International Journal of Women's Health

Dovepress
Taylor & Francis Group

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ORIGINAL RESEARCH

Effects of Shatavari (*Asparagus racemosus*) Root Extract on Sexual Wellness in Women: Findings from a Prospective, Randomized, Double-Blind, Three-Arm, Parallel-Group, Placebo-Controlled Study

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Purpose: Women's sexual health is affected by physical, psychological, and emotional aspects. In Ayurvedic medicine, Shatavari (*Asparagus racemosus*) is traditionally classified as a *Rasayana* known to promote reproductive health and overall well-being in women. The present study aims to evaluate the safety and efficacy of a standardized Shatavari root extract (SHT) in improving women's sexual health.

Patients and Methods: A prospective, randomized, double-blinded, placebo-controlled, three-armed study was conducted over 8 weeks with 135 women participants. Participants were randomly assigned to receive either SHT, Shatavari with Ashwagandha root extracts (SHT-ARE), or a placebo (PL). The primary outcome was assessed using the Female Sexual Function Index (FSFI). Secondary outcomes were measured by Satisfying Sexual Events (SSEs), Female Sexual Distress Scale (FSDS), Profile of Mood States (POMS), Oxford Happiness Questionnaire (OHQ), and Pittsburgh Sleep Quality Index (PSQI), which were used for efficacy analysis. The safety parameters were monitored by treatment-emergent adverse events and changes in liver, thyroid, and renal function markers.

Results: At post-intervention (8 weeks), the SHT-ARE group demonstrated improvements in FSFI Arousal ($P = 0.041$), Lubrication ($P = 0.027$), Orgasm ($P = 0.031$), and Total FSFI ($P = 0.005$) scores compared to the PL group, whereas the SHT group showed improvements in only Total FSFI ($P = 0.025$) and Satisfaction ($P < 0.0001$). The number of sexual intercourses between SHT-ARE and PL was increased significantly ($P = 0.001$), while FSDS scores showed a significant difference in both SHT-ARE ($P < 0.0001$) and SHT ($P = 0.008$) when compared to the PL group. Improved OHQ scores in the SHT-ARE group ($P < 0.0001$) signify greater happiness. Reduced POMS values (SHT-ARE) specified reductions in Tension, Anger, Depression, Fatigue, Esteem-related affect, Confusion, and Total score ($P < 0.0001$) compared to PL. The SHT-ARE group at week 8 represented no significant differences in PSQI scores, except for Sleep efficiency ($P = 0.045$) compared to PL. All reported events were mild and resolved with no intervention.

Conclusion: Shatavari root extract is considered a safe, effective, and well-tolerated treatment for improving women's sexual health and well-being. In addition, it shows an additive effect in combination with Ashwagandha.

Keywords: Shatavari, *Asparagus racemosus*, women's sexual health, sexual dysfunctions, sexual distress, sleep quality, Ashwagandha, *Withania somnifera*

Introduction

The World Health Organization states sexual health as a state of physical, emotional, mental, and social well-being in relation to sexuality, highlighting sexual rights and the potential for sexual pleasure.[1,2] This refers to no disease, dysfunction, or coercion following the complex nature of sexual health.[3,4] Sexual and reproductive health both play

https://doi.org/10.2147/IJWH.S561213
Received: 16 August 2025
Accepted: 27 December 2025
Published: 10 February 2026

a crucial role in the overall development and well-being of an individual.[5] Female sexual desire is not confined to the onset of puberty and the cessation of menstruation at menopause.[6] It extends through various life stages, including the capacity to enjoy and regulate sexual and reproductive behaviour[7], simultaneously taking measures to avoid disorders or diseases impacting sexual function,[8] and preventing the psychological factors such as guilt, shame, or anxiety that could impair sexual relationships. These are the most basic components of sexual health.[9,10] Unpleasant sexual health issues can affect women of any age, particularly in women undergoing menopausal transition and postmenopausal stages.[11] The public health care system must recognize and include sexual wellness as a basic idea in an attempt to overcome sexual disparities.[6] Epidemiological data indicate that approximately 40% of women may experience some form of sexual dysfunction in their lifetime.[12] Studies have consistently shown that women with fulfilling sexual relationships report higher emotional and relationship satisfaction, indicating the integral role of sexual health in overall well-being.[13]

Shatavari (*Asparagus racemosus* Willd.), an Ayurvedic herb, is well-known for its therapeutic values, such as supporting hormonal (gonadotropin-releasing hormone, follicle-stimulating hormone [FSH], luteinizing hormone [LH], estrogen, and progesterone) balance and improving physical and emotional health.[14] It was noted that Shatavari plays an important role in sustaining healthy estrogen during menopause.[15] In addition, it supports the adrenal gland in managing hot flashes,[16] insomnia, depression, and unnecessary sweating.[17] Shatavari's steroidal saponins improve progesterone emission and mimic hormonal properties, which ultimately help in hormonal regulation. In healthy women, Ashwagandha (*Withania somnifera* (L). Dunal) accompanies Shatavari with its adaptogenic and stress-modulating properties.[18,19] By acting on different physiological pathways, Shatavari balances estrogen and progesterone levels, while Ashwagandha enhances stress resilience and supports adrenal function.[20] This combination may provide additive advantages by promoting hormone balance and enhancing general sexual health, particularly during hormonal transitions.[21]

By acting through interrelated physiological pathways, Shatavari helps regulate estrogen and progesterone levels. Ashwagandha enhances stress resilience and supports adrenal function. Together, these mechanisms suggest a possible additive effect that may promote hormone balance and improve overall sexual and reproductive health, particularly during hormonal transitions. To assess this scientific rationale and test the additive hypothesis, a prospective, randomized, double-blinded, three-armed, placebo-controlled trial was conducted to evaluate and compare the efficacy and safety of Shatavari root extract (SHT) alone and in combination with Ashwagandha root extract (SHT-ARE) against a placebo (PL).

Materials and Methods

Study Design

This prospective, randomized, double-blind, three-armed, parallel, and placebo-controlled study was performed for 8 weeks. The trial was conducted at two centers (Tieten Medi City Hospital Thane, Maharashtra, India, and San Francisco Research Institute, SF, US). The protocol and study documents were reviewed and approved by the Institutional Ethics Committee (IEC) of Dr. D. Y. Patil Medical College and Hospital, Navi Mumbai, Maharashtra, India (IEC Reference: DYP/IECBH/2024/425) dated August 26, 2024, and the ALLENDALE investigational review board dated September 26, 2024.

Registration and Ethical Compliance

The study was registered with the Clinical Trials Registry of India (CTRI) on October 3, 2024, under registration number CTRI/2024/10/074616 and with Clinicaltrials.gov on November 29, 2024, under the registration number NCT06972706. The trial adhered to the ethical principles stated in the Declaration of Helsinki (2013 revision) to safeguard the participants' rights and confidentiality. In addition, the study was conducted in compliance with Good Clinical Practice (GCP) guidelines and the Consolidated Standards of Reporting Trials (CONSORT) statement.

Participant Enrollment and Informed Consent

Participants were enrolled after providing written informed consent in their preferred languages (Hindi, Marathi, and English). A comprehensive explanation of the study's objectives and anticipated outcomes was provided to all participants before enrollment.

Randomization and Blinding

Participants were randomly assigned to one of the three study arms in a 1:1:1 allocation ratio using an automated random number generation system (Rando version 1.2 R), which was pre-specified for the trial. For the efficient blinding process, the Shatavari combination (SHT-ARE) and PL capsules were prepared to have similarity in appearance, shape, color, and packaging. The randomization sequence was computer-generated by an independent statistician using a block design to ensure balanced group allocation. Sequentially numbered, opaque, and sealed envelopes were used to conceal allocation until participant enrollment. Investigators and study personnel involved in data collection and analysis remained blinded to treatment assignment throughout the study. In case of a medical emergency, unblinding was permissible only after consultation with the principal investigator, and the reason for unblinding was documented.

Inclusion Criteria

Women aged 18 to 55 years, who were willing to engage in at least four sexual intercourse attempts per month (this threshold was selected to ensure adequate exposure to sexual activity for meaningful assessment of changes in sexual function using the FSFI, consistent with prior clinical studies evaluating female sexual dysfunction)[22] provide written informed consent, and demonstrated the ability to comply with all study procedures were included. Participants with indicative stress signs and symptoms were eligible. Participants who were reliable, compliant, and willing to cooperate with all trial evaluations, including effective communication and sexual functioning discussions, were included.

Exclusion Criteria

Women were excluded from the study if they used any herbal extracts or hormone replacement therapy (HRT) for more than 3 months. Women with active medical, surgical, or gynecological conditions or a history of alcohol, tobacco, or substance abuse, with major systemic diseases (cardiovascular, gastrointestinal, hepatic, neurologic, endocrine, hematologic, etc)., which could influence the study procedure and results, were considered ineligible. Women with an understanding impairment, conflicting behaviour, incapability to attend follow-up visits, having an uncontrolled infection, or any medical condition that could interfere with the study objectives, Ashwagandha or Shatavari-hypersensitive women, and involvement in any clinical trial within the past 3 months were also excluded from the study. These criteria were applied to ensure participant safety, reduce confounding factors, and maintain data integrity; however, they may limit the generalizability of the findings to broader populations.

Study Interventions

Participants were instructed to consume the allocated capsule once daily after breakfast for 8 weeks. As per the randomization schedule SHT group (300 mg of Shatavari root extract powder supplied by Ixoreal Biomed Inc., Los Angeles, USA), SHT-ARE group (SHT 300 mg and ARE 250 mg), and PL group (Starch 300 mg) swallowed identical light brown capsules.

