporting bias. Second, the study population comprised otherwise healthy women aged 20–30 years with primary dysmenorrhea, limiting generalizability to older women, those with secondary dysmenorrhea, or those with comorbidities. Third, the study duration (three post-dosing cycles) may not fully capture long-term outcomes beyond 90 days. Fourth, while mechanistic biomarkers (PGF2α) were assessed, the study was not powered for definitive mechanistic conclusions. Fifth, the absence of a direct comparison with pharmacological treatments (e.g., NSAIDs or hormonal contraceptives) limits the ability to position ginger relative to standard therapies. Finally, while the placebo group showed progressive deterioration in sexual function, this may reflect natural variability rather than a true worsening, though the consistent divergence between groups supports a treatment-related effect.

Clinical Implications

These findings have important clinical implications. First, sexual health should be routinely assessed in women presenting with primary dysmenorrhea, as pain severity correlates with sexual dysfunction. Second, Standardized Ginger extract represents a safe, non-hormonal option that addresses both pain and its downstream effects on sexual function and quality of life. The absence of hormonal modulation (stable estradiol levels) and preservation of vaginal eubiosis make it an attractive alternative for women who cannot or prefer not to use hormonal therapies. Third, the multi-domain improvements spanning desire, arousal, lubrication, orgasm, satisfaction, and psychosocial well-being suggest that ginger may offer comprehensive benefits beyond simple analgesia. Fourth, the favorable gastrointestinal tolerability and twice-daily dosing support good compliance in clinical practice.

CONCLUSION

In conclusion, this randomized, double-blind, placebo-controlled trial demonstrates that a standardized Ginger extract produces clinically meaningful improvements in sexual function and sexual quality of life in women with primary dysmenorrhea. The intervention resulted in significant enhancements across all FSFI domains and SQoL-F factors, with participants moving from near-threshold sexual dysfunction to normal sexual function. These benefits are supported by a plausible biological mechanism involving prostaglandin reduction and NO-cGMP pathway modulation, achieved without hormonal disruption or adverse effects on the vaginal microbiome. This was well tolerated with a favorable safety profile. These findings suggest that it represents a safe, effective, non-hormonal option for managing both the pain and the sexual health impairments associated with primary dysmenorrhea, addressing a critical gap in comprehensive dysmenorrhea care. Future studies should explore long-term outcomes, comparative effectiveness against standard therapies, and mechanistic pathways in greater detail.

Ethics approval and consent to participate

The study protocol, informed consent form, and all associated documents were approved by the Pranav Diabetes Centre Ethics Committee(CTSRS/ 2501-01/17 Apr 25) prior to study initiation. Written informed consent was obtained from all participants prior to the initiation of any study-related procedures. Eligibility screening was conducted only after informed consent had been provided.

Consent for publication

Not Applicable.

Availability of data and materials

The original contributions presented in this study are included in this article. Further inquiries can be directed to the corresponding author(s).

Competing interests

The authors declare that they have no competing interests related to this work. The sponsor participated in study design and manuscript preparation but did not influence the interpretation of the results or the decision to publish.

Funding

This study was sponsored by India Glycols Limited, Dehradun, Uttarakhand, India.

Authors' contributions

P.K.B.: Conceptualization, Methodology, Project administration. P.N.: Data curation, Writing-review & editing. R.K.Y.: Conceptualization. H.T.M.: Conceptualization. J.D.: Data curation, Supervision. M.S.K.: Conceptualization, Methodology, Project administration. N.S.S.C.: Methodology. A.P.: Conceptualization, Methodology, Project administration, Data curation, Writing-review & editing.

Acknowledgements
The authors would like to acknowledge Ashish Kumar Singh, Vanshika Agrawal, Rohit Kumar Agrawal, Praveen Gupta, and Nasar Ahmed for their contributions to the formulation development and product analysis. The acknowledged contributors were not involved in the preparation, writing, or review of the manuscript.

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