

Efficacy and Safety of Shatavari (*Asparagus racemosus*) Root Extract for Perimenopause: Randomized, Double-Blind, Placebo-Controlled Study

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Purpose: Perimenopause is a natural phenomenon caused by hormonal changes, often accompanied by symptoms such as hot flashes and mood swings that can affect women's quality of life. Due to concerns about hormonal treatments, women often seek plant-based alternatives. Shatavari (*Asparagus racemosus* Willd.), a renowned herb in Ayurveda, is traditionally used for hormonal regulation and may help relieve these symptoms. Thus, the present study aimed to assess the efficacy and safety of 8-week oral administration of Shatavari root extract 300 mg once daily in women with perimenopausal symptoms.

Patients and Methods: This prospective, randomized, double-blind, placebo-controlled study screened 120 women, and 80 were eligible participants and were randomly assigned to receive either Shatavari root extract (SHT; n = 40) or placebo (PL; n = 40). Seventy-three participants completed the study per protocol (SHT: n = 37; PL: n = 36). Symptom changes were assessed using scales such as the Menopause Rating Scale (MRS), Menopause-Specific Quality of Life (MENQOL) scale, Profile of Mood States (POMS) scale, and Perceived Stress Scale (PSS) at baseline, week 4, and week 8. Blood tests were also conducted to monitor hormone levels and safety markers.

Results: The SHT group demonstrated a significant improvement in MRS (somato-vegetative, psychological, and urogenital domains) and PSS scores ($p < 0.0001$). Furthermore, it showed enhancements in fatigue ($p = 0.019$) at week 8, vigor ($p = 0.021$) at week 4, and stress reductions at week 4 ($p = 0.010$) and week 8 ($p < 0.0001$). Hot flashes improved significantly more ($p = 0.002$) with SHT group. Estradiol ($p = 0.003$), Follicle Stimulating Hormone ($p = 0.028$), and T3 ($p = 0.021$) levels increased with no adverse effects observed on liver or kidney function.

Conclusion: Shatavari root extract may be an effective and safe natural intervention for the treatment of perimenopausal symptoms.

Keywords: *Asparagus racemosus* Willd., perimenopause, randomization, shatavari root extract, MRS, POMS

Introduction

Perimenopause, or the menopausal transition, is a complex and often challenging period in a woman's life marked by fluctuating reproductive hormones and irregular menstrual cycles. It precedes menopause, which is defined as twelve consecutive months of amenorrhea. The perimenopausal period is typically divided into two phases: the early phase, during which menstrual cycles remain relatively regular but exhibit increased variability, and the late phase is characterized by prolonged intervals of amenorrhea lasting at least 60 days prior to the final menstrual period (FMP).¹ According to Duralde et al, approximately 60–80% of women in perimenopause report changes such as delayed cycles, amenorrhea, or oligomenorrhea, while 6.8% may experience shortened cycles, menometrorrhagia, or heavier menstrual flow.² Perimenopausal symptoms are highly prevalent worldwide, affecting nearly 80% of women, with vasomotor complaints such as hot flashes and night sweats being the most common. These symptoms often impair sleep, mood, and overall quality of life. Beyond symptomatic discomfort, the long-term decline in estrogen also contributes to osteoporosis, cardiovascular disease, and urogenital atrophy, making the menopausal transition a critical period for women's health.¹

Hormone replacement therapy (HRT) remains the gold standard for managing vasomotor and other menopausal symptoms. However, these has concerns over its long-term safety leading many women to seek non-hormonal alternatives such as herbal and dietary therapies. Evidence from the Women's Health Initiative (WHI) and subsequent studies has linked prolonged HRT use to increased risks of breast cancer, thromboembolism, and cardiovascular events, which has intensified the demand for safer alternatives.³ The therapeutic potential of phytoestrogens, plant-derived compounds structurally and functionally like endogenous estrogens, has attained significant scientific interest. Epidemiological studies (Chen et al, 2014) suggest that populations with high dietary intake of phytoestrogens report a lower prevalence of menopausal symptoms.⁴ This trend has increased interest in botanicals that may alleviate perimenopausal symptoms.

Shatavari (*Asparagus racemosus* Willd.) is a renowned adaptogenic herb in Ayurvedic medicine, which is traditionally recognized for its efficacy in promoting and maintaining female reproductive health. Referred to as the “Queen of Herbs”, Shatavari is believed to exert rejuvenating effects, promote hormonal balance, and enhance emotional well-being. Its primary bioactive constituents include steroidal saponins (Shatavarins), which have demonstrated progesterone-enhancing and estrogen-mimicking properties in preclinical studies.⁵ In addition, Shatavari contains phytoestrogens, flavonoids, alkaloids, and quercetin glycosides, which collectively contribute to its proposed role in modulating endocrine function and mitigating menopausal complaints such as hot flashes, insomnia, irritability, and mood disturbances.⁶ Despite its long-standing traditional use, clinical evidence supporting Shatavari's role in managing perimenopausal symptoms remains limited, with only a few well-designed trials conducted to date. This scientific gap underscores the importance of rigorous evaluation to establish both efficacy and safety.

Given its traditional use and emerging evidence for hormonal effects, Shatavari root extract is a promising natural plant-based intervention for perimenopausal women. The present randomized, double-blind, placebo-controlled study evaluated the efficacy and safety of a standardized Shatavari root extract in alleviating perimenopausal symptoms, focusing primarily on vasomotor, psychological, and somatic domains.

Materials and Methods

Study Design

This was an 8-week prospective, randomized, double-blind, two-arm, parallel-group, placebo-controlled clinical trial. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki (2013 revision) and followed Good Clinical Practice (GCP) guidelines. It also adhered to the Consolidated Standards of Reporting Trials (CONSORT) criteria for the design and reporting of randomized controlled trials.

Ethical Approvals

The clinical study protocol was reviewed and approved by the Institutional Ethics Committee (IEC) of Dr. D. Y. Patil Medical College & Hospital, Navi Mumbai, Maharashtra, India (IEC Reference No.: DYP/IECBH/2024/428). The study was prospectively registered with the Clinical Trials Registry of India (CTRI) under registration number CTRI/2024/09/074239 on September 24, 2024. The study was conducted at Tieten Medicity Hospital, Gynecology Division, Thane, Maharashtra, India, between 01 Oct 2024 and 13 Dec 2024.

Written informed consent was obtained from all participants prior to enrollment, in their preferred languages (Hindi, Marathi, and English). Before obtaining consent, participants were provided with a comprehensive explanation of the study's purpose, procedures, and anticipated outcomes. To ensure adherence to the intervention, participants were instructed to maintain a daily diary recording the time and date of capsule intake. Study staff reviewed these diaries at each follow-up visit. In addition, unused capsules were collected and counted to verify compliance. Participants who demonstrated adherence of $\geq 80\%$ were included in the per-protocol analysis, while all randomized participants were included in the intention-to-treat (ITT) analysis.