Investigational Products

The Shatavari root extract is a commercially available product. This extract was obtained in alignment with the green chemistry principles, devoid of any harsh solvents, in a current good manufacturing practice (cGMP) certified facility. The herb to extract ratio is 13:1. Every batch of this extract is standardized to a Total Shatavarin content of >10% by high-performance liquid chromatography (HPLC). The Shatavari root extract test product has a yellowish-brown powdery appearance. The PL group received only starch, and PL capsules were of the same size, shape, odor, color, and taste as the Shatavari capsule.

Study Assessments

The vital signs, such as systolic and diastolic blood pressure, pulse rate, respiratory rate, and body temperature, were recorded at baseline, week 4, and week 8.

Primary Outcome Measure

Measurement of the Female Sexual Function Index (FSFI) score is the primary outcome measure. FSFI is a 19-item questionnaire intended to measure sexual desire, arousal, lubrication, orgasm, satisfaction, and pain. Each of these categories was scored on a scale of 0.0 to 5.0. The sum of the responses multiplied by a correction factor provides a maximum score of 6.0 for each category.[23] The variations in FSFI scores evaluated the effects of the interventions over the 8-week study period.

Secondary Outcome Measure

The secondary outcome measures included the following assessments:

Satisfying Sexual Events (SSEs)

SSEs were evaluated using a structured survey in which participants were instructed to record their sexual activities, including the number of intercourse and non-intercourse sexual events, the occurrence of orgasms, sexual desire levels, and overall satisfaction.[24] The responses were rated on a scale of "no", "low", "moderate", or "strong", corresponding to scores from 0 to 3, where 0 indicates no desire and 3 indicates the highest level of desire.

Female Sexual Distress Scale-Revised (FSDS-R)

The FSDS is a 12-item Patient-Reported Outcome instrument designed to measure sexually related personal distress in women.[22] Both the original 12-item and the revised 13-item FSDS-R have demonstrated high internal consistency, test-retest reliability, and discriminative validity in identifying women's sexual function from dysfunction. Furthermore, the FSDS-R was used in this study, which has a 7-day recall period, has strong discriminant validity, excellent test-retest reliability, and a high level of internal consistency in measuring sexually associated personal distress in women.[25]

Profile of Mood States (POMS)

It is a 40-item questionnaire used to evaluate mood states relying on a 5-Point Likert Scale.[26] The scale considers the score of the participants at the current time of evaluation for the categories Tension, Anger, Fatigue, Depression, Esteem-related affect (ERA), Vigor, and Confusion. Additionally, the Total Mood Disturbance (TMD) was assessed by adding the negative subscales, such as tension, confusion, anger, fatigue, depression, and reducing the positive subscales (ERA, vigour).

Oxford Happiness Questionnaire (OHQ)

The OHQ has a series of statements associated with happiness. Participants rated their agreement with each statement through a scale from 1 to 6 (1 = strongly disagree; 2 = moderately disagree; 3 = slightly disagree; 4 = slightly agree; 5 = moderately agree; 6 = strongly agree).[27]

Pittsburgh Sleep Quality Index (PSQI)

PSQI measures subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, usage of sleeping medications, and daytime dysfunction, and differentiates "poor" from "good" sleep quality over the last month.[28] The total score ranges from 0 to 21, with higher scores showing poor sleep quality.

Serum Hormone and Hepatic Enzyme Levels

At baseline, serum hormone and hepatic enzyme levels were assessed for all the participants, which included: estradiol, FSH, LH, testosterone, bilirubin, and liver enzymes, including aspartate transaminase (AST), alanine transaminase (ALT), and alkaline phosphatase (ALP). Prior to intervention, these biomarkers were evaluated to guarantee comparability among the three study groups: SHT-ARE, SHT, and PL.

Safety Assessment

Safety assessments were conducted through the Treatment-Emergent Adverse Events (TEAEs) and Treatment-Emergent Serious Adverse Events (TESAEs), either noticed by the physician or reported by the participant. These events were recorded at week 4 and week 8. Adverse events were categorized and graded as per the Common Terminology Criteria for Adverse Events (CTCAE). Predefined study stop rules included the occurrence of any serious or product-related

adverse event requiring discontinuation. Additionally, changes in liver, thyroid, and renal parameters were evaluated by comparing baseline values to those recorded in week 8.

Sample Size

The study's sample size was calculated based on the primary outcome. As per Ajgaonkar et al (2022),[27] 126 participants (42 per arm) were expected, the sample size was calculated assuming an effect size of 0.5 and a standard deviation of 1.0 for the FSFI total score, with 80% power and a two-tailed alpha of 0.05. A total of 42 participants per arm were required, and to account for an estimated 10% dropout rate, the sample size was increased to 135 participants (45 per arm), ensuring sufficient statistical power to detect clinically meaningful differences.

Statistical Methods and Data Analysis

The safety and tolerability analysis was done on the intent-to-treat (ITT) dataset, which included all participants who had received at least one dose of study treatment, whereas efficacy analyses were done on the per-protocol (PP) dataset. Statistical computations were performed using Version 25.0 of the Statistical Package (Stata IC 13.1, Stata Corp, USA). The results of the ranking data and score analysis was denoted as mean ± SD. A 95% Confidence Interval (CI) was used to guarantee adherence to the best statistical techniques. Two-sided tests were used for all analyses, and a P-value of less than 0.05 was regarded as statistically significant. Between-group comparisons were analyzed using a one-way analysis of variance (ANOVA) with post hoc Tukey's test for pairwise comparisons. P-values for categorical variables were calculated using the Chi-square test, which compared the number and percentage of respondents in each category (with an additional category for missing data, if applicable) for the parameters. Descriptive statistics (mean ± SD) were calculated for all parameters at each visit. Between-group comparisons were performed using one-way ANOVA, followed by Tukey's post-hoc test for multiple comparisons. No missing data were observed; all data were accounted.

Results

The ITT dataset participants (n = 135) were randomized into three groups: SHT (n = 45), SHT-ARE (n = 45), and PL (n = 45). Of the 135 participants enrolled, 90 were recruited at the India site (Titen Medi City Hospital, Thane), and 45 at the USA site (San Francisco Research Institute). After 8 participants, lost to follow-up, the PP dataset consists of 127 participants (SHT = 41, SHT-ARE = 44, and PL = 42) (Figure 1).

Baseline Profile in the ITT Dataset

Table 1 presents the profile of participants at baseline in the ITT dataset, such as demographic data, physical examination results, sexual function scores (FSFI), sexual experience (SSE), mood (POMS), and sleep quality (PSQI). No significant differences were found in age (P = 0.230) or BMI (P = 0.534) at baseline. Additionally, FSFI, SSE, FSDS, POMS, OHQ, and PSQI scores were non-significant at baseline (P > 0.05).

FSFI Scores in the PP Dataset

At the baseline, the FSFI Desire scores were similar between the three groups, whereas by week 4, the SHT-ARE group showed a substantial improvement in Desire in comparison to the PL group (P = 0.031). At week 8, the Desire scores in the SHT-ARE group were better than those in the PL group (0.98 ± 0.89 vs 0.53 ± 0.68). For FSFI Arousal, the SHT-ARE group presented higher scores in comparison to PL at both week 4 (P = 0.015) and week 8 (P = 0.041). At baseline and week 4, Lubrication scores were similar between groups; however, by week 8, the SHT-ARE group depicted greater improvement than the PL group (P = 0.027). At week 8, Orgasm scores of the SHT-ARE group significantly improved than those of the PL group (P = 0.031).

Satisfaction in the SHT group was enhanced by week 8 (P < 0.0001); however, no improvement was observed in the SHT-ARE group (P = 0.065). Pain scores showed no significant variations at any point in time. Total FSFI scores at week 8 were significantly elevated in both the SHT-ARE (P = 0.005) and SHT (P = 0.025) groups in comparison to the PL.

There was no significant difference observed between SHT-ARE and SHT (P = 0.862), indicating comparable efficacy in overall sexual function improvement (Table 2 and Figure 2A).

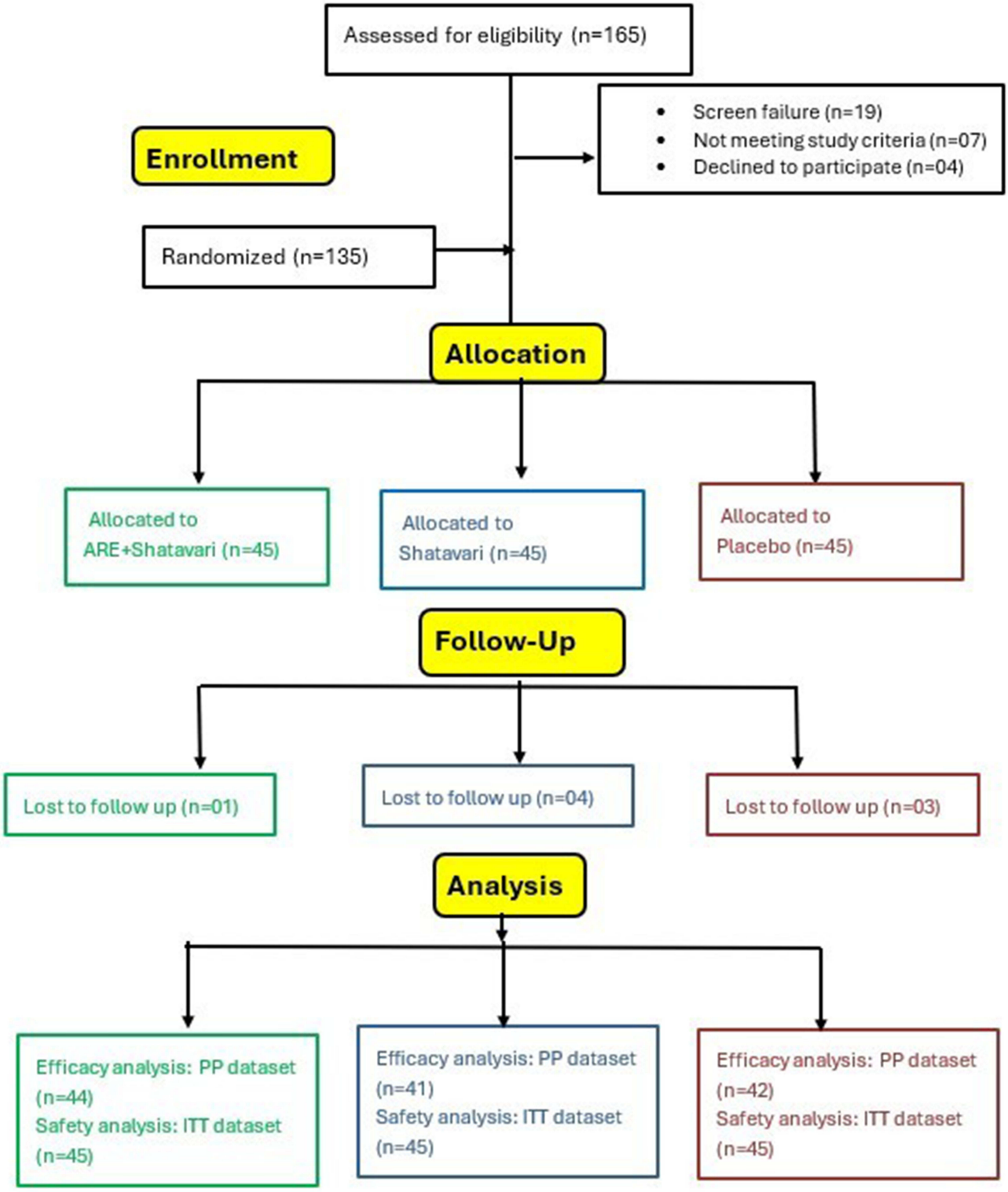

Figure 1 CONSORT flow diagram.
Abbreviations: ARE, Ashwagandha Root Extract; ITT, Intention-to-Treat; PP, Per Protocol.

SSE Scale, FSDS, and OHQ Scores in PP Dataset

The SHT-ARE group depicted statistically significant changes in the number of intercourses at Week 4 in comparison to SHT ($P = 0.032$) and Week 8 in comparison to the PL group ($P = 0.001$). The number of non-sexual events reduced significantly in the SHT-ARE group at weeks 4 and 8 ($P < 0.0001$), whereas the SHT group had significant changes

Table 1 Profile of Participants at Baseline in ITT Dataset (n=135)

Parameters	SHT-ARE (n=45)	SHT (n=45)	PL (n=45)	ANOVA
	Mean (SD.)	*Mean (SD.)*	*Mean (SD.)*	*p**
Demography				
Age (yrs.)	35.13 (8.82)	32.60 (9.78)	35.78 (9.10)	0.230
BMI (kg/sq.m)	26.20 (4.84)	27.42 (5.70)	26.70 (4.90)	0.534
Physical examination				
SBP (mm Hg)	112.47 (13.34)	111.64 (13.90)	108.51 (12.39)	0.329
DBP (mm Hg)	76.51 (9.85)	76.58 (10.42)	76.02 (10.57)	0.962
Pulse rate (per min.)	78.84 (12.07)	77.11 (11.18)	80.42 (11.61)	0.404
Body Temperature (^{0}F)	98.24 (0.63)	98.18 (0.66)	98.05 (0.63)	0.337
Respiratory rate (per min.)	15.47 (2.27)	15.56 (2.28)	15.96 (2.31)	0.559
FSFI Domain Score				
• Desire	2.65 (1.07)	2.65 (1.14)	2.61 (0.82)	0.977
• Arousal	2.62 (0.91)	2.67 (1.13)	2.69 (0.87)	0.943
• Lubrication	2.70 (1.31)	2.76 (1.42)	2.65 (1.24)	0.921
• Orgasm	2.26 (1.39)	2.45 (1.35)	2.43 (1.15)	0.743
• Satisfaction	2.45 (1.42)	2.29 (1.38)	2.46 (1.37)	0.811
• Pain	2.67 (1.62)	2.42 (1.24)	2.48 (1.33)	0.683
• FSFI Total Score	15.35 (6.74)	15.25 (6.70)	15.32 (6.19)	0.997
SSE Scale				
• No. of intercourse	5.44 (2.11)	6.04 (3.57)	4.89 (1.79)	0.114
• No. of non-sexual events	17.18 (11.43)	18.64 (11.52)	17.69 (11.96)	0.832
• No. of orgasms	2.78 (2.28)	3.98 (4.84)	2.33 (2.00)	0.053
• No. of satisfying sexual activity	3.33 (2.50)	4.87 (8.39)	2.96 (1.71)	0.180
• Level of sexual desire	1.33 (0.80)	1.27 (0.84)	1.24 (0.83)	0.867
FSDS Total Score	29.11 (12.29)	30.20 (10.89)	29.00 (11.68)	0.864
OHQ Total Score	2.49 (0.41)	2.58 (0.45)	2.50 (0.40)	0.517
Profile of Mood States (POMS)				
• Tension	15.87 (5.82)	15.67 (6.53)	13.98 (7.05)	0.319
• Anger	14.78 (6.65)	15.00 (6.54)	13.84 (7.18)	0.694
• Depression	16.82 (8.46)	16.71 (8.26)	16.24 (8.57)	0.942
• Fatigue	12.20 (4.84)	12.02 (4.62)	11.53 (5.00)	0.794
• Confusion	12.42 (4.97)	11.71 (5.45)	11.91 (5.59)	0.809
• Esteem-related Affect (ERA)	15.78 (5.90)	15.58 (4.83)	15.29 (6.24)	0.919
• Vigour	11.87 (3.97)	12.24 (3.32)	11.96 (4.44)	0.893
• Total Mood Disturbance	144.44 (21.41)	143.29 (24.51)	140.27 (23.26)	0.676
PSQI Domain Score**				
• Time to sleep	1.09 (0.85)	1.20 (0.89)	1.02 (0.72)	0.588
• Sleep duration (hrs.)	6.46 (2.39)	6.74 (2.11)	6.64 (2.29)	0.828
• Sleep quality (C1; Subjective)	2.07 (0.99)	2.04 (1.13)	1.91 (1.20)	0.772
• Sleep latency (C2)	1.80 (0.87)	1.93 (0.89)	1.80 (0.99)	0.729
• Sleep duration (C3)	1.44 (1.14)	1.52 (1.27)	1.48 (1.15)	0.951
• Sleep efficiency (C4)	1.29 (1.29)	1.20 (1.25)	1.13 (1.16)	0.836
• Sleep disturbance (C5)	2.09 (0.70)	2.16 (0.85)	2.02 (0.87)	0.738

(*Continued*)

Table 1 (Continued).

Parameters	SHT-ARE (n=45)	SHT (n=45)	PL (n=45)	ANOVA
	Mean (SD.)	*Mean (SD.)*	*Mean (SD.)*	*p**
• Sleep medication (C6)	1.49 (0.92)	1.67 (0.85)	1.47 (0.97)	0.526
• Daytime dysfunction (C7)	1.38 (0.98)	1.31 (1.12)	1.22 (1.22)	0.802
• Global PSQI score	11.49 (3.67)	11.80 (3.86)	11.00 (4.33)	0.628

Notes: p*-value was obtained using a two-way ANOVA test; **Component-wise Scoring of Sleep Parameters (C1–C7). Sleep Duration (hours: Total hours of actual sleep per night (eg, 9 hours). Score is derived from duration as reported. C1: Subjective Sleep Quality Score; C2: Sleep latency score based on time to fall asleep, ≤15 min = 0; 16–30 min = 1; 31–60 min = 2; >60 min = 3; C3: Sleep Disturbance Score – Based on #4 score (number of actual sleep hours), >7 hrs = 0; 6–7 hrs = 1; 5–6 hrs = 2; <5 hrs = 3; C4: Sleep Efficiency (Total hours asleep ÷ Total hours in bed) × 100 Scoring, >85% = 0; 75%–84% = 1; 65%–74% = 2; <65% =3; C5: Sleep Disturbances Composite Score; Sum of scores from items #5b to #5j, 0 = 0; 1–9 = 1; 10–18 = 2; 19–27 = 3; C6: Use of Sleep Medications; Score derived directly from item #6; C7: Daytime Dysfunction Score, Sum of scores from items #7 and #8:0 = 0; 1–2 = 1; 3–4 = 2; 5–6 = 3.

Abbreviations: ITT, Intent-to-treat; SHT-ARE, Shatavari-Ashwagandha Root Extract; SHT, Shatavari; PL, Placebo; ANOVA, Analysis of Variance; Age (yrs.), Age in years; BMI (kg/sq.m), Body Mass Index in kilograms per square meter; F, Fahrenheit; DBP, Diastolic Blood Pressure; ERA, Emotional Regulation Ability; FSDS, Female Sexual Distress Scale; FSFI, Female Sexual Function Index; PSQI, Pittsburgh Sleep Quality Index; No, Number; SSE, Satisfying Sexual Activities; OHQ, Oxford Happiness Questionnaire; POMS, Profile of Mood States; hrs, hours; min, minutes; SBP, Systolic Blood Pressure; mmHg, Millimeters of mercury.

compared to PL (Week 4: P = 0.001; Week 8: P = 0.002). There were no statistically significant differences in the number of orgasms or satisfying sexual activities among the groups at any time point (Table 3).