Study Population

Inclusion Criteria

Eligible participants were women aged 40 to 55 years with an intact uterus and ovaries, who provided written informed consent and agreed to comply with all study procedures. Eligibility criteria included a history of irregular menstrual cycles over the past 12 months (defined as cycles that were advanced or delayed by more than 7 days, or the absence of two cycles within the year), or amenorrhea lasting at least 60 days. Additional inclusion criteria included the presence of self-reported menopausal symptoms, such as hot flashes, insomnia, migraine, or increased irritability, and a body mass index (BMI) of 18–35 kg/m². Participants had to be literate in English or a local language and have no intention of initiating new treatments during the study period.

Exclusion Criteria

Women were excluded if they had used any herbal remedies or HRT for more than 3 months prior to the study. Women with active medical, surgical, or gynecological conditions, as well as those with a history of substance abuse (alcohol, tobacco, or drugs) were excluded. Additional exclusions applied to those with systemic diseases (cardiovascular, gastrointestinal, hepatic, neurologic, endocrine, and hematologic) that could interfere with study outcomes. Women with psychiatric or cognitive disorders that could impair informed consent, those with noncompliant behavior, or inability to attend scheduled follow-up visits, and those with any active infections or uncontrolled medical conditions were excluded. Further exclusion criteria included a history of bilateral ovariectomy, breast or cervical carcinoma, or use of medications affecting bone metabolism (e.g., glucocorticoids, anticonvulsants, methotrexate). Women who had participated in another clinical trial within the previous three months were also not eligible.

Randomization and Blinding

Block randomization was performed using an automated random number generator (Rando version 1.2 R), with allocation sequences pre-specified for the study. Participants were randomly assigned in a 1:1 ratio to receive either Shatavari root extract or a placebo. To ensure blinding, the Shatavari root extract and placebo capsules were identical in appearance, shape, color, and packaging. The randomization codes were securely stored in sealed envelopes and accessed only after assigning each participant a study identification number. The investigators, clinical staff, and biostatistics team were blinded to the treatment assignments throughout the study duration.

Study Interventions

The intervention group received capsules containing 300 mg of standardized Shatavari root extract (Ixoreal Biomed Inc., Los Angeles, USA). The placebo group received identical capsules containing 300 mg of inert starch. Participants were instructed to take one capsule daily with water after breakfast for 8 weeks and maintain their usual dietary and lifestyle practices throughout the study period.

Investigational Product

The investigational product used in this study was a standardized Shatavari root (*Asparagus racemosus* Willd.) extract, commercially sourced and manufactured under current Good Manufacturing Practice (cGMP) conditions. Shatavari is cultivated in sandy, dry soil with a pH of 7.0 to 8.0 to optimize the concentration of bioactive constituents such as Shatavarins. This extract was prepared in alignment with the green chemistry principles devoid of any harsh solvents. The final product had an herb-to-extract ratio of 13:1 and was standardized to contain a minimum of >10% total Shatavarins, as determined by high-performance liquid chromatography (HPLC). The resulting extract was a yellowish-brown powder encapsulated for oral administration.

Participants in the placebo group received capsules containing inert starch, matched to the investigational product in size, shape, and color to maintain blinding.

Sample Size Calculation

Sample size estimation was based on the expected change in total Menopause Rating Scale (MRS) scores from baseline to week 8. Due to the absence of prior clinical data on Shatavari root extract, assumptions were made based on published findings for Ashwagandha root extract (*Withania somnifera*). In a study by Gopal et al (2021), Ashwagandha treatment resulted in a mean MRS score reduction of -3.37 (SD = 3.94; 95% CI: -4.10 to -2.73), compared to -1.60 (SD = 1.76; 95% CI: -2.11 to -1.09) in the placebo group. Assuming a similar treatment effect for Shatavari, the sample size required to detect a between-group difference of -1.8 with 80.2% power and a one-sided alpha of 0.05 was calculated to be 37 participants per group using a two-sample *t*-test. The total enrollment target was 80 participants (40 per arm) to account for potential attrition.

Study Outcomes

Participants were assessed at baseline, week 4, and week 8. At each time point, vital signs including pulse rate, respiratory rate, and body temperature were recorded.

Primary Outcome Measure

The primary efficacy endpoint was the change in total MRS score from baseline to week 8. The MRS is a validated, self-administered questionnaire comprising 11 items rated from 0 (no symptoms) to 4 (very severe). It assesses symptoms across three domains: psychological, somatic, and urogenital. The total score is the sum of individual item scores.

Secondary Outcome Measures

Menopause Specific Quality of Life Questionnaire (MENQOL)

The MENQOL is a validated, 29-item self-administered questionnaire^{7,8} measuring the impact of menopausal symptoms on quality of life across four domains: vasomotor (items 1–3), psychosocial (items 4–10), physical (items 11–26), and sexual (items 27–29). Each symptom is rated for presence and degree of bother on a 0–6 Likert scale, with domain scores computed by adding relevant item responses.

Perceived Stress Scale (PSS)

The PSS score^{9,10} is a 10-item self-report tool assessing subjective stress over the preceding month. Each item is rated on a five-point Likert scale ranging from 0 (never) to 4 (very often). Total scores are calculated by summing all item scores after reversing the appropriate items.

Profile of Mood States (POMS)

The POMS is a 40-item self-report questionnaire of emotional status across eight subscales: tension, depression, anger, fatigue, confusion, vigor, esteem-related affect (ERA), and total mood disturbance (TMD). Each item is rated from 0 (not at all) to 4 (extremely). Subscale scores are derived by adding relevant items; TMD is calculated by subtracting the vigor and ERA scores from the sum of the negative mood scores.

Hormonal and Biochemical Assessments

Blood samples were collected at baseline and week 8 to evaluate serum hormone levels and assess liver, renal, and thyroid function. Samples were collected into Ethylenediaminetetraacetic acid (EDTA) and non-EDTA tubes, centrifuged, and serum aliquots were stored at -80°C for subsequent analysis. Hormonal concentrations were measured using commercially available ELISA kits (Thermo Fisher Scientific, USA), employing a sandwich ELISA format for protein hormones (e.g., insulin, TSH, LH, FSH) and a competitive ELISA format for steroid hormones (e.g., cortisol, testosterone, estradiol).

Assessment of Vasomotor and Mood-Related Symptoms

Vasomotor symptoms, specifically hot flashes, were assessed via the MRS by evaluating their frequency and severity on a 0–4 scale. Mood disturbances, including anxiety, irritability, and depressive affect, were assessed through relevant MRS

items and further supported by POMS data. Changes in symptom severity from baseline to week 8 were used to evaluate treatment efficacy.

Safety Assessments

Safety was evaluated by documenting all treatment-emergent adverse events (TEAEs) and treatment-emergent serious adverse events (TESAEs), whether observed by the investigators or reported by participants. These were recorded during study visits conducted in weeks 4 and 8. In addition, serum biochemical parameters were assessed at baseline and at week 8 to monitor potential treatment-related effects on thyroid function (triiodothyronine [T3], thyroxine [T4], and thyroid-stimulating hormone [TSH]), renal function (serum creatinine and blood urea nitrogen [BUN]), and hepatic function (alanine transaminase [ALT], aspartate transaminase [AST], alkaline phosphatase [ALP], and total bilirubin).