No differences in sexual desire were noted in any of the groups at baseline, Week 4, or Week 8, except minor increases in the SHT-ARE and SHT groups. FSDS total score showed significant improvements in the SHT-ARE group in comparison to the PL group at both Week 4 (P = 0.003) and Week 8 (P < 0.0001). The SHT group also showed improvement at Week 8 (P = 0.008), but no significant differences were found between SHT-ARE and SHT (Table 3, Figure 2B and C).

Table 2 FSFI Scores in PP Dataset (n=127)

	SHT-ARE (n=44)	SHT (n=41)	PL (n=42)	ANOVA	SHT-ARE vs SHT	SHT vs PL	PL vs SHT-ARE
	Mean (SD.)	*Mean (SD.)*	*Mean (SD.)*	*p**	*p**	*p**	*p**
FSFI (Desire)							
• Baseline	2.66 (1.09)	2.69 (1.16)	2.64 (0.84)	0.975	0.988	0.974	0.997
• Change at Week 4	0.94 (0.95)	0.83 (0.99)	0.44 (0.73)	0.030	0.848	0.121	0.031
• Change at Week 8	0.98 (0.89)	0.82 (1.27)	0.53 (0.68)	0.097	0.723	0.364	0.082
FSFI (Arousal)							
• Baseline	2.63 (0.92)	2.69 (1.16)	2.72 (0.88)	0.899	0.947	0.990	0.895
• Change at Week 4	1.14 (0.89)	1.08 (1.13)	0.59 (0.59)	0.011	0.944	0.041	0.015
• Change at Week 8	1.26 (1.16)	0.83 (1.27)	0.69 (0.72)	0.042	0.165	0.822	0.041
FSFI (Lubrication)							
• Baseline	2.71 (1.33)	2.83 (1.45)	2.71 (1.23)	0.892	0.904	0.916	1.000
• Change at Week 4	0.93 (0.85)	0.84 (1.04)	0.58 (0.87)	0.196	0.904	0.399	0.190
• Change at Week 8	0.83 (0.82)	0.61 (0.66)	0.40 (0.77)	0.036	0.406	0.400	0.027
FSFI (Orgasm)							
• Baseline	2.27 (1.41)	2.54 (1.35)	2.45 (1.19)	0.643	0.628	0.949	0.812
• Change at Week 4	1.09 (1.39)	0.56 (0.96)	0.74 (0.74)	0.068	0.059	0.707	0.291
• Change at Week 8	0.96 (1.24)	0.72 (0.79)	0.41 (0.91)	0.041	0.511	0.335	0.031

(*Continued*)

Table 2 (Continued).

	SHT-ARE (n=44)	SHT (n=41)	PL (n=42)	ANOVA	SHT-ARE vs SHT	SHT vs PL	PL vs SHT-ARE
	Mean (SD.)	*Mean (SD.)*	*Mean (SD.)*	*p**	*p**	*p**	*p**
FSFI (Satisfaction)							
• Baseline	2.42 (1.42)	2.33 (1.42)	2.52 (1.40)	0.825	0.957	0.810	0.936
• Change at Week 4	0.62 (1.22)	0.44 (1.24)	0.57 (1.22)	0.787	0.780	0.876	0.983
• Change at Week 8	0.96 (1.20)	1.49 (0.96)	0.48 (0.78)	< 0.0001	0.042	< 0.0001	0.065
FSFI (Pain)							
• Baseline	2.66 (1.64)	2.47 (1.21)	2.53 (1.35)	0.810	0.801	0.976	0.905
• Change at Week 4	0.73 (1.06)	0.83 (1.12)	0.82 (0.90)	0.880	0.892	0.999	0.910
• Change at Week 8	0.75 (1.12)	0.83 (0.96)	0.55 (0.77)	0.401	0.932	0.394	0.596
FSFI (Total Score)							
• Baseline	15.35 (6.81)	15.55 (6.74)	15.58 (6.31)	0.984	0.989	1.000	0.985
• Change at Week 4	5.44 (4.36)	4.58 (3.73)	3.75 (3.54)	0.136	0.563	0.600	0.113
• Change at Week 8	5.75 (4.77)	5.31 (3.50)	3.06 (3.12)	0.004	0.862	0.025	0.005

Note: *One-way analysis of variance (ANOVA) with post hoc Tukey's test (p-value).
Abbreviations: PP, Per Protocol; SHT-ARE, Shatavari-Ashwagandha Root Extracts; SHT, Shatavari Root Extracts; PL, Placebo; ANOVA, Analysis of Variance; FSFI, Female Sexual Function Index.

The OHQ total score improved in the SHT-ARE group than in SHT (Week 4: $P < 0.0001$; week 8: $P < 0.0001$) and PL (Week 4: $P < 0.0001$; Week 8: $P < 0.0001$) groups. No major differences were noted between SHT and PL throughout the study (Table 3 and Figure 2D). The SHT-ARE had improvements in sexual health, sexual distress, and happiness in comparison to PL, with few advantages over SHT alone, though no major differences were reported in orgasm frequency, satisfying sexual activity, or sexual desire.

POMS Scores in PP Dataset

The SHT-ARE group reported improvements in mood and emotional regulation as compared to the SHT and PL groups (Table 4 and Figure 3). The Anger ($P < 0.0001$) and Depression ($P < 0.0001$) changes were notable at week 8. A similar result was observed in Fatigue, with notable differences in the SHT-ARE group at Week 8 ($P < 0.0001$), whereas the SHT and PL groups showed a moderate impact. At week 8, the values of Confusion reportedly improved in the SHT-ARE group, in comparison to SHT ($P = 0.003$) and PL ($P < 0.0001$).

The ERA showed substantial gains in the SHT-ARE group at both time points (Week 4 and 8; $P < 0.0001$) compared to PL and at week 8 about SHT ($P < 0.0001$). SHT-ARE group showed a significant difference ($P = 0.048$) for Vigour compared to PL at week 8.

The POMS total score depicted a statistically significant difference in the SHT-ARE group at both time points compared to PL.

PSQI Scores in PP Dataset

Time to fall asleep, sleep duration, sleep quality, sleep latency, sleep disturbance, daytime dysfunction, and Global PSQI results varied among all three groups at baseline, week 4, and week 8, but with no statistical significance. Sleep efficiency showed a significant difference at week 8 ($P = 0.045$) in the SHT-ARE group in comparison to the PL group; however, no differences were reported in the pair-wise comparisons (Table 5 and Figure 2E). Overall, the results suggest that while some small changes were observed in the groups over time, none of the differences in sleep-related outcomes were statistically significant across the measures and time points.

Figure 2 shows the average scores for FSFI, FSDS, Total Mood Disturbance, OHQ, global PSQI assessments in PP datasets. Figure 3 presents the evaluation of POMS scores.

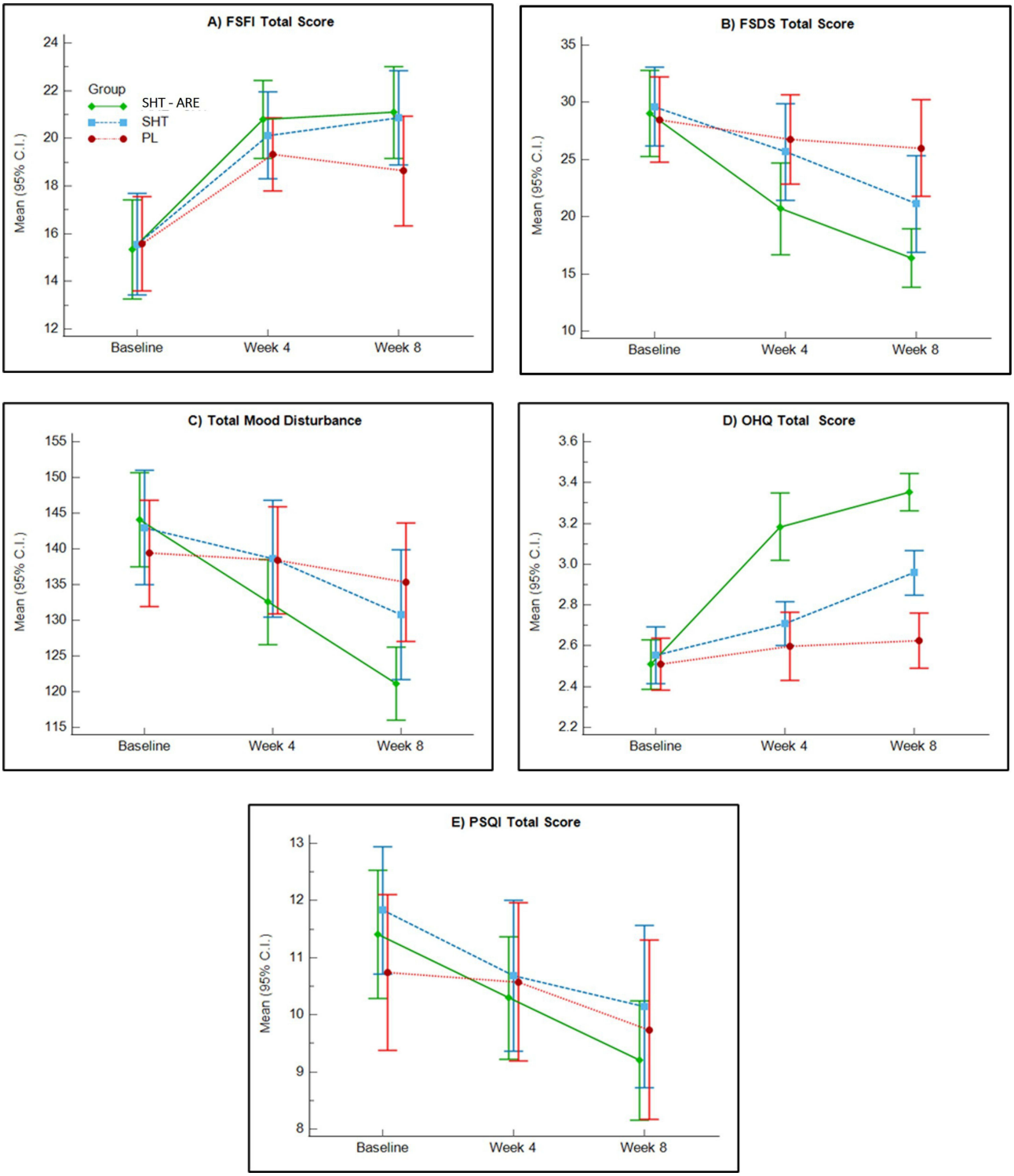

Figure 2 Average scores for FSFI total score (**A**), FSDS total score (**B**), Total Mood Disturbance (**C**), OHQ total score (**D**), and PSQI total score (**E**) at baseline, week 4, and week 8.

Serum Hormones in the PP Dataset

At baseline, no significant differences were reported in estradiol, FSH, LH, testosterone (Table 6), bilirubin, or liver enzymes (AST, ALT, ALP) in all groups. At Week 8, all liver enzyme levels were lower in the SHT-ARE group, with

Table 3 SSE Scale, FSDS, and OHQ Scores in PP Dataset (n=127)

	SHT-ARE (n=44)	SHT (n=41)	PL (n=42)	ANOVA	SHT-ARE vs SHT	SHT vs PL	PL vs SHT-ARE
	Mean (SD.)	*Mean (SD.)*	*Mean (SD.)*	*p**	*p**	*p**	*p**
SSE Scale							
No. of intercourse							
• Baseline	5.45 (2.13)	6.02 (3.66)	4.83 (1.83)	0.127	0.584	0.105	0.524
• Change at Week 4	1.95 (2.64)	0.34 (3.42)	0.74 (2.64)	0.031	0.032	0.810	0.134
• Change at Week 8	4.25 (3.21)	2.83 (5.71)	0.98 (3.32)	0.002	0.269	0.115	0.001
No. of non-sexual events							
• Baseline	17.00 (11.50)	19.27 (11.25)	17.14 (12.17)	0.610	0.643	0.684	0.998
• Change at Week 4	−5.41 (8.22)	4.44 (4.87)	−0.45 (3.22)	< 0.0001	< 0.0001	0.001	< 0.0001
• Change at Week 8	−7.16 (9.58)	−5.15 (5.70)	0.24 (4.02)	< 0.0001	0.374	0.002	< 0.0001
No. of orgasms							
• Baseline	2.77 (2.30)	4.07 (4.95)	2.40 (1.99)	0.060	0.173	0.062	0.865
• Change at Week 4	1.00 (2.78)	0.29 (3.95)	0.62 (2.52)	0.582	0.553	0.883	0.840
• Change at Week 8	1.09 (2.92)	0.17 (4.74)	0.67 (2.75)	0.495	0.462	0.802	0.846
No. of satisfying sexual activity							
• Baseline	3.36 (2.52)	5.05 (8.77)	2.95 (1.72)	0.165	0.310	0.172	0.931
• Change at Week 4	2.00 (2.86)	−0.15 (9.62)	0.95 (2.20)	0.244	0.213	0.670	0.685
• Change at Week 8	1.50 (2.53)	−0.22 (8.84)	1.00 (2.97)	0.341	0.325	0.573	0.907
Level of sexual desire							
• Baseline	1.34 (0.81)	1.27 (0.87)	1.26 (0.83)	0.887	0.915	0.999	0.899
• Change at Week 4	0.39 (1.10)	0.27 (1.00)	0.15 (0.82)	0.535	0.846	0.842	0.503
• Change at Week 8	0.55 (1.07)	0.53 (1.13)	0.24 (1.07)	0.373	0.996	0.478	0.411
FSDS total score							
• Baseline	29.02 (12.42)	29.61 (10.91)	28.50 (11.94)	0.912	0.971	0.904	0.977
• Change at Week 4	−8.32 (11.21)	−3.93 (8.04)	−1.76 (7.15)	0.004	0.068	0.520	0.003
• Change at Week 8	−12.64 (10.28)	−8.49 (8.53)	−2.50 (7.81)	< 0.0001	0.087	0.008	< 0.0001
OHQ Total Score							
• Baseline	2.51 (0.40)	2.56 (0.44)	2.51 (0.41)	0.846	0.865	0.874	1.000
• Change at Week 4	0.67 (0.46)	0.15 (0.30)	0.09 (0.41)	<0.0001	<0.0001	0.733	<0.0001
• Change at Week 8	0.85 (0.40)	0.40 (0.39)	0.12 (0.28)	<0.0001	<0.0001	0.001	<0.0001

Note: *One-way analysis of variance (ANOVA) with post hoc Tukey's test (p-value).
Abbreviations: PP, Per Protocol; SHT-ARE, Shatavari-Ashwagandha Root Extracts; SHT, Shatavari Root Extract; PL, Placebo; ANOVA, Analysis of Variance; FSDS, Female Sexual Distress Scale; No., Number; SSE, Satisfying Sexual Events; OHQ, Oxford Happiness Questionnaire.

changes staying within normal limits. No significant differences were reported in total protein, albumin, globulin, creatinine, blood urea nitrogen, or thyroid hormones (TSH, T3, T4) (Table 7).

Adverse Events

Mild adverse events (skin rashes, nausea, dizziness, abdominal bloating, headache, and diarrhea) were reported in all three groups. These events resolved spontaneously without any intervention. No serious or product-related adverse events were reported.

Table 4 POMS Scores in PP Dataset (n=127)

	SHT-ARE (n=44)	SHT (n=41)	PL (n=42)	ANOVA	SHT-ARE vs SHT	SHT vs PL	PL vs SHT-ARE
	Mean (SD.)	*Mean (SD.)*	*Mean (SD.)*	*p**	*p**	*p**	*p**
Tension							
• Baseline	15.80 (5.87)	15.49 (6.71)	13.62 (7.16)	0.262	0.975	0.403	0.280
• Change at Week 4	−4.09 (4.76)	−0.76 (3.40)	0.38 (4.49)	< 0.0001	0.001	0.448	< 0.0001
• Change at Week 8	−7.09 (5.38)	−3.44 (3.48)	−0.67 (4.63)	< 0.0001	0.001	0.018	< 0.0001
Anger							
• Baseline	14.68 (6.69)	15.10 (6.80)	13.52 (7.32)	0.563	0.959	0.558	0.720
• Change at Week 4	−3.73 (4.08)	−1.29 (4.61)	0.00 (3.44)	< 0.0001	0.018	0.320	< 0.0001
• Change at Week 8	−6.36 (5.30)	−2.90 (3.97)	−0.67 (4.76)	< 0.0001	0.003	0.083	< 0.0001
Depression							
• Baseline	16.70 (8.53)	16.71 (8.38)	15.86 (8.74)	0.871	1.000	0.893	0.890
• Change at Week 4	−3.36 (4.87)	−1.37 (5.18)	−0.05 (4.80)	0.009	0.155	0.448	0.007
• Change at Week 8	−7.16 (5.67)	−2.85 (4.70)	−0.81 (5.40)	< 0.0001	0.001	0.187	< 0.0001
Fatigue							
• Baseline	12.16 (4.89)	12.00 (4.77)	11.40 (5.15)	0.760	0.988	0.847	0.759
• Change at Week 4	−2.52 (3.59)	−1.22 (4.07)	−0.29 (3.40)	0.021	0.238	0.483	0.016
• Change at Week 8	−4.93 (3.98)	−2.71 (3.37)	−1.76 (3.30)	< 0.0001	0.013	0.453	< 0.0001
Confusion							
• Baseline	12.41 (5.03)	11.71 (5.69)	11.64 (5.68)	0.771	0.825	0.998	0.793
• Change at Week 4	−2.45 (3.32)	−0.93 (3.52)	−0.12 (3.42)	0.007	0.103	0.530	0.005
• Change at Week 8	−5.70 (4.08)	−3.07 (2.99)	−1.52 (3.52)	< 0.0001	0.003	0.123	< 0.0001
ERA							
• Baseline	15.75 (5.96)	15.63 (4.97)	14.98 (6.33)	0.803	0.995	0.863	0.810
• Change at Week 4	−3.57 (4.30)	−0.73 (4.35)	0.05 (3.73)	< 0.0001	0.006	0.667	< 0.0001
• Change at Week 8	−5.77 (5.46)	−1.59 (3.37)	−1.07 (3.87)	< 0.0001	< 0.0001	0.853	< 0.0001
Vigour							
• Baseline	11.91 (4.01)	12.37 (3.41)	11.69 (4.48)	0.735	0.858	0.722	0.965
• Change at Week 4	−1.07 (3.86)	−0.44 (4.09)	0.83 (3.57)	0.070	0.732	0.291	0.061
• Change at Week 8	−2.55 (4.76)	−1.17 (3.87)	−0.26 (4.61)	0.059	0.330	0.620	0.048
POMS total Score							
• Baseline	144.09 (21.53)	143.00 (25.37)	139.38 (23.83)	0.629	0.975	0.764	0.625
• Change at Week 4	−11.52 (13.29)	−4.39 (16.33)	−0.95 (17.18)	0.007	0.094	0.578	0.006
• Change at Week 8	−22.93 (16.23)	−12.22 (15.63)	−4.10 (16.76)	< 0.0001	0.008	0.062	< 0.0001

Note: *One-way ANOVA with post hoc Tukey's test (p-value).