Statistical Methods and Data Analysis

All participants who received at least one dose of the investigational product were included in both safety and efficacy analyses. Data analysis was performed using Stata 13.1 for Windows (StataCorp, College Station, TX, USA). Continuous variables were summarized as mean $\pm$ standard deviation (SD), while categorical variables were presented as frequencies and percentages. Between-group comparisons for continuous variables were conducted using the two-sample independent *t*-test. All statistical tests were two-tailed with a *p* value < 0.05 considered statistically significant.

Analyses were conducted following the ITT principle, with per-protocol (PP) analysis performed for efficacy outcomes.

Results

Study Population

A total of 120 participants were screened for eligibility. Of these, 80 participants met the inclusion criteria and were randomized in a 1:1 ratio to receive either Shatavari root extract (SHT; *n* = 40) or placebo (PL; *n* = 40). Among the 40 excluded, 18 did not meet the eligibility criteria, and 22 declined to participate.

During the study period, three participants from the SHT group and four from the PL group were lost to follow-up. Thus, the PP population comprised 73 participants with 37 in the SHT group and 36 in the PL group. A CONSORT flow diagram illustrating the participant disposition is presented in [Figure 1](#).

Baseline Characteristics (ITT Dataset)

[Table 1](#) presents the baseline demographic, clinical, and symptom profile characteristics for all randomized participants (*n* = 80) included in the ITT analysis. No statistically significant differences existed between the SHT and PL groups for any measured parameters at baseline. Mean age was 50.33 years (SD = 5.14) in the SHT group and 51.43 years (SD = 6.14) in the PL group (*p* = 0.388). Other anthropometric variables, including height, weight, and body mass index (BMI), as well as vital signs (systolic/diastolic blood pressure, pulse, temperature, and respiratory rate), did not differ significantly between groups (*p* > 0.05).

Baseline symptom burden, including MRS total and subdomain scores, MENQOL domains, PSS-10, and POMS scores, was also comparable between groups (all *p* > 0.05), confirming successful randomization.

MRS and MENQOL Outcomes (PP Dataset)

[Table 2](#) summarizes changes from baseline to weeks 4 and 8 in MRS ([Figure 2](#)) and MENQOL scores ([Figure 3](#)) among participants in the PP dataset (*n* = 73). No significant differences in baseline MRS or MENQOL scores were noted between groups.

At week 8, participants in the SHT group experienced statistically significant improvements compared to placebo in all MRS domains: somato-vegetative (mean change = -4.24 ± 4.23 vs 0.36 ± 3.41 ; *p* < 0.0001), psychological ($-4.65 \pm$

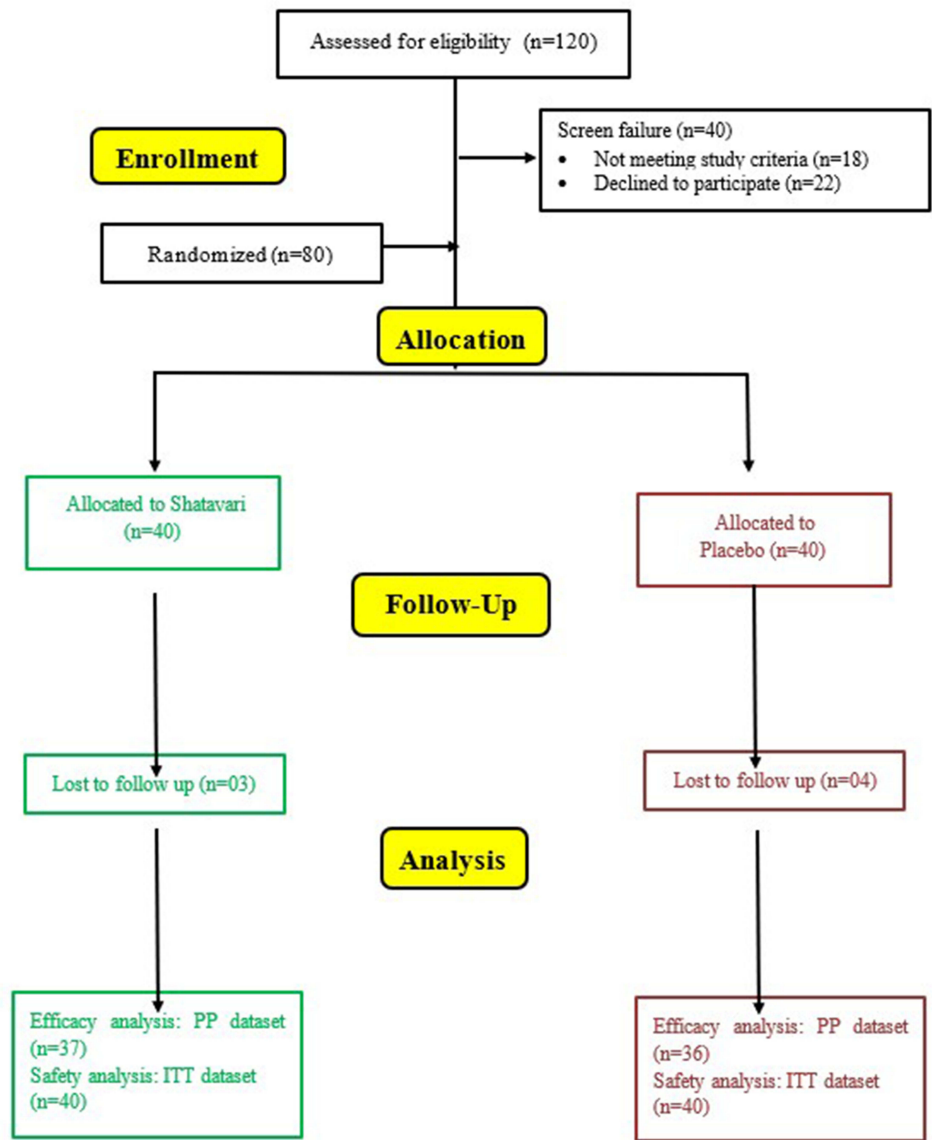


Figure 1 Consort Flow Diagram.
Abbreviations: ITT, Intention-to-Treat; PP, Per Protocol.

3.74 vs -0.75 ± 2.48 ; $p < 0.0001$), and urogenital (-3.65 ± 3.46 vs -1.22 ± 1.90 ; $p < 0.0001$). The reduction in MRS total score from baseline to week 8 was also significantly greater in the SHT group (-12.54 ± 9.69) compared to placebo (-1.61 ± 4.62 ; $p < 0.0001$).