Abbreviations: PP, Per protocol; SHT-ARE, Shatavari-Ashwagandha Root Extracts; SHT, Shatavari Root Extract; PL, Placebo; ANOVA, Analysis of Variance; POMS, Profile of Mood States; ERA, Esteem-related Affect.

Discussion

Deprived sexual health is an important condition impacting > 40% of women, and has been connected to a decline in overall quality of life.[15] Most of the time, women do not notice sexual health problems as medical conditions; however, these are important features of their health from adulthood to post-menopause.[29] Ashwagandha has already proven to improve women's overall health, including sexual satisfaction.[28] According to the WHO Standard Terminologies for Ayurveda, Shatavari possesses *Rasayana* (rejuvenating), *Balya* (strength-promoting), and *Stanya Janana* (lactogenic) properties, thereby supporting reproductive and hormonal balance. and might offer as a key supplemental product.[30]

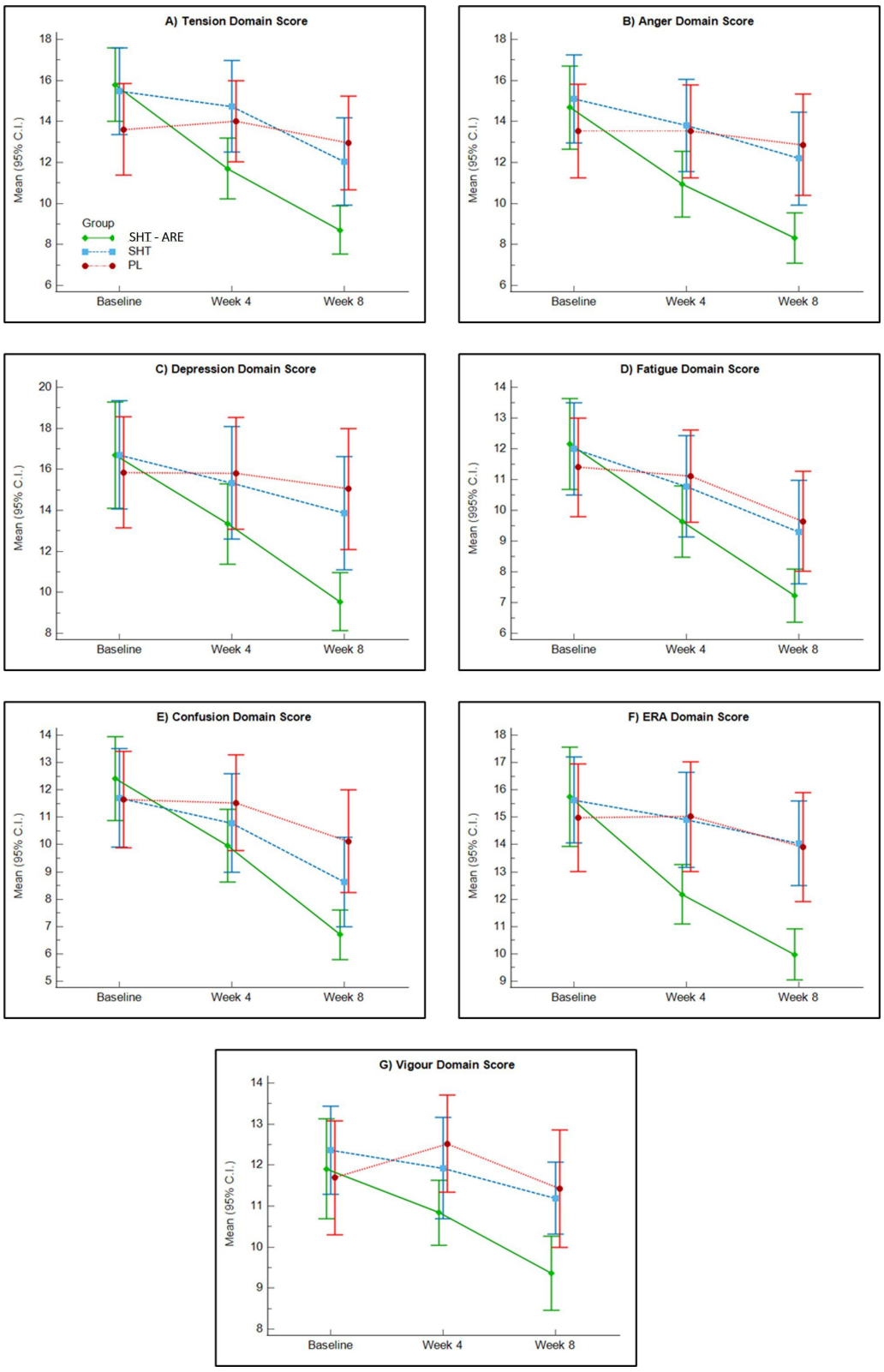

Figure 3 Evaluation of POMS domains: Tension (**A**), Anger (**B**), Depression (**C**), Fatigue (**D**), Confusion (**E**), ERA (Esteem-related Affect; **F**), and Vigour (**G**) at baseline, week 4, and week 8.

https://doi.org/10.2147/IJWH.S561213

Table 5 Sleep Parameters in PP Dataset (n=127)

	SHT-ARE (n=44)	SHT (n=41)	PL (n=42)	ANOVA	SHT-ARE vs SHT	SHT vs.PL	PL vs SHT-ARE
	Mean (SD.)	*Mean (SD.)*	*Mean (SD.)*	*p**	*p**	*p**	*p**
Time to sleep							
• Baseline	1.09 (0.86)	1.17 (0.92)	1.00 (0.73)	0.652	0.900	0.625	0.871
• Change at Week 4	−0.25 (0.72)	−0.20 (0.95)	−0.02 (0.75)	0.409	0.948	0.603	0.402
• Change at Week 8	0.39 (2.51)	0.00 (2.01)	0.17 (1.68)	0.697	0.675	0.931	0.879
Sleep duration (hrs.)							
• Baseline	6.42 (2.41)	6.67 (2.17)	6.61 (2.34)	0.873	0.872	0.991	0.926
• Change at Week 4	−1.13 (2.63)	−1.24 (3.01)	−1.31 (3.30)	0.959	0.982	0.994	0.956
• Change at Week 8	−2.01 (2.27)	−1.73 (2.84)	−1.54 (3.49)	0.751	0.897	0.952	0.733
Sleep quality (C1; Subjective)							
• Baseline	2.05 (0.99)	2.12 (1.08)	1.83 (1.21)	0.460	0.944	0.454	0.642
• Change at Week 4	−0.39 (1.08)	−0.32 (0.93)	−0.02 (0.75)	0.169	0.938	0.329	0.174
• Change at Week 8	−0.57 (1.21)	−0.37 (1.16)	−0.10 (0.73)	0.118	0.652	0.474	0.098
Sleep latency (C2)							
• Baseline	1.80 (0.88)	1.90 (0.89)	1.74 (0.99)	0.712	0.854	0.695	0.955
• Change at Week 4	−0.50 (1.15)	−0.17 (0.97)	−0.12 (1.11)	0.211	0.343	0.974	0.236
• Change at Week 8	−0.66 (1.03)	−0.34 (1.22)	−0.29 (1.17)	0.265	0.408	0.973	0.287
Sleep duration (C3)							
• Baseline	1.45 (1.15)	1.53 (1.28)	1.41 (1.14)	0.914	0.959	0.909	0.989
• Change at Week 4	−0.17 (1.15)	−0.15 (1.59)	−0.02 (1.39)	0.878	0.998	0.912	0.886
• Change at Week 8	−0.31 (1.28)	−0.25 (1.58)	−0.15 (1.42)	0.871	0.981	0.943	0.862
Sleep efficiency (C4)							
• Baseline	1.32 (1.29)	1.24 (1.24)	1.17 (1.19)	0.852	0.959	0.957	0.838
• Change at Week 4	0.55 (1.58)	0.17 (1.72)	0.36 (1.43)	0.551	0.519	0.853	0.845
• Change at Week 8	0.75 (1.78)	0.12 (1.42)	−0.05 (1.34)	0.042	0.146	0.869	0.045
Sleep disturbance (C5)							
• Baseline	2.07 (0.70)	2.12 (0.84)	2.00 (0.88)	0.789	0.950	0.772	0.919
• Change at Week 4	−0.23 (0.74)	−0.27 (0.90)	−0.10 (0.79)	0.595	0.970	0.595	0.731
• Change at Week 8	−0.48 (0.88)	−0.27 (0.71)	−0.19 (0.77)	0.223	0.445	0.895	0.216
Sleep medication (C6)							
• Baseline	1.45 (0.90)	1.68 (0.85)	1.52 (0.94)	0.492	0.473	0.700	0.932
• Change at Week 4	−0.14 (1.07)	−0.24 (0.97)	−0.21 (1.05)	0.883	0.881	0.991	0.935
• Change at Week 8	−0.50 (1.13)	−0.41 (1.20)	−0.21 (1.02)	0.484	0.935	0.695	0.467
Daytime dysfunction (C7)							
• Baseline	1.34 (0.96)	1.27 (1.10)	1.10 (1.16)	0.558	0.948	0.745	0.542
• Change at Week 4	−0.25 (0.78)	−0.17 (0.89)	−0.05 (0.91)	0.550	0.906	0.792	0.522
• Change at Week 8	−0.45 (1.00)	−0.17 (1.05)	−0.02 (1.14)	0.164	0.437	0.804	0.148
Global PSQI score							
• Baseline	11.41 (3.67)	11.83 (3.54)	10.74 (4.37)	0.435	0.872	0.408	0.702
• Change at Week 4	−1.11 (3.53)	−1.15 (2.91)	−0.17 (3.08)	0.282	0.999	0.345	0.357
• Change at Week 8	−2.20 (3.63)	−1.68 (3.35)	−1.00 (2.64)	0.229	0.739	0.603	0.200

Notes: *One-way analysis of variance (ANOVA) with post hoc Tukey's test (p-value). Component-wise Scoring of Sleep Parameters (C1–C7). Sleep Duration (hours: Total hours of actual sleep per night (eg, 9 hours). Score is derived from duration as reported. C1: Subjective Sleep Quality Score; C2: Sleep latency score based on time to fall asleep, ≤15 min = 0; 16–30 min = 1; 31–60 min = 2; >60 min = 3; C3: Sleep Disturbance Score – Based on #4 score (number of actual sleep hours), >7 hrs = 0; 6–7 hrs = 1; 5–6 hrs = 2; <5 hrs = 3; C4: Sleep Efficiency (Total hours asleep ÷ Total hours in bed) × 100 Scoring, >85% = 0; 75–84% = 1; 65–74% = 2; <65% =3; C5: Sleep Disturbances Composite Score; Sum of scores from items #5b to #5j, 0 = 0; 1–9 = 1; 10–18 = 2; 19–27 = 3; C6: Use of Sleep Medications; Score derived directly from item #6; C7: Daytime Dysfunction Score, Sum of scores from items #7 and #8:0 = 0; 1–2 = 1; 3–4 = 2; 5–6 = 3.

Abbreviations: PP, Per protocol; SHT-ARE, Shatavari-Ashwagandha Root Extracts; SHT, Shatavari Root Extract; PL, Placebo; ANOVA, Analysis of Variance; Age (yrs.); PSQI, Pittsburgh Sleep Quality Index; No.; Number; hrs., hours; min., minutes.

Table 6 Serum Hormones in PP Dataset (n=127)

Parameters	SHT-ARE (n=44)	SHT (n=41)	PL (n=42)	ANOVA	SHT-ARE	SHT vs PL	SHT-ARE vs PL
	Mean (SD.)	*Mean (SD.)*	*Mean (SD.)*	*p**	*p**	*p**	*p**
Estradiol (pg/mL)							
• Baseline	30.78 (9.10)	33.20 (10.25)	32.36 (11.95)	0.558	0.540	0.930	0.765
• Week 8	37.11 (12.38)	37.95 (11.26)	36.96 (13.93)	0.927	0.948	0.931	0.998
FSH (IU/L)							
• Baseline	12.92 (2.20)	13.28 (2.06)	13.79 (2.47)	0.200	0.748	0.549	0.175
• Week 8	15.00 (2.79)	15.31 (2.54)	14.81 (2.63)	0.681	0.849	0.661	0.940
LH (IU/L)							
• Baseline	6.55 (3.31)	6.24 (2.98)	7.16 (2.50)	0.355	0.873	0.333	0.612
• Week 8	8.95 (4.10)	8.57 (3.19)	7.93 (2.23)	0.345	0.852	0.644	0.317
Testosterone (ng/dL)							
• Baseline	18.88 (8.62)	18.02 (8.35)	17.34 (8.08)	0.694	0.882	0.928	0.670
• Week 8	28.88 (6.79)	30.65 (5.49)	22.79 (9.44)	0.000	0.519	0.000	0.001

Note: *One-way analysis of variance (ANOVA) with unpaired *t* test.

Abbreviations: SD., Standard Deviation; PP, Per Protocol; SHT-ARE, Shatavari-Ashwagandha Root Extracts; SHT, Shatavari Root Extract; PL, Placebo; FSH, Follicle-Stimulating Hormone; IU/L, International Units per liter; LH, Luteinizing Hormone; mIU/L, Milli-international units per liter; ng/dL, Nanograms per deciliter; pg/mL, Picograms per milliliter.

Table 7 Safety Data-Laboratory Parameters Dataset

Parameters	SHT-ARE	SHT	PL	ANOVA	SHT-ARE	SHT vs PL	SHT-ARE vs PL
	Mean (SD.)	*Mean (SD.)*	*Mean (SD.)*	*p**	*p**	*p**	*p**
Total Bilirubin (mg/dL)							
• Baseline	1.05 (0.12)	1.00 (0.23)	0.96 (0.30)	0.357	0.745	0.757	0.324
• Week 8	0.97 (0.24)	0.92 (0.36)	0.90 (0.35)	0.733	0.860	0.966	0.722
Direct Bilirubin (mg/dL)							
• Baseline	0.18 (0.02)	0.17 (0.04)	0.16 (0.05)	0.455	0.831	0.776	0.422
• Week 8	0.16 (0.04)	0.15 (0.06)	0.15 (0.06)	0.685	0.823	0.965	0.675
Indirect Bilirubin (mg/dL)							
• Baseline	0.27 (0.03)	0.26 (0.06)	0.25 (0.08)	0.382	0.756	0.774	0.348
• Week 8	0.24 (0.06)	0.23 (0.09)	0.23 (0.09)	0.738	0.867	0.964	0.726
Alkaline Phosphatase - (IU/L)							
• Baseline	115.95 (6.31)	114.21 (8.41)	115.79 (6.00)	0.590	0.617	0.681	0.996
• Week 8	103.79 (9.55)	102.45 (7.59)	102.30 (10.13)	0.796	0.845	0.998	0.816
AST (IU/L)							
• Baseline	34.52 (2.57)	35.28 (2.78)	34.07 (2.58)	0.236	0.534	0.214	0.795
• Week 8	30.64 (3.68)	32.63 (2.70)	30.30 (3.22)	0.018	0.059	0.024	0.916
ALT (IU/L)							
• Baseline	42.99 (2.52)	42.09 (4.48)	42.25 (4.14)	0.634	0.644	0.987	0.746
• Week 8	38.49 (3.40)	37.66 (5.00)	37.36 (4.68)	0.608	0.756	0.966	0.604
Total Protein (g/dL)							
• Baseline	7.03 (0.82)	6.92 (0.72)	7.38 (1.01)	0.118	0.879	0.117	0.276
• Week 8	6.43 (0.81)	6.25 (0.71)	6.76 (1.07)	0.094	0.734	0.082	0.322

(*Continued*)

Table 7 (Continued).

Parameters	SHT-ARE	SHT	PL	ANOVA	SHT-ARE	SHT vs PL	SHT-ARE vs PL
	Mean (SD.)	*Mean (SD.)*	*Mean (SD.)*	*p**	*p**	*p**	*p**
Albumin (g/dL)							
• Baseline	4.18 (0.77)	3.98 (0.85)	3.91 (0.91)	0.468	0.648	0.952	0.466
• Week 8	4.02 (0.73)	4.08 (0.88)	3.81 (0.90)	0.471	0.954	0.466	0.639
Globulin (g/dL)							
• Baseline	2.68 (0.98)	2.29 (1.26)	2.45 (0.73)	0.349	0.319	0.820	0.684
• Week 8	2.56 (1.09)	2.14 (1.09)	2.17 (1.02)	0.261	0.305	0.994	0.367
Creatinine - (mg/dL)							
• Baseline	0.76 (0.20)	0.74 (0.14)	0.75 (0.20)	0.897	0.887	0.971	0.971
• Week 8	0.71 (0.19)	0.71 (0.19)	0.73 (0.19)	0.941	1.000	0.952	0.949
BUN (mg/dL)							
• Baseline	12.34 (4.35)	12.28 (3.81)	9.83 (4.05)	0.038	0.998	0.072	0.061
• Week 8	10.62 (1.93)	11.15 (2.50)	11.32 (2.74)	0.524	0.689	0.961	0.523
TSH (µIU/mL)							
• Baseline	5.94 (1.71)	5.45 (1.88)	5.81 (1.29)	0.518	0.508	0.700	0.954
• Week 8	5.58 (1.55)	5.31 (1.56)	5.57 (1.08)	0.716	0.753	0.764	1.000
T3 (ng/dL)							
• Baseline	124.34 (21.75)	131.45 (14.14)	137.53 (24.25)	0.060	0.394	0.515	0.047
• Week 8	122.53 (21.76)	130.96 (15.38)	136.02 (24.38)	0.061	0.319	0.673	0.052
T4 (µg/dL)							
• Baseline	8.46 (2.58)	8.39 (2.07)	7.89 (1.60)	0.563	0.992	0.664	0.584
• Week 8	8.20 (2.58)	8.23 (1.92)	7.50 (1.41)	0.334	0.998	0.388	0.416

Note: *One-way analysis of variance (ANOVA) with unpaired *t* test.
Abbreviations: SD, Standard Deviation; PP, Per Protocol; SHT-ARE, Shatavari-Ashwagandha Root Extracts; SHT, Shatavari Root Extract; PL, Placebo; ALT, Alanine Transaminase; AST, Aspartate Transaminase; BUN, Blood Urea Nitrogen; g/dL, Grams per deciliter; IU/L, International Units per liter; IU/mL, International Units per milliliter; mIU/L, Milli-international units per liter; mg/dL, Milligrams per deciliter; ng/dL, Nanograms per deciliter; pg/mL, Picograms per milliliter; T3, Triiodothyronine; T4, Thyroxine; TSH, Thyroid Stimulating Hormone; µg/dL, Micrograms per deciliter.

The current study investigates the effects of SHT and SHT-ARE in various aspects of sexual health, emotional regulation, mood, and biochemical markers for an 8-week period in comparison to PL. The selected dosages of Shatavari root extract (300 mg)[16] and Ashwagandha root extract (250 mg)[23] were based on previously published clinical evidence demonstrating efficacy and safety in women's health studies. The once-daily regimen was selected based on prior pharmacological and clinical evidence showing sustained exposure and better compliance with single daily dosing.[16] Administration after breakfast was chosen to improve gastrointestinal tolerability and absorption, aligning with modern clinical research practices. Although Ayurveda traditionally recommends intake on an empty stomach, this timing was selected for safety and consistency with clinical trial procedures. The 8-week duration was chosen as sufficient to evaluate measurable changes in psychosexual and hormonal outcomes while maintaining participant adherence.