Table 1 Summary of All Parameters for Participants in ITT Dataset

	Shatavari Root Extract	Placebo	p*
	Mean (SD)	Mean (SD)	
Number of participants	40	40	
Demography			
Age (yrs.)	50.33 (5.14)	51.43 (6.14)	0.388
Height (cm.)	156.80 (5.23)	159.00 (6.21)	0.090
Weight (kg.)	63.03 (9.24)	63.08 (8.03)	0.979
BMI (kg/m ²)	25.63 (3.59)	25.13 (4.28)	0.574

(Continued)

Table 1 (Continued).

	Shatavari Root Extract	Placebo	p*
	Mean (SD)	Mean (SD)	
Physical examination			
SBP (mm Hg)	121.65 (7.82)	120.55 (17.23)	0.714
DBP (mm Hg)	78.80 (7.56)	79.13 (5.27)	0.824
Pulse rate	76.90 (5.42)	76.90 (4.46)	1.000
Temperature	98.21 (0.63)	98.10 (0.66)	0.457
Respiratory rate	17.68 (2.15)	17.93 (1.85)	0.579
MRS			
Somato-vegetative domain	10.35 (2.65)	9.70 (2.79)	0.289
Psychological domain	10.73 (2.23)	11.03 (2.42)	0.566
Urogenital domain	8.35 (2.07)	8.50 (2.08)	0.747
MRS total Score	29.43 (4.99)	29.23 (5.32)	0.863
PSS-10			
PSS total score	23.75 (2.97)	24.03 (2.77)	0.669
MENQOL			
Vasomotor	3.93 (1.00)	3.78 (0.87)	0.390
Psychosocial	3.53 (0.73)	3.50 (0.72)	0.992
Physical	3.45 (0.43)	3.60 (0.44)	0.534
Sexual	3.63 (1.04)	3.46 (0.98)	0.493
MENQOL total Score	3.53 (0.35)	3.58 (0.32)	0.852
POMS			
Tension	5.23 (3.57)	5.45 (3.60)	0.780
Anger	6.00 (2.85)	6.95 (4.66)	0.274
Depression	6.43 (4.34)	6.48 (4.06)	0.958
Fatigue	8.78 (2.74)	9.78 (2.82)	0.112
Confusion	6.40 (3.48)	6.95 (3.01)	0.452
ERA	13.40 (2.73)	13.68 (2.44)	0.637
Vigour	8.08 (2.59)	8.80 (2.30)	0.189
TMD	110.63 (14.01)	113.13 (14.15)	0.430
Hot flashes (MRS)			
Hot flashes	14.70 (2.34)	14.68 (2.10)	0.960

Notes: *p-value was obtained using an independent two-sample t-test for differences between two means (two-tailed).

Abbreviations: BMI, Body Mass Index; DBP, Diastolic Blood Pressure; ERA, Esteem Related Affect; ITT, Intent-to-Treat; SBP, Systolic Blood Pressure; PSS, Perceived Stress Scale; POMS, Profile of Mood States; MenQol, Menopause-Specific Quality of Life; MRS, Menopause Rating Scale; SD, Standard Deviation; TMD, Total Mood Disturbance.

Table 2 Summary of MRS Scale and MENQOL Assessment in PP Dataset

	Shatavari Root Extract	Placebo	p*
	Mean (SD)	Mean (SD)	
Number of participants	37	36	
MRS scale			
Somato-vegetative domain			
Baseline	10.46 (2.71)	9.83 (2.61)	0.319
Change at week 4	-2.97 (3.91)	-0.75 (2.89)	0.007
Change at week 8	-4.24 (4.23)	0.36 (3.41)	<0.0001

(Continued)

Table 2 (Continued).

	Shatavari Root Extract	Placebo	<i>p</i> *
	<i>Mean (SD)</i>	<i>Mean (SD)</i>	
Psychological domain			
Baseline	10.65 (2.29)	11.11 (2.44)	0.406
Change at week 4	−2.51 (3.69)	−1.97 (2.98)	0.493
Change at week 8	−4.65 (3.74)	−0.75 (2.48)	<0.0001
Urogenital domain			
Baseline	8.35 (2.12)	8.50 (2.13)	0.766
Change at week 4	−2.59 (3.37)	−1.64 (3.51)	0.240
Change at week 8	−3.65 (3.46)	−1.22 (1.90)	<0.0001
MRS total score			
Baseline	29.46 (5.17)	29.44 (5.05)	0.990
Change at week 4	−8.08 (8.41)	−4.36 (6.18)	0.035
Change at week 8	−12.54 (9.69)	−1.61 (4.62)	<0.0001
MENQOL scale			
Vasomotor domain			
Baseline	3.94 (1.04)	3.81 (0.88)	0.264
Change at week 4	−0.42 (1.54)	−0.04 (1.33)	0.141
Change at week 8	−0.81 (1.46)	−0.29 (1.66)	0.595
Psychosocial domain			
Baseline	3.56 (0.74)	3.43 (0.70)	0.614
Change at week 4	−0.16 (1.06)	0.01 (0.82)	0.228
Change at week 8	−0.28 (1.17)	0.16 (1.10)	0.702
Physical domain			
Baseline	3.45 (0.44)	3.57 (0.42)	0.930
Change at week 4	−0.09 (0.68)	−0.02 (0.58)	0.245
Change at week 8	−0.10 (0.67)	−0.11 (0.73)	0.607
Sexual domain			
Baseline	3.68 (1.03)	3.42 (0.98)	0.558
Change at week 4	−0.47 (1.28)	0.06 (1.55)	0.402
Change at week 8	0.21 (1.48)	−0.02 (1.61)	0.417
MENQOL total score			
Baseline	3.55 (0.35)	3.55 (0.30)	0.488
Change at week 4	−0.18 (0.53)	0.00 (0.44)	0.102
Change at week 8	−0.19 (0.48)	−0.05 (0.68)	0.043

Notes: **p*-value was obtained using an independent two-sample *t*-test for differences between two means (two-tailed).

Abbreviations: MENQOL, Menopause-Specific Quality of Life; MRS, Menopause Rating Scale; PP, Per-Protocol; SD, Standard Deviation.

While the SHT group showed numerically greater improvements across MENQOL domains, between-group differences were statistically significant at week 8 (total MENQOL score: -0.19 ± 0.48 vs -0.05 ± 0.68 ; $p = 0.043$).