The results support the efficacy of both SHT and SHT-ARE, with SHT-ARE showing more pronounced improvements across multiple domains, suggesting an additive effect of the combination in improving women's overall sexual well-being.

A 4-week, randomized, double-blind, placebo-controlled trial was conducted by Akhtari et al (2014) to determine the safety and effectiveness of *Tribulus terrestris* (7.5 mg/day) in sexually dysfunctional women. The FSFI assessment was used to assess the improvement in sexual function. The domains, including desire ($P < 0.001$), arousal ($P = 0.037$), lubrication ($P < 0.001$), satisfaction ($P < 0.001$), pain ($P = 0.041$), and total FSFI score ($P < 0.001$), were significant.[31]

Similarly, the current study showed enhanced FSFI scores at week 4 and week 8, depicting the possible benefits of the SHT and SHT-ARE combination, when compared to PL. A pilot study by Dongre et al (2015) performed on Ashwagandha aimed to analyze its use for female sexual dysfunction, reporting that the significance of plant-based constituents in regulating healthy sexual function is in line with the current study findings.[32] For Desire and Arousal, the SHT and SHT-ARE groups have not depicted any significant difference, indicating the role of ARE, however, the numerical changes depict the additive effect. The FSFI Satisfaction and Total scores at week 8 support these findings. The reported changes align with the estrogenic properties of Shatavari, stating that it influences vaginal lubrication and sexual function.[33,34] No major improvements in FSFI Pain stating that, though SHT and ARE improve sexual arousal and satisfaction, they do not alter the pain perception, and this opens a key area for further research to either identify the products which could address the pelvic floor health or try dose-varied studies.[35]

The present investigation's SHT-ARE combination showed reduced sexual distress at week 4 and week 8 in comparison to the PL group, while SHT alone showed moderate improvement. These results are significant, as sexual distress in most cases is considered the primary sign for sexual dysfunction.[36] A systematic review reported by Salm et al (2023) also reported similar results, stating that the herbal therapeutic modules have the tendency to impact sexual distress by regulating the hormonal and psychological factors.[37] The combination of SHT and ARE appears to exert a complementary or additive effect by enhancing estrogenic modulation and stress resilience, which together may contribute to reduced sexual distress and improvements in sexual desire and satisfaction.[38] In addition, the SHT-ARE group showed an increased number of intercourses at both week 4 and 8 in comparison to SHT alone and the PL groups. This supports that the combination may have an additive effect on overall sexual well-being.

The SHT-ARE group depicted significant variations in mood disturbances, like decreases in Tension, Anger, Depression, and Fatigue at Week 4 and Week 8. These were related to better emotional regulation, as replicated in the significant changes detected in the ERA scores.[39] Earlier reported studies proved that the herbal formulations containing Shatavari could positively impact mood regulation by regulating the hormonal secretions of the hypothalamic-pituitary-adrenal axis. These early findings further support the activity of Shatavari-based treatments for dealing with sexual health.[16] Moreover, the SHT-ARE combination demonstrated significant improvements, suggesting that ARE has additive effects towards SHT.

An eight-week randomized trial by Shahmoradi et al (2023)[40] was conducted in 54 females for sexual dysfunction and depression in females. The Aphrodite (a combination of ginger, saffron, cinnamon, thistle, and *Tribulus terrestris*) and PL were given to observe the improvement assessed by PSQI scales in sleep quality. A significant change was observed in week 4 ($P = 0.001$) and week 8 ($P = 0.001$) between the groups.[26]

In the current study, no statistical significance was found in sleep duration, sleep latency, or subjective sleep quality, whereas the SHT-ARE combination helped to improve sleep efficiency by the end of the study. The overall lack of significant improvements for sleep-based outcomes implies that the SHT and SHT-ARE have not made a noteworthy impact; these findings are consistent with the previous studies, where the authors stated that the herbal formulation's effect on sleep varies and is mostly context-dependent. As per the analysis, it can be understood that the minute effect on sleep latency and sleep quality can be related to the short duration of the study or the complex nature of the sleep, which generally gets affected by physiological and psychological parameters.[41] To have an extensive understanding, it is advised to have long-term studies with higher doses of the subject herbal supplements, along with more emphasis on physiological attributes.

A study conducted by Cheng et al (2013)[42] reported that when desvenlafaxine was administered to post-menopausal women in varying doses, participants were divided into three groups receiving 100 and 150 mg/day, or a placebo for 12 weeks. The POMS scale was utilized to evaluate improvements in mood. The parameters, such as Vigor, Confusion, and Fatigue, showed no significant changes at varied doses for the previously reported studies.[27] Comparatively, the current study reported significant improvements in these domains at week 4 and week 8. About between-group comparisons (SHT-ARE vs SHT), the combination treatment produced additive benefits, enhancing the effects of SHT.[27]

Gopal et al (2021) reported that Ashwagandha root extract drastically enhanced the perimenopausal symptoms, quality of life, and hormone profiles in comparison to a placebo, while testosterone levels were unchanged. Shatavari has a long history of traditional Ayurvedic use in supporting women's reproductive health, including indications for

menstrual irregularities and lactation; modern evidence for specific clinical benefits remains limited and requires further confirmation.[43] The current study supports the fact that phytoestrogenic effects of Shatavari have been shown to affect estrogenic activity, possibly helping women with hormonal imbalances.

However, although the changes in estradiol with SHT and PL were similar, the mean estradiol values of SHT (37.95 ± 11.26) were higher compared to PL (36.96 ± 13.93). The notable alterations in liver enzyme activity and bilirubin levels found in the SHT-ARE group are significant, as they reflect the broad impact of the intervention. Future studies should assess the safety of such interventions, particularly in populations with pre-existing liver conditions.

Mild adverse events (skin rashes, nausea, dizziness, abdominal bloating, headache, and diarrhea) were reported in each of the three groups, and the lab parameters assessed for safety were within normal range, proving the test product to be safe and tolerable.

The strength of the current study includes its randomized controlled design, the comparative evaluation of numerous domains like sexual function, emotional well-being, and biochemical markers, the inclusion of both ITT and PP datasets, and the reliability and generalizability of the results. The inclusion of a PL group helped differentiate true treatment effects from expectancy bias, with the SHT group showing significant improvements over PL, confirming Shatavari's independent benefits, while the SHT-ARE combination produced greater additive effects across sexual and emotional outcomes.

The study has certain limitations, including its short duration (8 weeks), which limits the assessment of long-term effects, and a relatively small sample size that may restrict generalizability. Additionally, menstrual status and the timing of blood sample collection were not controlled, which could have introduced variability, as hormone levels fluctuate naturally throughout the menstrual cycle. While the average age of menopause is around 51 years, some women may continue to menstruate until 55, further contributing to hormonal variation. Moreover, although multiple secondary endpoints were analyzed, no multiplicity correction was applied, as the study was exploratory and not powered for confirmatory inference. Despite these limitations, the study provides meaningful insights into the efficacy of SHT and its combination with ARE in improving sexual health outcomes, warranting further research with larger cohorts and extended follow-up periods.

Instead of these limitations, the study provides an important understanding of the efficacy of SHT and SHT in combination with ARE, where further research with larger sample sizes and longer durations can explore the therapeutic applications.

Conclusion

The present exploratory study indicates that standardized Shatavari root extract may help improve sexual function, reduce sexual distress, and support emotional regulation in women, potentially through favorable modulation of hormonal (eg, estrogen, testosterone) and biochemical (eg, cortisol) parameters compared with placebo. Moreover, its combination with Ashwagandha root extract showed a trend toward greater overall improvement, suggesting a possible additive effect. However, these findings should be interpreted cautiously given the short study duration, modest sample size, reliance on self-reported outcomes, and limited statistical power for secondary endpoints. Larger, long-term, and well-powered studies are warranted to confirm these preliminary observations and determine their clinical significance.

Abbreviations

SHT, Shatavari Root Extract; SHT-ARE, Shatavari-Ashwagandha Root Extracts; PL, Placebo; FSFI, Female Sexual Function Index; SSEs, Satisfying Sexual Events; FSDS, Female Sexual Distress Scale; POMS, Profile of Mood States; OHQ, Oxford Happiness Questionnaire; PSQI, Pittsburgh Sleep Quality Index; IEC, Institutional Ethics Committee; CTRI, Clinical Trials Registry of India; GCP, Good Clinical Practice; CONSORT, Consolidated Standards of Reporting Trials.

Data Sharing Statement

De-identified individual participant data underlying the findings of this study, along with the complete study results, will be made available to qualified researchers upon reasonable request. Data will be provided for academic and non-commercial research purposes only, following a formal written request and approval of the proposed use by the

corresponding author. To protect participant confidentiality, no personally identifiable information will be shared. The data will be available for a period of three years from the date of publication.

Ethical Approval and Informed Consent

The study protocol and related documents were reviewed and approved by the Institutional Ethics Committee of Dr. D. Y. Patil Medical College and Hospital, Navi Mumbai, Maharashtra, India (IEC Reference: DYP/IECBH/2024/425; approval dated August 26, 2024) and by the ALLENDALE Investigational Review Board (approval dated September 26, 2024). All participants provided a written informed consent form.

Acknowledgments

The authors would like to thank Ixoreal Biomed for providing Shatavari root extract (SRI-81) and Ashwagandha root extract (KSM-66). Ixoreal Biomed had no role in study design, data collection, statistical analysis, interpretation, or manuscript preparation. The authors sincerely acknowledge Dr. Yvette Gentry for her valuable contribution during the revision of this manuscript.

Author Contributions

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

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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