POMS

Changes in emotional well-being were evaluated using the POMS. Statistically significant between-group differences were observed in two domains. At week 8, fatigue scores improved significantly more in the SHT group compared to PL (mean change: -2.49 ± 3.34 vs -0.72 ± 2.92 ; $p = 0.019$). Additionally, at week 4, vigor scores were significantly higher in the SHT group (1.65 ± 2.78) than in the PL group (0.28 ± 2.15 ; $p = 0.021$). No significant between-group differences

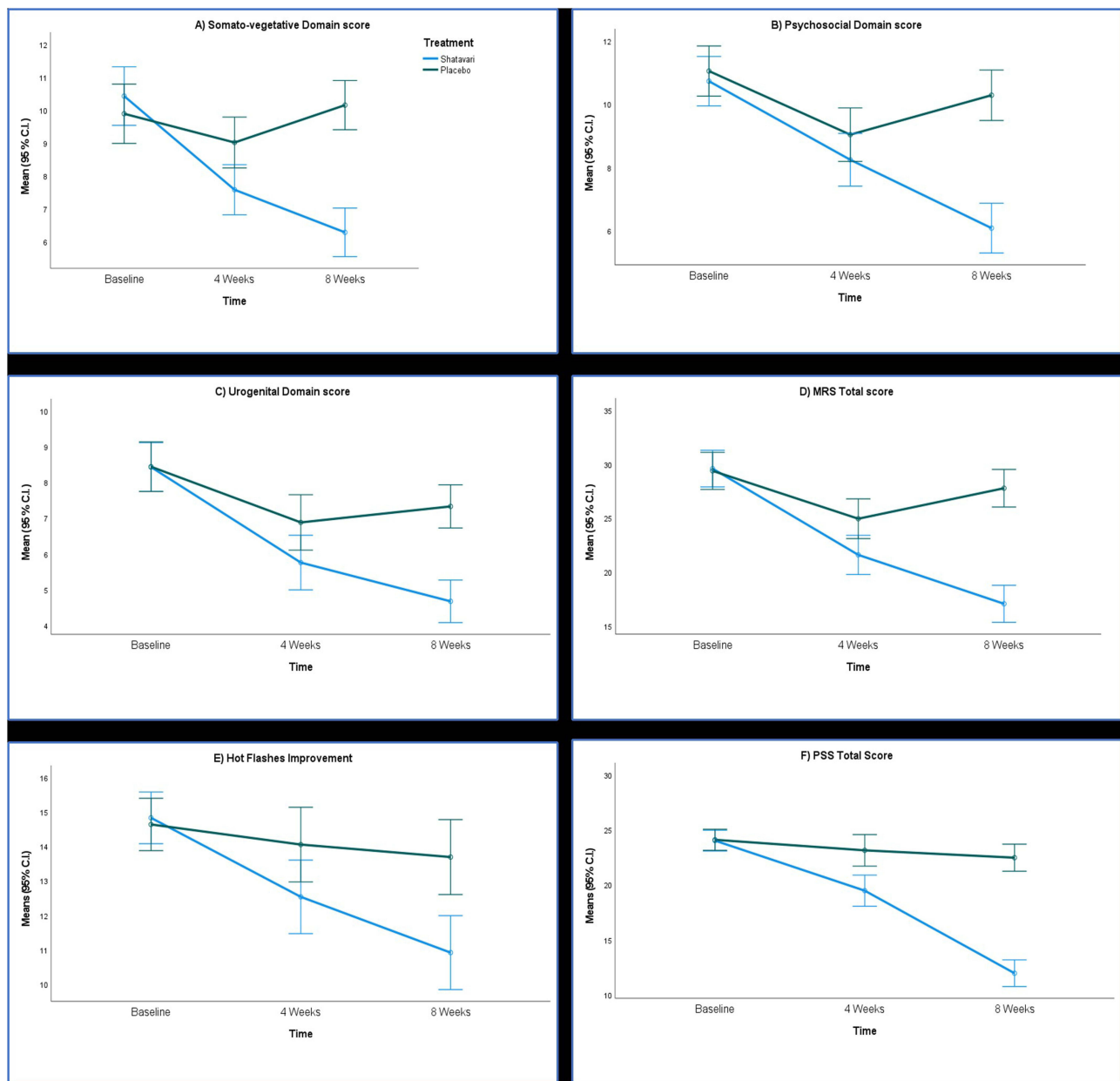


Figure 2 Mean score of Somato-vegetative Domain (A), Psychological Domain (B), Urogenital Domain (C), MRS Total Score (D), Hot Flashes Improvement Score (E), PSS Total Score (F).

Abbreviations: CI, Confidence Intervals; MRS, Menopause Rating Scale; PSS, Perceived Stress Scale.

were detected in other POMS subdomains, including tension, anger, depression, confusion, ERA, or TMD at any time point (all $p > 0.05$).

Table 3 presents detailed results for POMS scores in the PP dataset (Figure 4).

Perceived Stress (PSS-10)

At baseline, PSS-10 scores were identical between the SHT and PL groups (24.03 ± 2.87 vs 24.03 ± 2.77 ; $p = 0.999$). However, the SHT group demonstrated significantly greater reductions in perceived stress at both week 4 (-2.65 ± 6.43 vs 1.06 ± 5.54 ; $p = 0.010$) and week 8 (-7.11 ± 6.95 vs 3.81 ± 4.97 ; $p < 0.0001$). These data indicate a progressive and statistically robust reduction in perceived stress following SHT supplementation (Figure 2).

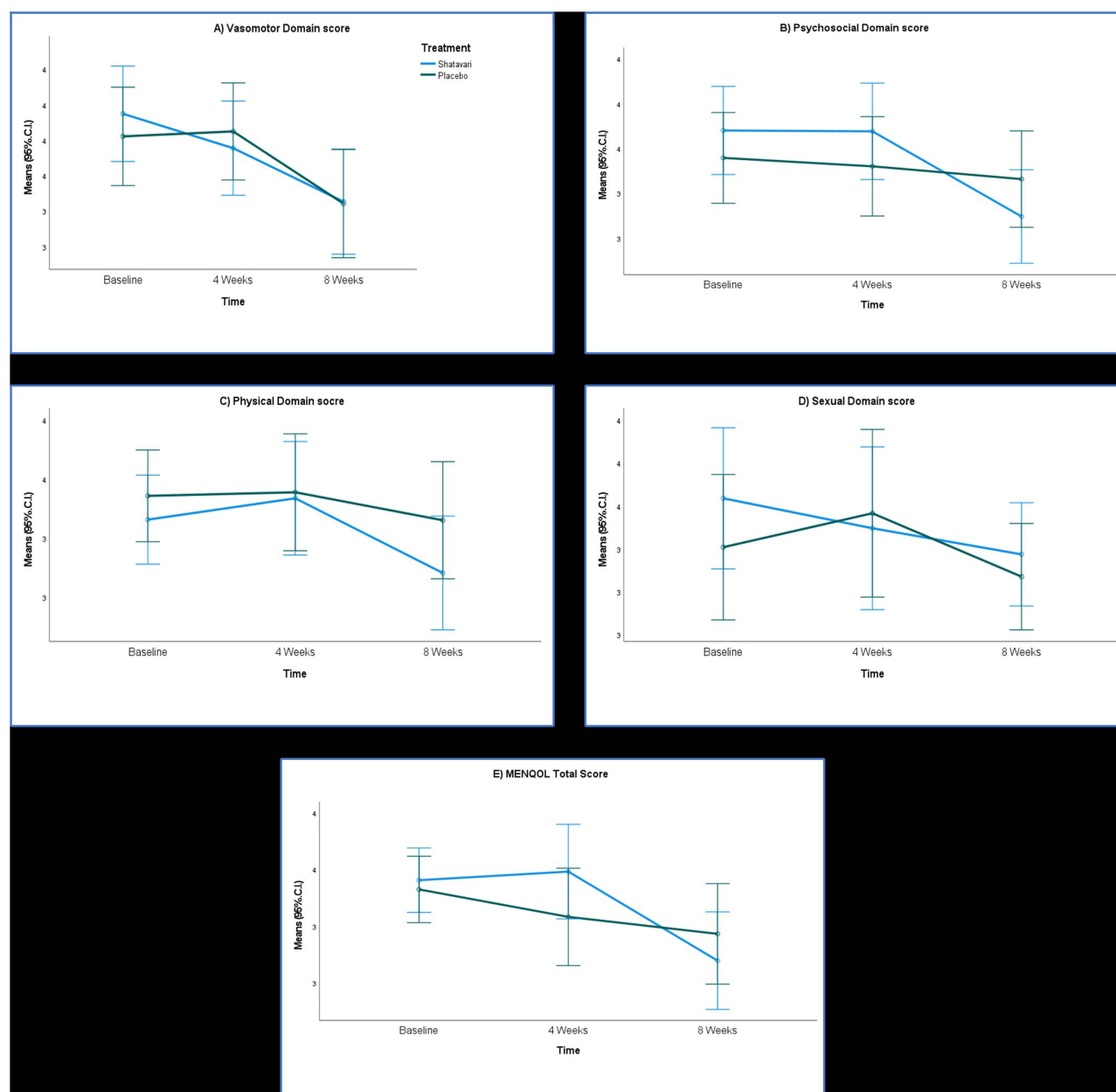


Figure 3 Mean scores of Vasomotor Domain (A), Psychosocial Domain (B), Physical Domain (C), Sexual Domain (D), MENQOL Total Score (E).
Abbreviations: CI, Confidence Intervals; MENQOL, Menopause-Specific Quality of Life Questionnaire.

Hot Flash Frequency

Baseline hot flash scores were comparable between groups (SHT: 14.81 ± 2.34 ; PL: 14.64 ± 2.21 ; $p = 0.748$). By week 8, the SHT group experienced a significantly greater reduction in hot flash frequency than PL (-3.84 ± 3.79 vs -1.03 ± 3.78 ; $p = 0.002$). A non-significant trend was observed at week 4 (-2.22 ± 3.99 vs -0.67 ± 3.70 ; $p = 0.090$).

Table 4 summarizes outcomes related to PSS-10 and hot flashes in the PP dataset (Figure 2).

Hormonal and Laboratory Parameters

At week 8, statistically significant between-group differences were observed in estradiol (53.88 ± 9.95 pg/mL vs 47.27 ± 8.33 pg/mL; $p = 0.003$), FSH (49.66 ± 13.57 IU/mL vs 42.11 ± 15.21 IU/mL; $p = 0.028$), and T3 levels (141.81 ± 36.29 ng/dL vs 125.48 ± 20.78 ng/dL; $p = 0.021$), favoring the SHT group. However, changes from baseline to week 8 in these hormone

Table 3 POMS Scores in PP Dataset

	Shatavari Root Extract	Placebo	<i>p</i> *
	Mean (SD)	Mean (SD)	
Number of participants	37	36	
POMS scale			
Tension domain			
Baseline	5.14 (3.33)	5.39 (3.59)	0.755
Change at week 4	−0.43 (3.45)	−0.33 (3.76)	0.907
Change at week 8	−1.24 (3.92)	−0.75 (3.39)	0.568
Anger domain			
Baseline	5.95 (2.74)	7.19 (4.81)	0.176
Change at week 4	−0.92 (3.93)	−0.78 (5.92)	0.905
Change at week 8	−2.51 (3.64)	−1.44 (4.56)	0.271
Depression domain			
Baseline	6.46 (4.46)	6.64 (4.22)	0.861
Change at week 4	−1.65 (5.06)	−0.22 (5.94)	0.273
Change at week 8	−2.35 (5.36)	−0.97 (4.54)	0.240
Fatigue domain			
Baseline	8.73 (2.75)	9.89 (2.89)	0.083
Change at week 4	−0.49 (3.16)	−0.97 (4.23)	0.579
Change at week 8	−2.49 (3.34)	−0.72 (2.92)	0.019
Confusion domain			
Baseline	6.43 (3.40)	6.83 (2.91)	0.591
Change at week 4	−1.03 (4.27)	−0.53 (3.23)	0.576
Change at week 8	−0.78 (3.28)	−0.17 (2.86)	0.396
ERA domain			
Baseline	13.41 (2.82)	13.50 (2.50)	0.880
Change at week 4	−1.16 (3.86)	−0.14 (3.32)	0.229
Change at week 8	−1.00 (3.36)	−0.06 (3.52)	0.245
Vigour domain			
Baseline	8.00 (2.55)	8.83 (2.26)	0.144
Change at week 4	1.65 (2.78)	0.28 (2.15)	0.021
Change at week 8	2.84 (3.51)	2.14 (3.05)	0.367
TMD total score			
Baseline	110.51 (13.65)	113.61 (14.69)	0.354
Change at week 4	−4.22 (14.61)	−2.97 (16.19)	0.731
Change at week 8	−10.43 (15.53)	−6.14 (12.88)	0.203

Notes: *p-value was obtained using an independent two-sample t-test for differences between two means (two-tailed).

Abbreviations: ERA, Esteem Related Affect; POMS, Profile of Mood States; PP, Per-Protocol; SD, Standard Deviation; TMD, Total Mood Disturbance.

levels were not statistically significant between groups (all $p > 0.05$). No significant differences were noted in LH, testosterone, TSH, T4, or liver and renal function parameters (including AST, ALT, bilirubin, creatinine, and urea) at week 8.

Table 5 details hormonal and biochemical outcomes across both study arms.

Safety Assessment

No adverse events were reported during the study.

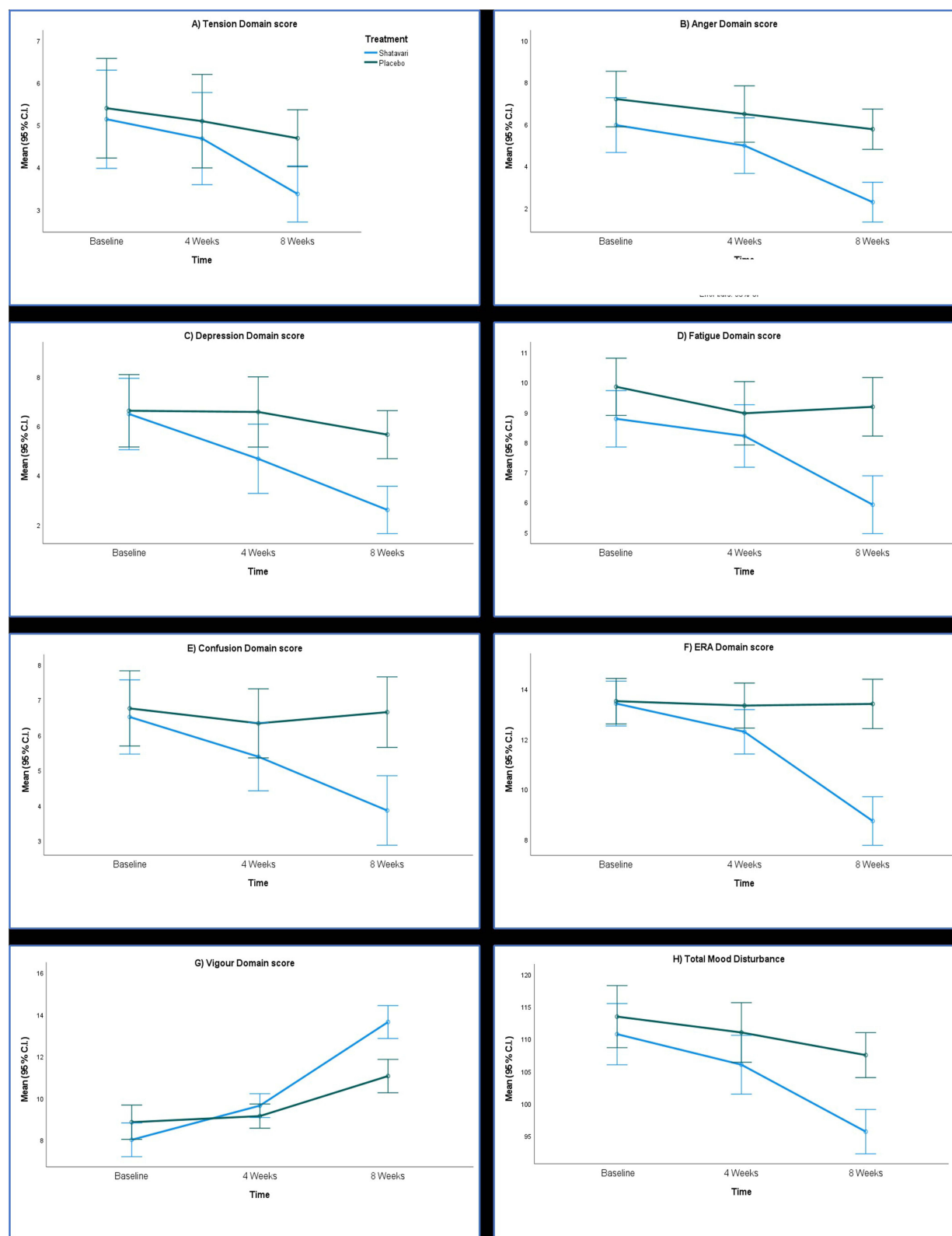


Figure 4 Mean score of Tension Domain (A), Anger Domain (B), Depression Domain (C), Fatigue Domain (D), Confusion Domain (E), ERA Domain (F), Vigour Domain (G), Total Mood Disturbance (H).

Abbreviations: CI, Confidence Intervals; ERA, Esteem-related Affect.

Table 4 Summary of PSS Assessment and Recording of Hot Flashes Improvement in PP Dataset

	Shatavari Root Extract	Placebo	<i>p</i> *
	Mean (SD)	Mean (SD)	
Number of participants	37	36	
PSS-10			
Baseline	24.03 (2.87)	24.03 (2.77)	0.999
Change at week 4	-2.65 (6.43)	1.06 (5.54)	0.010
Change at week 8	-7.11 (6.95)	3.81 (4.97)	<0.0001
Hot Flashes improvement			
Baseline	14.81 (2.34)	14.64 (2.21)	0.748
Change at week 4	-2.22 (3.99)	-0.67 (3.70)	0.090
Change at week 8	-3.84 (3.79)	-1.03 (3.78)	0.002

Notes: *p-value was obtained using an independent two-sample t-test for differences between two means (two-tailed).

Abbreviations: PP, Per-Protocol; PSS, Perceived Stress Scale; SD, Standard Deviation.

Table 5 Summary of Serum Hormonal Levels and Laboratory Parameters for PP Dataset

	Shatavari Root Extract	Placebo	<i>p</i> *
	Mean (SD)	Mean (SD)	
Estradiol (pg/mL)			
Baseline	40.56 (47.00)	45.92 (26.33)	0.551
Week 8	53.88 (9.95)	47.27 (8.33)	0.003
Change at week 8	13.32 (48.45)	1.35 (24.78)	0.190
FSH (IU/mL)			
Baseline	42.67 (31.10)	41.37 (39.13)	0.875
Week 8	49.66 (13.57)	42.11 (15.21)	0.028
Change at week 8	6.98 (32.29)	0.74 (48.85)	0.521
LH (IU/L)			
Baseline	26.41 (20.72)	25.10 (17.88)	0.773
Week 8	29.31 (8.18)	26.14 (6.12)	0.066
Change at week 8	2.89 (22.17)	1.04 (20.87)	0.714
Testosterone (ng/dL)			
Baseline	9.41 (13.00)	11.20 (12.09)	0.545
Week 8	10.99 (3.51)	11.23 (2.63)	0.737
Change at week 8	1.58 (14.62)	0.04 (11.90)	0.623
Total Bilirubin (mg/dL)			
Baseline	0.54 (0.28)	0.59 (0.63)	0.682
Week 8	0.46 (0.18)	0.51 (0.26)	0.284
Change at week 8	-0.09 (0.31)	-0.08 (0.69)	0.934
Alkaline Phosphatase (IU/L)			
Baseline	83.21 (26.36)	73.39 (21.84)	0.088
Week 8	77.73 (23.68)	77.39 (14.47)	0.941
Change at week 8	-5.48 (38.13)	4.00 (24.18)	0.210

(Continued)

Table 5 (Continued).

	Shatavari Root Extract	Placebo	p*
	Mean (SD)	Mean (SD)	
AST (IU/L)			
Baseline	24.23 (4.44)	22.56 (4.25)	0.105
Week 8	23.22 (4.69)	22.50 (5.39)	0.546
Change at week 8	-1.01 (5.44)	-0.06 (6.96)	0.515
ALT (IU/L)			
Baseline	18.49 (5.52)	22.86 (15.13)	0.103
Week 8	18.70 (4.67)	19.98 (7.17)	0.368
Change at week 8	0.22 (7.29)	-2.88 (17.54)	0.326
Creatinine (mg/dL)			
Baseline	0.74 (0.19)	0.79 (0.18)	0.252
Week 8	0.78 (0.16)	0.76 (0.18)	0.620
Change at week 8	0.04 (0.25)	-0.03 (0.26)	0.245
Urea (mg/dL)			
Baseline	13.31 (7.61)	13.23 (5.39)	0.962
Week 8	12.97 (5.79)	13.37 (4.77)	0.749
Change at week 8	-0.33 (8.49)	0.14 (6.64)	0.792
TSH (mIU/L)			
Baseline	7.82 (11.14)	5.59 (3.50)	0.254
Week 8	5.72 (3.65)	6.01 (2.65)	0.707
Change at week 8	-2.10 (11.21)	0.42 (4.13)	0.210
T3 (ng/dL)			
Baseline	133.67 (31.67)	125.82 (17.96)	0.199
Week 8	141.81 (36.29)	125.48 (20.78)	0.021
Change at week 8	8.14 (49.72)	-0.35 (22.91)	0.355
T4 (µg/dL)			
Baseline	8.30 (2.34)	7.94 (2.13)	0.486
Week 8	9.03 (2.89)	8.12 (1.73)	0.107
Change at week 8	0.73 (3.32)	0.18 (2.11)	0.406

Notes: *p-value was obtained using an independent two-sample t-test for differences between two means (two-tailed).

Abbreviations: ALT, Alanine Transaminase; AST, Aspartate Aminotransferase; FSH, Follicle-stimulating Hormone; LH, Luteinizing Hormone; PP, Per-Protocol; SD, Standard Deviation; TSH, Thyroid-stimulating Hormone; T3, Triiodothyronine Serum; T4, Thyroxine Serum.

Discussion

Perimenopause is characterized by progressive alterations in ovarian function and fluctuating hormone levels, eventually culminating in menopause, or the complete cessation of menstruation for 12 consecutive months. Common clinical manifestations include vasomotor symptoms (e.g., hot flashes, night sweats), mood disturbances, sleep irregularities, urogenital atrophy (including vaginal dryness and epithelial thinning), urinary incontinence, and increased risk for osteoporosis and cardiovascular disease.^{1,10–12}

Shatavari (*Asparagus racemosus* Willd.) is a well-known adaptogenic and gynecological herb in Ayurvedic medicine, traditionally used to support reproductive function, alleviate menopausal symptoms, enhance lactation, and promote emotional well-being.⁵ The root contains phytoestrogens plant-derived compounds that exhibit estrogen-like activity which may help ameliorate symptoms of low estrogen experienced during perimenopause.^{6,13} This study represents the first investigation demonstrating the potential of Shatavari root extract in reducing perimenopausal symptoms.

Phytochemical analyses have identified steroidal saponins (e.g., Shatavarins), quercetin, and other flavonoid glycosides as the principal bioactive constituents.⁶ Phytoestrogens in Shatavari are believed to modulate estrogenic activity by binding to estrogen receptors.¹⁴ Patibandla et al and other researchers have demonstrated the potential of Shatavari in alleviating perimenopausal symptoms, suggesting a plausible role for this botanical as a natural menopause treatment.¹⁵

In the present study, significant improvements were observed in all three domains (somato-vegetative, psychological, and urogenital) of the MRS in the SHT group ($p < 0.0001$), indicating a broad-spectrum effect on perimenopausal symptomatology. These findings suggest that Shatavari root extract may offer a viable botanical intervention for managing multifaceted menopausal complaints. A key strength of this trial is the use of a standardized Shatavari root extract containing >10% shatavarins. Standardization at this level provides greater consistency in dosing, enhances the reliability of the observed effects, and contributes novel evidence regarding both the efficacy and safety of shatavarin (>10%) content in perimenopausal women.

Significant reductions in fatigue and improvements in vigor were observed in the POMS, consistent with the adaptogenic properties attributed to Shatavari.^{15–18} Additionally, perceived stress, as measured by the PSS-10, showed a progressive and statistically significant reduction in the SHT group compared to PL. These findings align with the work of Takanari et al, who reported that an enzyme-treated extract of *Asparagus racemosus* (ETAS) improved sleep quality and reduced fatigue and psychological distress under stress conditions.^{19,20}

Hot flash frequency, one of the most distressing vasomotor symptoms during perimenopause, was significantly reduced in the SHT group over the eight-week study period ($p = 0.002$). This result is consistent with the findings of Gudise et al, who reported a significant reduction in both the frequency and severity of daily hot flashes in menopausal women treated with Shatavari root extract.^{21,22}

Biochemical analysis revealed a significant post-treatment increase in serum estradiol and T3 levels in the SHT group, suggesting a hormonal modulatory effect. The inclusion of T3 was considered important because thyroid dysfunction can mimic or exacerbate perimenopausal symptoms such as fatigue, mood changes, menstrual irregularities, and sleep disturbances. Measuring T3 therefore, allowed for a more comprehensive hormonal profile and facilitated differentiation between menopausal and thyroid-related symptomatology. Additionally, FSH levels were significantly higher at week 8 in the SHT group compared to placebo, though changes from baseline were not statistically significant.

In this study, four validated self-reported questionnaires (MRS, MENQOL, PSS, and POMS) were employed to comprehensively evaluate the effects of Shatavari on perimenopausal health. Each instrument was selected to capture a distinct domain: MRS for symptom severity, MENQOL for quality of life, PSS for perceived stress,²³ and POMS for mood states. This multidimensional approach provided a more holistic understanding of the intervention's impact. There were no adverse changes in liver or renal function markers, which supports the short-term safety profile of Shatavari root extract. These results align with previous studies indicating favorable endocrine modulation by Shatavari root extract with no hepatic or renal toxicity.^{21,22}

It is important to distinguish between perimenopause and menopause when interpreting the findings of this study. Perimenopause is characterized by fluctuating ovarian hormone levels and irregular cycles, which often result in a broader spectrum of vasomotor, psychological, and somatic symptoms compared to the postmenopausal stage, where estrogen deficiency is more stable. The present results provide novel evidence that Shatavari root extract may be particularly effective during this transitional phase, where symptom variability is greatest. While some of these benefits may also extend into the postmenopausal period, stating that trials in menopausal women are needed to establish its efficacy beyond the perimenopausal population.

Nonetheless, current study has limitations. The 8-week timeframe was chosen as it is sufficient to evaluate short-term outcomes such as vasomotor symptoms, sleep disturbances, mood changes, and psychological well-being. However, it is acknowledged that symptoms such as urogenital atrophy and bone-related changes typically require longer interventions to demonstrate clinically significant improvement. The single-site design limits external validity, and the absence of longitudinal follow-up restricts insights into sustained therapeutic effects or delayed adverse outcomes. Future studies should include longer intervention periods, diverse populations, and mechanistic biomarker assessments to fully elucidate the clinical utility and biological pathways of Shatavari.

Conclusion

Shatavari (*Asparagus racemosus* Willd.) root extract appears to be a promising botanical intervention for the management of perimenopausal symptoms. The current study demonstrated statistically significant improvements in vasomotor symptoms, mood, perceived stress, and selected hormonal parameters over an eight-week period without adverse effects. While these findings support the therapeutic potential of Shatavari, further well-powered, long-term clinical trials are warranted to confirm efficacy, elucidate mechanisms of action, and establish its use as an effective and safe alternative to hormone-based therapies.

Acknowledgments

The authors thank Ixoreal BioMed of Los Angeles, California, USA, for supplying the Shatavari root extract (SRI-81) used in the study treatment, and also want to thank Prashant Patel for the manuscript writing support.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit organizations.

Disclosure

The authors report no conflicts of interest in this work.

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